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VIA AIRBORNE

June 4, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Comments regarding Prescription Drug Importation (Docket No. 2004N-0115)

Dear Sir or Madam:

Please accept this as our response to the Drug Importation Task Force's request for comments concerning the importation of prescription drugs. Cardinal Health supports the premise that low cost prescription drugs should be available to all Americans – especially those such as the poor and elderly. However, we are concerned that drug importation does not necessarily provide the best solution to this problem.

We do not believe that a safe and effective solution involves opening up our pharmacy and drug distribution system to drugs imported from abroad. There exist significant risks that those imported drugs may lack the same safeguards as those drugs currently available in the United States. It is those safeguards which ensure that drugs provided to U.S. citizens are approved by the FDA and distributed under a closed system by U.S. wholesalers and pharmacies. The importation concept proposed has the potential to undermine our current closed system of delivering healthcare, and more importantly, places patients at risk by doing so.

As such, we respectfully submit our attached comments in an attempt to have the Task Force better refine and improve the important task it has begun and to seriously consider those challenges posed in the event it decides to recommend that drug importation should occur.

Sincerely,



Robert P. Giacalone

cc: Gary Dolch (Cardinal Health)

Attachment

2004N-0115

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Scope and Volume of Imported Drugs

I. Assess the scope, volume and safety of unapproved drugs, including controlled substances, entering the United States via mail shipment.

The issue of assessing the scope of what products enter the U.S. marketplace from abroad is not a simple task. By opening up the domestic marketplace to prescription drugs from abroad, we essentially also open up the closed regulatory system which currently exists in the U.S. for the distribution of prescription drugs. This action increases the opportunity and risk for counterfeit and/or diverted drug to enter into our country. Also, given the limited amount of "legitimate" product available for importation from abroad, one questions how the demand that will be created by American consumers can be met. More likely than not, products originating from countries such as Thailand and Pakistan (where counterfeiting and inadequate drug manufacturing is more prevalent) will find their way into countries such as Canada which, in turn, will supply product to the U.S. consumers. Since trans-shipped drugs (e.g., products imported into other countries solely for export purposes) are not subject to the same level of scrutiny as drugs provided to Canadian citizens, we open the U.S. drug supply up to questionable product. As a result, our drug supply will be at risk to infiltration by exactly those types of products we have historically worked to stop.

Among the conditions that need to be met and can not with the current system are: (1) imported product must be authenticated to ensure against substitution of products that are substandard, not bioequivalent or worse yet, counterfeit; (2) imported product must have its integrity preserved to avoid product degradation or adverse effects attributed to the product through mishandling; and, (3) imported product must be readily available such that supplies of the product are sufficient to deter counterfeiters and others from using diverted, unapproved or adulterated product in an attempt to address product shortages. Without the implementation of proper steps addressing these areas, there simply will not be the same assurances and safeguards as those currently provided for by domestically sourced prescription drugs distributed by licensed U.S. wholesalers and dispensed to patients by U.S. pharmacies.

IMPACT ON PHARMACEUTICAL DISTRIBUTION SYSTEM

II. Assess the pharmaceutical distribution chain and the need for, and feasibility of, modifications in order to assure the safety of imported products.

While we struggle with a solution as to how to establish an ironclad system which ensures the safety and efficacy of imported prescription drugs, we believe that any system employed should involve safeguards addressing issues surrounding terrorism. Prescription drugs sold in the U.S. have historically been associated with safety and quality. This is a long standing belief based in part upon our system of healthcare which is considered to be the best in the world. Imported drugs, given their potential for wide-spread use by consumers, pose a unique vehicle through which intentional adverse acts can be perpetrated by terrorist groups on an unsuspecting public. At a minimum, in order to attempt to ensure the safety of imported products we would recommend that the same level of security that U.S. Customs and Border Protection ("CBP") is recommending with its Customs-Trade Partnership Against Terrorism ("C-TPAT") program be applied in the case of imported drugs. Specifically, there should be a security program in place validated by CBP which addresses plant, personnel, and supply chain security. Furthermore there should be a program in place that from time to time validates the security measures in place to ensure that the imported products have not been compromised.

A. The Task Force is seeking information and comments on whether it is appropriate or necessary to limit importation to specific persons (e.g. pharmacists, wholesalers, individuals under certain circumstances) in order to adequately assure the safety of imported drugs, and how such limitations would impact the availability of such products. Should importation be limited only to distributors, pharmacies or other entities that are licensed or approved by the exporting country? Because foreign drug safety systems generally focus on the safety and security of the domestic drug supply of the foreign country, should a licensure or certification process overseen by U.S. regulators be used to help assure safety for U.S. consumers?

While we question whether those steps outlined above would suffice to address the issues and risks posed by importation of foreign prescription drug product, we have the following comments on the matter. First, we believe that if any importation of prescription drugs is allowed to take place, then that process should be limited to entities skilled in handling drugs and who are currently involved in the drug distribution process. To accomplish this task, those types of operations should be limited to entities such as wholesalers and pharmacies. Furthermore, that group should be further limited to only those wholesalers and pharmacies (and not necessarily

pharmacists) who can clearly demonstrate that they have the requisite skill and knowledge to be able to source and import prescription drugs and do so in a safe and secure manner. Simply identifying a foreign seller/supplier and a Customs Broker to facilitate a transaction alone should not suffice. Rather, the day-to-day handling of a large number of products coupled with the ability to assess the veracity of foreign suppliers is essential. Furthermore, this system should be conducted solely through a closed linear system so as to ensure product integrity. Specifically, this would necessitate that product flow directly from the manufacturer to the exporter to the importer to the pharmacy. In addition, all this must be done in compliance with rigorous regulatory standards (which have yet to be clearly defined), established registration requirements, and diligent inspection programs so as to ensure that all those engaged in exporting and importing prescription drugs are identified and suitably qualified to do so.

Conversely, we believe that individual consumers or patients should not be permitted to import drugs into the United States for personal use or otherwise. Also, persons should be prohibited from assisting patients who are attempting to do this on their own given the inherent risks associated in the process. This view is predicated on the fact that consumers generally are unable to differentiate drug product; adequately assess those supplying such product from abroad; or, be situated to affectively determine how what should be done to ensure against adverse events occurring as result. Leaving patients and consumers to act as drug importers simply places them in a position of significant risk without any safeguards to properly evaluate those threats. Worse yet, it not only places those individuals at risk, but also their families and friends with whom they assist in furthering this process. While those patients may have the best of intentions in importing drug products, the end result may be a significant threat to both themselves and those for which they care.

In considering what entities should be involved in the importation process, the question was raised as to whether importation should be limited to only those distributors, pharmacies or other entities that are licensed or approved by the exporting country to be allowed to import into that originating country. We question the rationale to that approach. First, there are no guarantees that simply because an entity is licensed in a foreign jurisdiction that it will take steps needed to ensure the integrity of product destined for the U.S. market. In fact, there may be less of an incentive to do so. As laws in the various jurisdictions appear to indicate, if products are imported into a foreign jurisdiction for purposes of trans-shipping to other foreign locations (such as the United States), those safeguards allegedly present in those foreign locations evaporate. As a result, those "safeguards" which many argue are in place in foreign jurisdictions no longer exist for those exported products coming to the United States. Hence, our citizens have the very real

potential of receiving product not meeting U.S. standards nor the regulatory standards of those countries we believe to have similar (albeit lesser) standards.

This is a serious concern given that a number of countries (e.g., Canada, United Kingdom, Germany) which are being considered possible suppliers of prescription drugs to the United States, allow for this regulatory exception wherein products are imported into that country for purposes of exportation. This poses a significant issue given that U.S. demand for imported prescription drugs will outweigh supply in those countries considered to be possible sources of imported product. For example, one study indicted that Canada could not supply the needs of the American marketplace. In fact, it was cited that if only half the U.S. seniors purchased their medications from Canada, the Canadian drug supply would have increase by 2.5 times to meet this demand. *Study by Marv Shepherd, Director of the Center for Pharmacoeconomic Studies at University of Texas-Austin as quoted in the USA Today, May 16, 2004.* More disconcerting is the fact that this same study found that drug imports into Canada have increased significantly over time. The Study found that Canada doubled the value of its drug imports since 1999, from \$2.3 billion to \$4.7 billion last year. However, even more disconcerting was the fact that in 2003, only 44% of those drugs imported into Canada came from the United States. The rest came from more than 80 countries, including Ireland, Italy, Mexico, India, Cuba, Colombia and Guyana. As such, one must question whether U.S. citizens have been and will continue to be the unfortunate beneficiaries of prescription drug products sourced and/or originating from locations such as Mexico, Colombia and Guyana.

This being the case, it is highly unlikely that limiting importation to distributors, pharmacies or other entities that are licensed or approved by the exporting country is the solution. This especially true given the fact that a foreign entity's first priority is to the country in which it resides. Foreign regulators will be concerned about ensuring that those foreign distributors and pharmacies provide their own citizens with safe and effective drug product. As countries such as Canada have affirmed, their first and foremost concern is that of their own citizens. Rather, the primary responsibility for the health and welfare of U.S. citizens is the concern and responsibility of U.S. regulators. That being the case, if importation of drugs is to take place, it is domestic entities that are better situated to ensure that proper product is delivered to U.S. citizens. The established presence of drug wholesalers in the U.S. indicates their commitment to domestic customers and patients. Furthermore, for purposes of accountability – both from a regulatory and civil liability standpoint – they are better situated and incentivized to ensure that product provided to U.S. citizens is appropriate.

Given the exceptions and nuances which exist in foreign jurisdictions, those same assurances are lacking.

If one was to consider the viability of drug importation, it would require the active and ongoing involvement of the FDA. The question was raised as to whether a licensure or certification process overseen by U.S. regulators should be used to help assure safety for U.S. consumers. We believe that while perhaps useful, this would constitute the minimum of resources needed by the FDA and other regulators (e.g., U.S. Customs, etc.) to ensure the integrity of the supply chain. More importantly, there would need to be a very hands-on, active approach by U.S. regulators in terms of licensure assessment, inspections and evaluations of how and where product slated to be imported into the U.S. is to be sourced. This evaluation should include assessing the means by which that product is to be delivered to the United States. Again, this would involve the U.S. regulatory agencies obtaining and validating, on an ongoing basis, the supply chain beginning with the manufacturer and finishing with the domestic supplier (e.g., wholesaler or pharmacy). Anything short of this would result in the potential for U.S. citizens to receive substandard, or worse yet, dangerous product.

Some prior discussion involved the merits of physically testing imported product. While the concept of testing may appear to be a rational approach to verifying the legitimacy of imported product, the practical application of such testing provides issues. First, the testing involved would have to evaluate each product sample for both active and inactive ingredients. In addition this testing would have to be applied to each lot of each product received in every shipment by the importing entity. Third, the cost and expense associated with such testing is significant. Tests needed to be performed to establish product identity (e.g., high performance liquid chromatography (HPLC), gas chromatography (GC), Fourier transform infrared (FT-IR) spectroscopy, nuclear magnetic resonance (NMR), and Capillary Electrophoresis(EC)) could total as much as \$15,000 per sample. Unfortunately, while this testing might establish center parameters regarding drug product, it would not establish whether the product was actually made pursuant to FDA standards and done so in a U.S. approved facility. Furthermore, testing of this nature would not establish bioavailability or bioequivalence between imported product and drug product used in the United States. Again, that too would involve additional information, time and tests. In addition, depending upon what products are permitted for importation (e.g., unapproved generic versions of branded products), bioequivalency requirements could not be met because of the differences inherent in those products. In that case, there should be serious consideration as to whether allowing such product into the U.S. is prudent and in the best interest of the public health.

B. The Task Force is seeking information on the appropriateness of any additional requirements for the import distribution system that may be needed to assure import safety, including changes involving: limitations on ports of entry; enhanced chain of custody requirements; prohibitions on importer resale; other changes in wholesale distribution as a result of importation; additional labeling of imported products; additional recordkeeping requirements; or any additional limitations on foreign sources of products that would be needed to assure the safety of imported products.

While there appears to be no absolute way to ensure the security of the distribution system as it pertains to importing prescription drugs in its current form, there are, at minimum, some areas which should be reviewed in trying to address those concerns. First, consideration should be given to establishing some type of enhanced custody requirements along the lines of those set forth under the Bioterrorism Act. Under the Bioterrorism Act, facilities that manufacture, process, and pack the drugs should apply for a registration number. This approach should apply here too. This would include all facilities involved in the process (e.g., facilities from which the product is sent and those facilities from which the product is received) as well as the importer in the case where the importer is a different or unrelated entity. In addition, prior notice is something that should be expected and required. However, for this to be practically feasible, this prior notice of when drug product is to be shipped and imported into the U.S. should be reasonably short in duration. For example, prior notification time of less than 2 hours for air shipments would be a reasonable period to ensure proper and effective movement of product.

As mentioned before, chain of custody demands that, the process be a closed linear system to ensure product integrity. Specifically, this would necessitate that product flow directly from the manufacturer to the exporter to the importer to the pharmacy. The problem in maintaining this condition is ensuring that the system remains closed. Furthermore, even if the system is closed, the second concern is validating that the drugs are the same as those currently approved in the United States. Again, as mentioned above, this validation involves its own inherent challenges.

As to the closed linear system, the ability to establish whether that system remains "closed" is problematic. The only sure way to do so, would be for the importer to arrange for and receive the imported drug product directly from the manufacturer. Few if any manufacturers who currently market drugs in the U.S. would willingly participate in such a system. If the manufacturer is unwilling to participate, the purchase of foreign drugs will have to go through third parties such as foreign wholesalers, pharmacies or other suppliers who may be able to provide product. Again, the practical

concern here is the ability of manufacturers to limit supplies of product to foreign wholesalers, thus further limiting product availability. Even where there were no manufacturer limits, the reality of the situation is that there are insufficient quantities of prescription drug which can supply U.S. needs. As a result, we are again left with reality that their will be insufficient quantities, or worse, that this demand will be met by foreign wholesalers, pharmacies or other suppliers providing U.S. citizens with drugs originating from questionable sources.

To attempt to ensure that imported drug is what it purports to be, recordkeeping is crucial. The traceability of product from its origins at the manufacturer, through the foreign supplier to the domestic wholesaler and finally to the pharmacy level is essential. In this way, an attempt can be made to identify all parties involved in the process. Furthermore, in the event of a drug recall or related event, all parties can be appropriately notified down to the patient level. While recordkeeping is essential, questions exist as to the veracity of such documentation for product sourced outside the United States. In the U.S., the Prescription Drug Marketing Act of 1987 (PDMA) sets forth the requirements for recordkeeping. In addition, the U.S. Drug Enforcement Administration (DEA) sets forth additional requirements when dealing with the distribution of controlled substances. These regulatory systems and requirements help to ensure the authenticity of product. However, when dealing with entities outside of the U.S., those same systems and requirements are no longer in place. As a result, assurances as to product distribution outside of the U.S. become more problematic. For this reason alone, it is prudent that only select entities be permitted to import drug product into the U.S. – specifically, wholesale distributors with an established presence in the U.S. Only by understanding our current regulatory system and standards can entities skilled in the handling of drug product help to ensure that product received is what it purports to be.

Commentators have stressed the importance of using technology in the process of validating the authenticity of product. Specifically, track and trace technologies such as Radio Frequency Identification (RFID) have been suggested to help in this regard. While such technology is still in its developmental stages, the concept may eventually prove useful. However, practical limitations still exist including the level of application, the nature of the data base, the information flow and the level of adoption throughout the world or at least in countries that are potential sources of imported product.

Lastly, appropriate product labeling will pose a challenge if drug importation is allowed. Imported products will most likely have to be repackaged and relabeled to meet FDA specifications. This in turn means ensuring that the product's label, which may appear in a foreign language, is now accurately

translated into English. In the alternative, this means conforming English language labeling to meet FDA requirements. Furthermore, the labeling requirements become more problematic when dealing with product sourced from locations outside Canada. Generally, products sold in Europe come in blister or unit dose packaging. The expiration dating for those products are determined by a foreign jurisdiction based upon packaging components and climate zones used for that country. This dating determination may not be in accord with the time parameters set forth by the FDA. Thus, there may be a discrepancy on how long the product can be used by consumers regardless of how they are originally labeled. Furthermore, the English language labeling requirements become more difficult to address if product is sourced outside of Canada where blister or unit dose packaging is predominately used. The repackaging of blister packages is a more laborious process subject to more opportunities for error and mix up. Furthermore, FDA's position on the repackaging of unit dose product into other unit dose packaging limits that product's expiration dating to six (6) months dating unless costly stability studies are conducted to validate that longer expiration dating is warranted. All of these steps are critical, and they will result in additional time in getting drugs to the patient and have costs associated with them that also need to be factored into the process.

C. What processes and criteria would be necessary to ensure (i.e., certify) that a specific importer (pharmacy, wholesaler, etc.) abides by standards of pharmacy practice that are at least as rigorous as U.S. pharmacy standards? Would limiting the countries from which importation be permitted (e.g., Canada) make the process of certification less costly and more effective?

As mentioned above, the only way to help ensure that a specific importer abides by U.S. standards is to require that this entity have an established presence in the United States and that jurisdiction exists over that entity. In doing so, the process works towards having experienced U.S. based entities involved in the distribution process play an active role in this new endeavor. This approach also ensures that entities currently involved in the drug distribution process and having an established history are also licensed at both the federal and state level.

D. Should legal importation be limited to wholesale shipments, rather than a much higher volume of small individual drug shipments?

As mentioned above, the process of drug importation, if permissible, should be limited to wholesale shipments done by established and licensed U.S. wholesale drug distributors. This is predicated upon the fact that U.S. drug wholesalers understand and abide by U.S. regulatory requirements for drug distribution and are better able to evaluate and assess foreign suppliers. Small individual shipments to small entities, pharmacies, or, worse yet,

consumers does not provide for the level of understanding or review of the distribution process needed to help ensure the process is done appropriately or to evaluate whether the parties involved are what they purport to be. While there is no way short of purchasing product directly from a manufacturer to ensure product identity and integrity, established U.S. domestic drug wholesalers are in the best position to ascertain the legitimacy of suppliers based upon distribution methods and the historical dealings with drug manufacturers.

E. Should legal importation by individuals be restricted to pharmacies that actually serve a significant number of citizens in the exporting countries, or should entities that only export to the United States be allowed?

As we support the position that only domestic drug distributors should be involved in the importation of drugs, we similarly reject that concept that drug importation be restricted to pharmacies that actually serve a significant number of citizens in the exporting countries. As mentioned above, we question whether foreign pharmacies can adequately serve the needs of U.S. citizens. First, there is the question of which citizens will have priorities when it comes to prescription services and the quality of those drugs dispensed. In the case of a foreign pharmacy, more likely than not, it will be those citizens of the country in which that pharmacy resides that will receive preferential treatment over U.S. citizens. This is based upon presence in that country and the regulatory scheme which mandates such activities on the part of foreign licensed entities.

Second, we believe that only U.S. licensed pharmacies and pharmacists should be providing pharmacy services to U.S. citizens. The pharmacy licensure standards and requirements are not uniform around the world. As such, only those healthcare professionals licensed in the U.S. should be permitted to serve U.S. patients. This ensures that the quality of pharmacy services a patient receives is what is mandated under U.S. law and meets practice standards. Second, we believe that pharmacies should do what pharmacies do best and drug wholesalers should do what they do best. Pharmacies are not in the business of drug distribution – wholesalers are. As such, any drug importation should be relegated to those who are the experts in the field – drug wholesalers. Likewise, serving patients should be limited to the experts in that field – U.S. pharmacists.

F. Does FDA, or other Federal agencies, need additional authority to inspect facilities making products intended for importation into the United States? If inspection authority is needed, what types of inspections are needed?

As mentioned beforehand, we believe that it is imperative that the FDA and other applicable agencies inspect facilities involved in the manufacture of pharmaceuticals intended for importation into the US. Since we advocate that drugs being imported be sourced from those manufacturing sites, approved to manufacture the drug under the drug's approved marketing application (NDA, ANDA), we believe this inspection authority already exists. If other sources are contemplated, they should be inspected in the same manner as the approved manufacturing sites. Furthermore, this process should not be limited to facilities, but also include the ability to review the distribution process to ensure that storage as well as transportation is done appropriately. We also recommend that the FDA take a more active role in helping domestic drug wholesalers to validate the origins of drugs slated for importation. Given the FDA's role in the drug approval process, the agency could take a more active role in determining which drug product is suitable for importation and which international manufacturers and associated sites are suitable sources for distribution into the U.S. This is especially important given the fact that the drug approval process in the U.S. differs from those currently in place in other countries which includes Canada, England, Germany and France.

G. Would additional requirements for drug pedigree and "track and trace" records be useful in assisting FDA and other Federal and state agencies to assure the security of these drug imports, i.e., to prevent the introduction of drug products from illegitimate sources? What other mechanisms would be required to enable tracking these products to ensure compliance with applicable considerations or restrictions that are put on them as a result of US law or regulations?

As mentioned above, the use of track and trace technologies such as Radio Frequency Identification (RFID) may provide some benefit in terms of validating the authenticity of product. However, such technology has yet to be perfected or standardized so as to be useful in the near term. Moreover, there is the question as to whether manufacturers will choose to implement such technology outside of the U.S.

H. Would special import packaging and prior notification be useful?

While special import packaging may provide some value, it will probably be limited. Rather, prior notification may be the preferable route provided it sets forth reasonable time frames. Specifically, prior notification should be limited to no more than eight (8) hours for ocean no more than two (2)

hours for air prior to shipment. Anything longer than these time periods will most likely make the process overly expensive and difficult to manage.

I. How would adequate reporting for foreign sources be assured if quality problems are discovered with imported products after they have entered U.S. commerce and provided to patients? What reporting requirements would be needed for adverse events and how would they be enforced?

The question as to how adverse event identification and reporting would take place is a significant issue. In the U.S., there is a well established system for identifying and reporting adverse events. This is coupled with a regulatory system by which recalls are effectuated. In the case of foreign product, the system is only as good as the identification and notification process on the part of the foreign entity. We are confident that when an event is reported to domestic distributors, it will be handled appropriately. However, there is still a concern as to how to ensure that foreign entities provide the same level of diligence that licensed and domestically regulated entities do. Unless the FDA is able to require (via cooperation with foreign healthcare agencies) this type of reporting by affected manufacturers and foreign wholesalers, this issue may prove to be problematic.

III. Determine the extent to which foreign health agencies are willing and able to ensure the safety of drugs being exported from their countries to the U.S.

Given our understanding of the trans-shipment process which takes place in numerous countries (and as mentioned above), this requirement on the part of foreign agencies may prove to be an issue. Unless, FDA can establish a system by which analogous foreign agencies review and inspect such products and these standards are equal to or better than those the FDA requires, there will be shortcomings in the process.

ADEQUACY OF SAFETY PROTECTIONS AND RESOURCES

V. Estimate agency resources, including additional field personnel, needed to adequately inspect the current amount of pharmaceuticals entering the country.

Resources will be needed by various government agencies to help ensure that the drug importation process is done safely and effectively. However, funding of such programs should be left to federal appropriations. Funding for such programs should not be financed through user fees on importers. To do so would simply increase further those costs and expenses associated

with this process. As a result, those fees will be passed down to consumers thus further eroding any potential savings which might be realized through this program.

Similarly, additional resources should be devoted to the FDA to determine what products are suitable for inclusion as imported products. For example, are unapproved generic versions of a branded product suitable for importation? If so, which of these products are acceptable from an importation and product substitution (e.g., AB rating) standpoint for the U.S. marketplace? These and similar issues must be evaluated and addressed for such a program to be successful.

VI. Identify ways in which importation could violate U.S. and international intellectual property rights and describe the additional legal protections and agency resources that would be needed to protect those rights.

Obviously, the importation of generics that are approved in another country but not in the U.S., will provide a disincentive for generic companies to seek U.S. approval. The system will be undermined by the fact that the generic approval process which allows for limited exclusivity will no longer be effective if it can be circumvented by the approval of a generic product in another country prior to its formal entry through the U.S. regulatory system. In essence, if this is allowed to occur, there will be no need for a generic approval process in the United States. This will occur elsewhere in the world with the FDA relying solely upon the capabilities of other healthcare regulatory agencies to assess which products are suitable for generic approval.

ROLE OF NEW TECHNOLOGIES

VII. Estimate the costs borne by entities within the distribution chain to utilize anti-counterfeiting technologies that may be required to provide import security.

As discussed above, the utilization of track and trace technologies may help in the process of drug importation. However, the current limitations of those systems bring into question their practical utility on a global scale. In addition, the implementation of such technology on a global basis will increase the costs associated with any reimportation program thus further minimizing its economic benefits.

LIABILITIES, OTHER COSTS, AND IMPACTS ON INNOVATION

X. Identify the liability protections, if any, that should be in place if importation is permitted for entities within the pharmaceutical distribution chain.

Significant concerns center on the exposure that will exist for drug importers. Under the current system, drug wholesale distributors are essentially indemnified by manufacturers where product is found not to meet FDA requirements (provided there is no negligence on the part of the wholesaler in handling and storing the product). This is due in large part to the fact that wholesalers purchase product directly from manufacturers and that the chain of custody for such purchases can be established readily. Under the importation scenario that process is less likely. First, more likely than not, there will be no direct purchases between domestic wholesalers (or pharmacies) and foreign manufacturers. Rather, those transactions will occur with a foreign wholesaler. Second, manufacturers who do not support importation, will be less likely to indemnify entities which source products from abroad. In those cases, manufacturers will be in a position to question the authenticity of such product coupled with the manner in which it was handled. As a result, wholesale distributors and pharmacies will assume increased liability. For this process to be workable, consideration should be given by the government in trying to provide some type of immunity or shield from liability (both civil and regulatory) where an importer acts in good faith and uses due diligence in completing an import transaction. Without such protections, the wholesaler will have to incorporate higher prices for services rendered so as to offset this potential exposure.