Drug Importation: The Realities of Safety and Security
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Testimony

Thank you, Mr. Chairman and members of the Committee for this opportunity to provide testimony on current efforts to further ensure and strengthen the integrity of the nation's prescription drug supply. I appreciate the opportunity to provide the perspective of the domestic healthcare distribution industry as this Committee considers the issue of importation of prescription drug products from abroad.

My name is John Gray, and I am the President and CEO of the Healthcare Distribution Management Association (HDMA). For more than 125 years, HDMA has worked with its members – the nation's 46 full-service healthcare distributors – to secure a safe, efficient and reliable distribution system that provides life-saving healthcare products and services. On any given day, HDMA's member companies are responsible for delivering nine million of the nation's prescription drug products to more than 130,000 retail pharmacies, hospitals, nursing homes, clinics and other provider sites in all 50 states.

My purpose here today is to emphasize four principal points:

1. The primary responsibility of the healthcare industry is to ensure patient health and safety.
2. Our mission as healthcare distributors is to ensure that the prescription drug supply chain remains safe, secure and tightly regulated. Any efforts to permit the importation of prescription drug products from abroad must not weaken this system.
3. Significant efforts are underway, and must continue, to further secure the domestic supply chain in the face of increasing incidents of counterfeit and adulterated products entering markets, both domestic and abroad.
4. There is no single solution to secure the integrity of the prescription drug supply – the only effective response is one that involves multiple strategies and includes the participation and commitment of all supply chain partners.

Patients in the United States expect that when they receive a prescription from their medical provider, the medication will be available for dispensing upon their arrival at a pharmacy. They expect and deserve authentic medicine that has been handled and stored properly. Each member of the supply chain -- from the manufacturer, to the distributor, to the pharmacy -- has an important role and we must work in tandem to ensure a safe and reliable supply of prescription drugs for patients.

Current Regulatory Environment

The responsibility to provide a safe and reliable supply of prescription drugs requires constant vigilance. The nation's drug distribution system is highly regulated at both the federal and state levels of government, under the Prescription Drug Marketing Act1 (PDMA), which was enacted in 1988 and amended in 1992. At the time of the PDMA's original enactment, Congress found that "American consumers [could not] purchase prescription drugs with the certainty that the products [were] safe and effective," and that there [was] an "unacceptable risk that counterfeit, adulterated, misbranded, subpotent, or expired drugs will be sold to American consumers."2 The PDMA established a closed and highly regulated domestic supply chain. The PDMA also established minimum federal licensing standards and delegated to the states the responsibility to serve as the licensing bodies. The states, therefore, are empowered to inspect, regulate and approve the firms conducting business as pharmaceutical distributors.

HDMA full service distributor members are also strictly regulated by the Drug Enforcement Administration (DEA), both as distributors of List I Chemicals and Controlled Substances. The DEA, along with State Controlled Substance Authorities, add an additional and important level of inspection and regulation of our member facilities, ensuring that products with abuse potential are kept in a highly secure environment with strong recordkeeping requirements.

This federal/state regulatory and oversight partnership has served the nation well to date. However, even the United States is not immune from the growing and increasingly sophisticated threat of counterfeiting. According to FDA's report entitled Combating Counterfeit Drugs (February, 2004), patients in some countries actually have a better chance of getting a fake drug than the legitimate product. While still extremely rare, instances of counterfeit or adulterated3 products entering the domestic supply chain have been on the increase in recent years. According to the FDA, the number of instances where counterfeit products have breached the domestic supply chain has increased from six cases in the year 2000 to twenty-two cases in 2003. Each of these situations poses a serious public health threat. As healthcare distributors, we recognize there is no greater responsibility than doing everything we can to ensure that the products we deliver to pharmacies and other healthcare providers are authentic, and have been stored and handled properly.

Ongoing Supply Chain Improvements

Given the increasing sophistication and frequency of product counterfeiting, it is imperative that our nation remains vigilant and constantly seeks new approaches to further secure the domestic prescription drug supply. These ongoing efforts include:
1. strengthening government regulation, oversight and enforcement;
2. adopting new technologies; and
3. developing and implementing industry best practices.

1. Strengthening Government Regulation, Oversight & Enforcement

With regard to the strengthening of regulations that provide oversight and licensure of domestic healthcare distributors, HDMA joined in the FDA's call for states to review and revise their current wholesale licensing statutes and regulations. HDMA has taken the added step of drafting model legislation that is under consideration in multiple states. This HDMA model bill calls for additional requirements to be met in order to receive a prescription drug distribution license, as well as increased state oversight and enforcement measures.

While many states have taken their licensure and inspection responsibilities seriously, we remain concerned that too few states have devoted sufficient attention or resources to this area. For example, some states will issue a distribution license without ever conducting a pre-license inspection. Many states struggle with the ability to regulate out-of-state distributors in an industry that is increasingly shipping products across state lines. Many states also are slow to update and make publicly available the licensing status of a distributor or pharmacy.

HDMA believes that significant variation in the levels of state regulations of pharmaceutical distributors has led to inconsistent standards being applied across the states. We believe this must change and we will continue to advocate for stronger, more uniform national standards for the licensure of pharmaceutical distributors. HDMA believes an essential responsibility of government is to ensure that only legitimate, law-abiding organizations are licensed to distribute pharmaceutical products.

2. Adopting New Technologies

HDMA strongly believes that technology can serve an important role in securing the nation's prescription drug supply; however, no single technology can absolutely prevent counterfeiting. Rather, a layering of various strategies can create a significant barrier to entry. Overt and covert authentication technologies currently are being used by manufacturers today.

As those who seek to introduce counterfeit or adulterated products into the supply chain become more sophisticated, so, too, must the technologies that manufacturers, distributors and pharmacies employ to frustrate and defeat them. We believe technologies employing electronic product codes (EPC)/radio frequency identification (RFID) hold the most promise for tracking, tracing and authenticating a product's movement across the supply chain. Using RFID technology, a tiny radio frequency chip containing essential

data in the form of an electronic product code will allow supply chain stakeholders to track the chain of custody (or pedigree) of every unit of medication on an individual basis. By tying each discrete product unit to a unique electronic ID, a product can be tracked electronically through the supply chain.

Further, EPC/RFID technology represents an opportunity to significantly improve efficiencies in managing supplies and inventory. According to a recent HDMA Healthcare Foundation Report entitled, "Adopting EPC in Healthcare: Costs and Benefits," patient safety can be enhanced and efficiencies to the healthcare supply chain can be achieved via the industry-wide adoption of EPC/RFID. EPC/RFID is more efficient and cost-effective than paper pedigrees or alternative electronic tracking methods that do not involve the serialization of individual products. Paper pedigrees have been forged in previous domestic counterfeiting situations. Moreover, paper pedigrees would literally halt the efficient distribution of drugs given the volume of products delivered and the sophisticated automation technology utilized to do so safely and efficiently.

I am pleased to report to the Committee that tremendous progress is being made in the development and adoption of EPC/RFID technology with respect to pharmaceutical products. This is a monumental endeavor that will require close collaboration among all constituents of the healthcare supply chain and will take several years to proliferate the market in the United States. Industry, commercial vendors and government agencies are working together to develop the necessary standards for communication of tagged items across the supply chain. HDMA is working closely with standards development organizations such as EPCglobal to further the awareness, adoption and implementation of EPC in healthcare. While progress is extremely positive, there are many hurdles to overcome including business and technology challenges such as data management issues, interoperability of tags and readers and standards development. HDMA's focus has been to advocate for the adoption of this technology in the United States.

FDA's November 15, 2004 issuance of a Compliance Policy Guide (CPG) for implementing RFID feasibility studies and pilot programs was an important and essential step in moving this technology forward. The policy guide clarified the Agency's position with regard to any labeling or current Good Manufacturing Practices (GMP) issues that may arise by affixing an RFID tag to a pharmaceutical product. Several manufacturers and distributors simultaneously announced their intention to move forward with pilot programs that will involve the tagging of products susceptible to counterfeiting. These studies will significantly enhance the understanding and operability of this technology in the healthcare system.

Although the industry is moving forward in the development and adoption of EPC/RFID technology, it will take time and an unwavering commitment on the part of government and each partner in the supply chain to realize adoption of RFID technology in a measured, meaningful and universal way. HDMA members look forward to the support of the Committee in ensuring that our laws and regulations continue to support the adoption of this important and patient safety enhancing technology.

3. Developing and Implementing Industry Best Practices

Finally, the entire supply chain is constantly identifying new ways to improve upon business practices that can enhance product safety. Many of HDMA's full service distributor members have adopted a voluntary set of best practices known as the "Recommended Guidelines for Pharmaceutical Distribution System Integrity." These guidelines establish a rigorous due diligence process for pharmaceutical distributors in order to further protect the integrity of the pharmaceutical supply chain.

Conclusion

In conclusion, HDMA members recognize the public trust placed upon them to ensure that authentic pharmaceutical products are handled, stored and ultimately, dispensed to patients safely and efficiently. Our message to the Committee today is that securing the nation's prescription drug supply chain requires constant vigilance in the face of increasingly sophisticated threats. We do not believe there is a single solution to this effort; rather, a combination of many approaches is required, involving the government and all supply chain partners. Technology plays an important and essential role in this effort, but technology is evolving and must be combined with strict regulation and best business practices to be most effective. Any consideration of the importation of prescription drugs from abroad must, at a minimum, incorporate these multiple approaches to safety and security. The health and safety of our nation, literally, is at stake.

HDMA appreciates this opportunity to provide the perspective of the nation's full-service healthcare distributors on these critically important issues.