DRUG WHOLESALING AND IMPORTATION: CHALLENGES AND OPPORTUNITIES[†]

ROBERT P. GIACALONE, R.PH., J.D.[*]

ABSTRACT

Much interest and controversy abounds regarding the benefits and perils associated with the importation of pharmaceuticals. The Internet has provided an uncertain vehicle for such importation especially as it pertains to two key areas: product authentication and product integrity. As a result, questions exist as to whether other U.S. entities may provide a more legitimate and safer alternative to the Internet for supplying imported prescription pharmaceuticals into the United States. One such avenue may be the involvement of U.S. pharmaceutical wholesale distributors in the importation process. The pros and cons of that concept are addressed herein. This essay examines various facets of the U.S. pharmaceutical supply chain with a focus upon legal and regulatory requirements currently in place. In addition, challenges facing the U.S. pharmaceutical supply chain, such as counterfeit drugs, are discussed, as well as what is being done to address those issues in terms of operational and technological approaches. Lastly, domestic and international legal and regulatory implications for drug importation by non-manufacturers, as well as importation's potential impact on the integrity of the U.S. pharmaceutical supply chain, are assessed. The U.S. pharmaceutical supply chain currently provides for a closed system wherein safeguards have been established to help ensure product integrity. While issues have arisen in the past, the U.S. pharmaceutical wholesale distribution industry has taken significant steps in strengthening its systems to help prevent

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[†] The views reflected in this essay are those of the author alone and do not necessarily reflect the views of Cardinal Health, Inc. or any of its subsidiaries.

[*] Mr. Giacalone is Vice President, Regulatory Affairs and Chief Regulatory Counsel for Cardinal Health, located at 7000 Cardinal Place, Dublin, Ohio 43017. E-mail: robert.giacalone@cardinal.com.

counterfeit drugs from entering the U.S. pharmaceutical supply chain. In addition, while emerging technologies such as Radio Frequency Identification (RFID) provide promise, significant work is still needed to ensure effective implementation and consistent results. As such, given today's environment, the infusion of imported drugs into the U.S. pharmaceutical supply chain from foreign non-manufacturing sources may work to substantially undermine the integrity of the U.S. pharmaceutical supply chain.

INTRODUCTION[1]

There has been much discussion about the importation of foreign pharmaceuticals into the United States. Through the Internet, a variety of pharmacies across the world have emerged to service the demand by U.S. citizens for less expensive drugs. In addition, various initiatives through Congress have begun, but to date, have not been implemented to legally provide for the importation of pharmaceuticals into this country.[2] Some of those initiatives have suggested a potential role that U.S. pharmaceutical wholesale distributors may play in the importation of prescription pharmaceuticals into the United States. While the concept has merit, the challenges that exist are significant.

There are two key areas that any approach to importation must address. The first is product authentication. When U.S. citizens order their medication, they must be assured that they receive the prescription drug in the exact specification ordered by their physician. However, prescription products are produced differently for various markets, based on differing standards. In addition to legal differences in same–brand name pharmaceuticals, it is clear that counterfeiting is a much more pervasive criminal activity outside the United States. As such, there is a need to protect against the effects of this insidious practice. The second key area in approaching importation is to address product integrity. There should never be a question about the strength or safety of any medication supplied to patients. Hence, a

1. Much of the information referred to in this essay is a result of first-hand knowledge on the part of the author; accordingly, secondary sources have not been referenced for that information.

2. *See* 21 U.S.C. § 384(b)(1) (2005). Section 384(b)(1) permits the Secretary of the U.S. Department of Health and Human Services to promulgate regulations to permit pharmacists and wholesalers to import prescription pharmaceuticals into the United States, provided that safeguards are in place to ensure that such imported items are safe and effective for their intended use and that the items are in accord with other requirements set forth under the Federal Food, Drug, and Cosmetic Act. To date, the Secretary has yet to establish a system that can ensure the safety of such imported product.

system cannot be developed that does not properly address the multitude of factors that cause degradation of pharmaceuticals.

This essay intends to provide an overview of some of the issues that currently impact pharmaceutical wholesale distributors, while evaluating those issues against the backdrop of importation.

DISCUSSION

The U.S. Pharmaceutical Wholesaling Industry

The pharmaceutical wholesaling industry has historically been one that very few people outside of the health care sector even knew existed. The general public is aware of health care providers (e.g., physicians, hospitals, pharmacies, and clinics), in addition to the manufacturers of pharmaceuticals such as Pfizer (Viagra® and Lipitor®), GlaxoSmithKline (Paxil®), and Abbott (Synthroid®). However, very little recognition or appreciation was given to how exactly the drug products make their way from the manufacturer to the thousands of health care providers across the country. This, in essence, is the role of the U.S. pharmaceutical wholesale distributor. Without the efforts of the drug wholesale distributor, pharmaceuticals would not be received on almost a daily basis by the millions of patients that depend upon them.

The pharmaceutical wholesale distribution industry is comprised of a number of distributors. Cardinal Health is one of those pharmaceutical distributors. Generally, over 90% of the wholesale distribution industry is serviced by three national wholesale distributors. These distributors, commonly referred to as the "Big Three," are Cardinal Health, AmerisourceBergen, and McKesson. Some other statistics of note are as follows. The trade association to which the Big Three belong, the Healthcare Distribution Management Association (HMDA), has approximately forty-six distributor members operating 214 distribution centers in the United States. The average HDMA distribution center stocks approximately 22,400 items, of which 50% are prescription pharmaceuticals. In the case of Cardinal Health, the numbers are bit more daunting. Currently, Cardinal Health keeps over 75,000 different products in its inventory (which averages approximately 35,000 to 40,000 SKUs per facility). In addition, Cardinal Health picks and delivers more than two million items per day for 35,000 U.S. customers from their twenty-four pharmaceutical distribution centers. Cardinal also makes over 25,000 deliveries per day across the country while servicing approximately 30% of the nation's

needs.

Wholesale distributors are licensed and regulated by a number of governmental agencies. On a federal level, the U.S. Drug Enforcement Administration (DEA) licenses and inspects pharmaceutical distributors that handle and distribute controlled substances (e.g., narcotics and other potential drugs of abuse). While not directly licensed by the U.S. Food and Drug Administration (FDA), there are federal laws and standards that apply to the industry and allow for the FDA to inspect and take action against distributors who fail to act in accordance with legal mandates.[3] Other agencies such as the U.S. Environmental Protection Agency (EPA) also dictate how distribution centers are run, and the U.S. Department of Transportation (DOT) impacts how deliveries of pharmaceuticals are made. In addition, on a state level, there are a number of entities that also license and regulate distributors. In many cases, the state boards of pharmacy license and regulate distributors that reside in or provide products into their respective state from non-resident facilities. However, some states assign this authority to state departments of health or, in one case, to a board of wholesalers.[4] Furthermore, some states also have their own state versions of the DEA, referred to as state controlled substance agencies, while still others may have their own versions of the FDA that may also provide another layer of oversight and regulation of pharmaceutical wholesale distributors. Hence, as is apparent, a regulatory process to oversee pharmaceutical wholesale distributors is in place. However, until recently the diligence on the part of regulators to enforce established legal requirements has, at times, varied.

The way the drug distribution process generally works is as one would expect. Pharmaceutical products originate at the manufacturer and then are shipped directly to the pharmaceutical wholesale distributor. At that point, the pharmaceutical wholesale distributor receives and stores the product in their climate-controlled warehouses pursuant to the manufacturer's requirements or regulatory dictates (e.g., some products must be refrigerated, while others, such as controlled substances and narcotics, are required to be stored in secure areas, such as a caged-in area of the facility or a vault). Once orders are received

3. *See* Prescription Drug Marketing Act of 1987, 21 U.S.C. § 353 (2005); 21 C.F.R. § 205 (2005).

4. For example, in states such as Ohio and Nevada, it is the state pharmacy board that licenses, inspects, and disciplines wholesale distributors. However, in Louisiana, there exists a state board of wholesalers who is tasked with this responsibility. Lastly, in other states such as Texas and Florida, the state department of public health is the entity responsible for regulating wholesalers.

from health care providers such as pharmacies and hospitals, those products are then picked and delivered to the appropriate location for administration to patients. This, in essence, is how the system works in the majority of cases.

However, in a few cases, there may be pharmaceutical wholesale distributors that purchase pharmaceuticals for the exclusive purpose of selling them to other wholesalers. These wholesalers are commonly referred to as alternate source vendors (ASVs), or secondary market distributors. In this case, a pharmaceutical wholesale distributor may have purchased product from an ASV, as opposed to obtaining the product directly from the manufacturer. In addition, some pharmaceutical wholesale distributors that are not ASVs per se may also have purchased product from each other depending upon the situation. Lastly, there are situations where even pharmacies and health care providers may purchase product and sell it between themselves. As such, the concept that pharmaceutical products only come from the manufacturer directly to one wholesaler, who in turn sells it to one health care provider, who then dispenses or administers it to a patient, does not occur in every situation. However, this is indeed the case a vast majority of the time.

One question that may arise is why a pharmaceutical distributor would purchase from an ASV or another distributor as opposed to only purchasing product directly from the manufacturer. In addition to pricing issues that motivate some purchases in the ASV marketplace, there are also situations where product shortages, backorders and limitations occurring at the manufacturer result in product outages. To be able to service health care provider demands, non-manufacturer suppliers have been utilized. Unfortunately, it appears that this has been one of the avenues by which counterfeit product has, on rare occasions, entered the distribution system.

In light of the potential risk of counterfeit product being introduced into the drug distribution system through the ASV marketplace, the wholesale drug distribution industry, and in particular the Big Three distributors, has taken steps to help protect against such occurrences. Through its trade association, the industry has established standards in the *HDMA Recommended Guidelines for Pharmaceutical Distribution System Integrity*,[5] which establish how distribution activi-

5. *See* HEALTHCARE DISTRIBUTION MGMT. ASS'N, RECOMMENDED GUIDELINES FOR PHARMACEUTICAL DISTRIBUTION SYSTEM INTEGRITY (2003), http://www.healthcare distribution.org/gov_affairs/anti.asp (follow "Recommended Guidelines for Pharmaceutical Distribution System Integrity" hyperlink).

ties should be conducted to substantially reduce any threat of counterfeit products. In addition, some distributors such as Cardinal Health, have established internal requirements and procedures that exceed regulatory or industry guidelines to help further ensure the integrity of products received into their distribution systems. In Cardinal Health's case, today over 99% of pharmaceuticals are purchased directly from the manufacturer. Purchases from other distributors are only made from fully licensed (federal and state) entities, and only after Cardinal Health performs a rigorous assessment to validate that the systems those vendors use are compliant and robust. This includes Cardinal Health auditing those vendors and establishing that they meet its supplier qualifications. In addition, today Cardinal Health will only source brand name prescription pharmaceuticals directly from their manufacturers. Cardinal Health also continually evaluates which new and existing products may pose a potential counterfeiting risk and excludes the purchase of such drugs from anyone other than the manufacturer. Also, all of Cardinal Health's non-manufacturer suppliers are reviewed on a regular basis, and Cardinal Health discontinues doing business with any supplier when a concern arises about the integrity of the product being sold by that supplier or where the supplier fails to comply with regulatory and industry guidelines.

Technology

As a result of concerns regarding the integrity of the supply chain, the FDA and a number of state agencies and lawmakers have focused upon what more can be done to help prevent counterfeit drugs from entering the U.S. health care system. The FDA's February 18, 2004 report entitled *Combating Counterfeit Drugs: A Report of the Food and Drug Administration,* and subsequent update on May 18, 2005, discussed various technologies that may provide value in this regard.[6] We will discuss two such technologies: 2D Serialized Bar Codes and Radio Frequency Identification (RFID). Both technologies employ an Electronic Product Code (EPC) that utilizes a unique identification number that provides serialization for each individual item. In doing so, the EPC number accompanies each legitimate item, thus allowing those parties distributing the product to authenticate the product as it

6. FDA, COMBATING COUNTERFEIT DRUGS: A REPORT OF THE FOOD AND DRUG ADMINISTRATION (2004), *available at* http://www.fda.gov/oc/initiatives/counterfeit/report02_04.html; FDA, COMBATING COUNTERFEIT DRUGS: A REPORT OF THE FOOD AND DRUG ADMINISTRATION ANNUAL UPDATE (2005), *available at* http://www.fda.gov/oc/initiatives/counterfeit/update2005.html.

moves through the supply chain. Ideally, EPC-based technology should work to identify only a legitimate item and determine where it has been.

2D Serialized Bar Codes

2D Serialized Bar Codes (2D Bar Codes) are similar to the typical linear bar codes (e.g., 1D bar codes) that many consumers see at the checkout line. However, 2D Bar Codes provide much more information. Unlike a typical linear bar code, 2D Bar Codes have the ability to hold literally hundreds of characters in a very compressed area. In addition, 2D Bar Codes can contain information specific for that particular drug product, such as a unique serial number per drug unit, a manufacturer's lot number, expiration dating for the product, and the FDA's National Drug Code (NDC) number. This 2D Bar Code "serialization" process would have to begin with each manufacturer assigning a 2D Bar Code and information to its product, and placing the bar code on each commercial sale unit it distributes. From there, each bar coded unit could then be physically scanned by each entity in the supply chain (e.g., the wholesale distributor, the pharmacy, or another health care provider) to help verify the packages' authenticity. In order to track and trace authentic product movements, the read information would have to be stored in a database and updated on a continual basis.

There are some significant challenges to the use of this technology from the pharmaceutical wholesale distributor's perspective. First, it is essential that manufacturers using the 2D Bar Code technology adopt the same data standard. If different standards are employed, this will adversely impact the ability of distributors (and health care providers such as pharmacies) to cost-effectively adopt this infrastructure. Second, the process of physically scanning each and every item so as to input that information into a supply chain database will increase costs and slow down efficiencies. Distribution centers receive cases of product from manufacturers. To be able to record what product was received, each item would have to be removed from its case at the warehouse, physically scanned, and then stored. Currently, manufacturers' cases are not opened until product is needed for deliveries. In addition, many large wholesale distribution operations have automated pickers that are used to retrieve product within the warehouse, which is then placed into delivery totes. An example of such technology is a machine called the A-Frame. A typical A-Frame holds about 50,000 items and on average picks about 8300 items per hour. This amounts

to approximately 138 items being picked every minute. The A-Frame is not situated to be able to scan 2D Bar Code labels. Hence, human intervention would be needed to scan each unit slated for delivery. Thus, the efficiencies associated with this technology would be adversely impacted. Lastly, there is uncertainty over who would develop and maintain a single database to store the millions of records of all pharmaceuticals manufactured and distributed in the United States. This would be a significant undertaking and critical to the success of an industry-wide technology initiative.

Radio Frequency Identification

RFID is another form of track and trace technology that has received significant public attention. RFID generally consists of electronic tags (comprised of an electronic circuit and an integrated antenna) that allow for electromagnetic waves to be identified by readers. These readers capture the signals received from these electronic tags and interpret the data stored on the tag's chip. This data could include a unique identifier per drug unit, a NDC number, or other information. The benefit that RFID ideally has over other technologies such as 2D Bar Codes is that RFID does not require line-of-sight scanning since radio waves are transmitting information to electronic readers. Thus, ideally RFID, if implemented as intended, should help to address the efficiency issue mentioned earlier. While RFID holds much promise, the application of this technology currently has significant limitations.

A pilot study was commenced in October 2003 as a proof of concept to determine whether RFID technology could effectively be used within the pharmaceutical supply chain system. Cardinal Health participated with a dozen companies comprised of manufacturers, other wholesale distributors, and retail pharmacies in an RFID pilot program referred to as Project Jumpstart.[7] The pilot program involved the manual tagging of certain drug items at the manufacturer level with readers provided at the pharmaceutical wholesale distributor and pharmacy level to read and record the information provided by the

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7. Companies involved in the Project Jumpstart pilot program included manufacturers such as Abbott Laboratories, Barr Laboratories, Merck & Co., Johnson & Johnson, Novartis, Procter & Gamble, Pfizer, Sanofi-Synthelabo, and Wyeth; pharmaceutical wholesale distributors such as Cardinal Health and McKesson; and retail pharmacies such as CVS, Rite-Aid and Walgreens. In addition, Accenture served as the program manager for the group and industry trade associations. The Healthcare Distribution Management Association (HDMA) and the National Association of Chain Drug Stores (NACDS) were also part of the working group.

electronic tags. The results of the pilot, while promising, were not a resounding endorsement for using this technology in its current state. Some of the data provided from the pilot found that of the 20,564 RFID tags received for use, only 73% of those tags were readable prior to their application to the pharmaceutical containers by the manufacturer. In addition, of those RFID tags that were readable at the manufacturer level, the failed reads for wholesaler distributors of those same tags at the distributors' warehouses were between 3.5% and 21%. In addition, it took between three and fifteen minutes to read a full case containing RFID labeled drugs, due to radio wave interference which, at times, was caused by the RFID tags themselves.

As such, while RFID technology holds promise for the future in terms of deterring counterfeiting, improving supply chain efficiencies (e.g., inventory management, tracking returns, and outdated product), assisting in recall identification and process, and ideally enhancing patient safety (e.g., bedside administration), the technology currently has significant limitations. RFID (and to some extent 2D Bar Codes) provide added costs and expenses in terms of tags or bar codes and readers or scanners. Also, such technology requires additional labor and time in the distribution process due to their current incompatibility with existing systems. Furthermore, the issue regarding ownership of the supply chain database, as in the case of 2D Bar Code technology, still exists. In addition, RFID technology has been shown to be adversely affected by other existing technology (e.g., wireless telephones), and there exists a lack of standards currently in place for RFID that also poses a problem in determining which RFID system(s) to utilize. Lastly, there remains a significant question as to whether all participants will choose to take part in the process and which technology they will adopt. Without the participation of each and every stakeholder (e.g., manufacturers, wholesale distributors, pharmacies, and other affected health care providers), the system will not operate efficiently or effectively. Partial implementation of RFID or other technology adds significant costs and expenses without establishing the safeguards needed to ensure product integrity and traceability throughout the continuum of the supply chain.

Potential Implications of Importation into the United States Supply Chain Integrity

Recently, there has been much discussion of drug importation and the potential economic benefit to U.S. citizens in being able to purchase affordable pharmaceuticals. While numerous consumer groups

and some legislators support such efforts, the legality of doing so under existing law is questionable. First, the American Goods Returned provisions of the Federal Food, Drug, and Cosmetic Act essentially state that no prescription drug that "is manufactured in a State and exported may be imported into the United States unless the drug is imported by the manufacturer of the drug."[8] Furthermore, violations of this statute carry potential criminal penalties of up to ten years in prison and/or $250,000 in fines. In addition, while Congress passed legislation to allow pharmacists and wholesalers to import prescription pharmaceuticals into the United States, this could only be done provided the Secretary of the U.S. Department of Health and Human Services found that sufficient safeguards were in place to ensure that such imported product is safe and effective for its intended use and is in accord with other requirements set forth under the Food, Drug, and Cosmetic Act. Furthermore, the Secretary was to certify to Congress that the implementation of this section will "pose no additional risk to the public's health and safety" and will "result in a significant reduction in the cost of covered products to the American consumer."[9] To date, the Secretary has yet to provide this certification.

In addition, the Food, Drug, and Cosmetic Act only permits products approved by the FDA to be marketed and sold within the United States. Hence, products not having an approved New Drug Application (NDA) or Abbreviated New Drug Application (ANDA) with the FDA or falling under some other limited exception (e.g., pre-1938 or pre-1962 grandfathered products) cannot legally be sold within the United States. Furthermore, the FDA has established manufacturing, packaging, and labeling requirements which may not be met by a significant number of foreign produced pharmaceutical products. Hence, those products also cannot be sold in the United States under existing federal requirements.[10] In addition, the FDA has been fairly adamant in its position that drug reimportation is illegal and that it will prosecute those choosing to undertake such activities. Various states have also taken action against pharmacies that have either directly or indirectly tried to have product dispensed to U.S. citizens from pharmacies located outside of the United States.[11]

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8. 21 U.S.C. § 381(d)(1) (2005).

9. 21 U.S.C. § 384(l) (2005).

10. *See* U.S. DEP'T OF HEALTH & HUMAN SERVS., HHS TASK FORCE ON DRUG IMPORTATION: REPORT ON PRESCRIPTION DRUG IMPORTATION (2004), *available at* http://www.hhs.gov/importtaskforce/Report1220.pdf [hereinafter HHS TASK FORCE].

11. One example of such state activity was where the Alabama State Board of Pharmacy obtained injunctive relief against Discount Drugs of Canada prohibiting them from dis-

Aside from the significant legal hurdles that currently exist with drug importation by pharmaceutical wholesale distributors (and other non-manufacturing entities), supply chain concerns also exist. Currently, the U.S. drug distribution system is essentially a "closed" system, wherein product moves between certain select entities (e.g., manufacturers, wholesale distributors, and pharmacies) until it ultimately reaches the patient. All of these health care entities fall under the jurisdiction and authority of federal and/or state regulatory bodies. Thus, licensure requirements, inspection activities, and enforcement activities can and do occur, wherein the regulated entities all follow essentially the same standards and requirements depending upon their industry. In contrast, foreign entities many times do not follow U.S. requirements and standards. In addition, it has been found that a number of foreign governments have little incentive to ensure that drugs exported from their respective countries are safe and effective. Thus, reliance upon the regulatory process, paper validation, and licensing practices conducted by foreign regulatory bodies, where product is destined for export to U.S. citizens, may be misplaced.[12] As a result, what was once a "closed" system is again "opened" by the addition of foreign suppliers such as foreign wholesale distributors or pharmacies.

Some commentators have asserted that technology such as RFID and bar coding can be employed to ensure that product entering the United States is not counterfeit and can validate that such product meets those requirements set forth under the Federal Food, Drug, and Cosmetic Act. As mentioned earlier in this essay, practical challenges currently exist for the effective implementation of technologies such

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pensing prescription medications to residents of Alabama. *See* Alabama State Bd. of Pharmacy v. Discount Drugs of Canada, No. CV 03-1742 (Ala. Cir. Ct. Jefferson County Mar. 31, 2003) (order granting preliminary injunction). In addition, the FDA was also successful in obtaining injunctive relief against another pharmacy, Rx Depot, wherein Rx Depot, Inc. and Rx of Canada, LLC assisted U.S. residents in having prescriptions filled outside of the United States by Canadian pharmacies. *See* United States v. Rx Depot, Inc., 290 F. Supp. 2d 1238 (N.D. Okla. 2003) (order granting preliminary injunction).

12. *See* HHS TASK FORCE, *supra* note 10, at xi, 62. For example, in Canada, the Health Products and Food Branch (HPFB) of Health Canada regulates drugs by the review of applications for marketing authorizations and Drug Establishment licenses. However, under section 37(1) of the Canadian Food and Drugs Act, an entity can be exempted from the requirements of obtaining a Drug Establishment license and complying with Canadian Good Manufacturing Practices (GMP) if the drug is intended for export from Canada and so identified. Thus, "[i]f a Canadian fabricator chooses to invoke Section 37 for a drug, the Inspectorate will not verify GMP compliance for the process related to that specific drug, and therefore the Inspectorate cannot attest to the quality of the fabricator's products." *See* HEALTH PRODS. & FOOD BRANCH, HEALTH CAN., GUIDANCE DOCUMENT ON THE COMMERCIAL IMPORTATION AND EXPORTATION OF DRUGS IN DOSAGE FORM UNDER THE FOOD AND DRUGS ACT (2003).

as RFID. In addition, standards for technology like RFID have yet to be uniformly established in the United States, as well as the rest of the world. For example, differences exist as to what radio frequency is permitted in Europe versus the United States. Also, countries with limited supplies of pharmaceuticals (such as Canada) are taking steps to limit exports, in an effort to guard against product shortages that might result from the flow of their lower-priced drugs to the United States. Manufacturers may also be economically disincentivized to tag and readily identify foreign product suitable for sale and importation into the United States. Price control mandates in foreign countries limit what manufacturers can charge for such products abroad. To have those foreign products readily identifiable and capable of being shipped into a more lucrative market such as the United States would adversely affect that manufacturer's U.S. sales.

CONCLUSION

The pharmaceutical wholesale distribution industry has taken significant strides to establish a secure distribution system where patient safety is the leading goal. Ongoing assurance programs, audits of suppliers, increased regulatory requirements, and work with emerging technologies have all been instrumental in helping to prevent counterfeit drugs from entering the U.S. pharmaceutical supply chain. If a decision to move forward with importation is made, pharmaceutical wholesaler distributors, with systems and infrastructures in place to protect product integrity and detect and deter counterfeit drugs, would be best equipped to maintain the safety and security of the national drug supply. Nonetheless, there are significant challenges that must first be addressed to ensure the broad safety of imported products while maintaining the desired cost benefits for consumers. The two key areas that any approach to importation must address are product authentication and ensuring the integrity of imported products for the U.S. market. However, until more reliable means are established, significant concerns remain as to the safety of importing or reimporting prescription pharmaceuticals from foreign non-manufacturing sources.