

DETAILED DRUG IMPORTATION QUESTIONS FOR TASK FORCE PUBLIC DOCKET AND MEETINGS

The Drug Importation Task Force has been asked by the Department of Health and Human Services (HHS) to compile information and provide advice to assist in responding to the eleven issues the Department was requested by Congress to study and report on as outlined in the Conference Report to P.L. 108-173.

As part of this effort, HHS has opened a public docket and is requesting public comment. As part of the issues mandated by Congress for HHS to consider, the Department has requested that the Task Force and the public provide comments on more specific questions relevant to evaluation of the Congressionally-mandated issues. These are grouped below with the Congressional issues in bold and the additional Task Force inquiries listed below each.

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.

- A. In conducting the study, Congress directed the Department to take into account the distinctions between drugs that are biological products with licenses under section 351 of the Public Health Service Act (PHSA) and drugs with approved applications under subsection (b) or (j) of section 505 of the Food Drug and Cosmetic Act (FDCA). The Task Force seeks information relating to the scope, volume and safety for importation of these differing types of products.
- B. Are there product characteristics that might be associated with lower risk when imported without going through the usual FDA approval and regulatory process? (For example, the type of product (injectable, controlled substance, etc.), country of origin of the import, Internet mail-order vs. personally transported products, manufacture in U.S. (though not approved for U.S. use) or other country, inclusion of U.S.-approved patient labeling, or characteristics of the shipping entity (e.g., pharmacy that primarily serves individuals of another nation, vs. a pharmacy set up primarily or entirely to handle drugs that will be consumed by residents of the United States).
- C. The Task Force seeks additional information on the volume of various categories and the types of imported products, and on ways in which products of different risk levels could be reliably distinguished or otherwise differentiated at the border or elsewhere.
- D. The Task Force seeks information on whether or not these imports, or some of these imports, could meet U.S. approval standards or the

equivalent. What is the scope and volume of drugs commercially available in other countries that are actually FDA-approved? For imported drugs that are not U.S.- approved, what approaches can be used to determine whether they are equivalent to U.S. approved drugs?

- E. If the scope of imported products is not limited to specific list of authorized products, how would FDA, working with other Federal agencies, identify, track and limit or prohibit importation of products that are not eligible for importation?
- F. What proportion of these different kinds of imported drugs meet typical standards of U.S. pharmacy practice (e.g., no faxed prescriptions from individuals, proper oversight by practicing pharmacist, proper repackaging and labeling, proper notification procedures in the event of product recall)?
- G. If FDA, working with other Federal agencies and state partners, could not assure the same level of safety for imported drugs as consumers expect from drugs purchased at a state licensed pharmacy within the traditional U.S. regulatory system, would a different level of risk would be acceptable and how could that risk be conveyed accurately to consumers?
- H. Should certain products be excluded from importation because of special risk concerns? What impact would limiting the number, types or categories of drugs that would be legally authorized to be imported have on the ability of the FDA and other Federal agencies to assure the safety of such products? The Task Force seeks input on how to establish risk-based criteria for any such limitations, e.g., chronic-use medicines, small-molecule drugs less sensitive to shipping conditions, medicines with wide therapeutic indices, medicines not subject to risk management or controlled-substance restrictions, medicines not prone to misuse.

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.

- 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?

- 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.
- 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?
- D. Should legal importation be limited to wholesale shipments, rather than a much higher volume of small individual drug shipments?
- 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?
- 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?
- 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?
- H. Would special import packaging and prior notification be useful?
- 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?

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.

- ?? The Task Force seeks information on the role that foreign health agencies would be willing or able to play in assuring safety of drugs exported to the United States, or if necessary, implementing additional protections to ensure safety of exported or transshipped drugs?

ADEQUACY OF SAFETY PROTECTIONS AND RESOURCES

IV. Identify the limitations, including limitations in resources and in current legal authorities that may inhibit the Secretary's ability to certify the safety of imported drugs.

- A. The Task Force seeks comments on the changes in law, regulations, and guidances as well as increases in resources needed for the Agency and its other Federal and state regulatory partners to provide a level of safety assurance comparable to that provided by the federal and state regulatory systems that are currently required by law to assure the safety of legal medications. The Task Force is seeking additional information on whether, and to what extent, in order to assure the safety of imported prescription drugs, the government needs:
 - ?? modified authorities to limit the incoming distribution channels to enable the federal agencies to redirect inspectional and compliance resources to manage this new flow of drugs;
 - ?? limitations on importation to U.S.-licensed pharmacists from licensed Canadian wholesalers and individuals;
 - ?? requirements for registration of foreign sellers who would consent to inspection;
 - ?? requirements for enhanced chain of custody requirements to enable track and trace of illegal or illicit imports that pose a safety risk to US consumers;
 - ?? any additional controls to address transshipment of products from third countries;
 - ?? any additional labeling and other information on imported drug products to enable U.S. inspectors to properly inspect the drugs and to adequately inform consumers about the origin of such products.

- ?? any additional information disclosure requirements for pharmacies selling drugs on the Internet.
- ?? any additional authorities for U.S. inspectors to test imported products and to suspend or otherwise refuse admission to products that pose a serious safety risk.

- B. What impact would restricting importation to products *manufactured in* certain countries (e.g., U.S.) have on adequately regulating these products? How would limitations on importations relating to products *shipped from* certain countries, certain entities within countries, and/or certain ports of entry affect the ability to assure drug safety?
- C. How do authorities currently available to FDA and USDA to promote the safety and security of food imports, such as registration, plant and distributor inspection authority, recordkeeping requirements, and prior notice of importation, provide useful information on the development of a system for safety assurances for drug imports?

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

- A. The Task Force seeks information on prioritizing various components of an importation program to provide options at various funding levels. For example, could importation be limited to select countries, select importers, or select classes of drugs as a means to manage costs, and if so, what should be the priority?
- B. Should the costs of an importation program be financed by federal appropriations, user fees on importers, a combination of the two, or some other means?
- C. In addition to additional resources to enhance field operations and hire and train additional inspectors to assure the safety and efficacy of any new channel of imported drugs, what other programmatic changes would be required to generate and collect data about these products, including their equivalence to FDA-approved products if they are not FDA-approved, and to assure good manufacturing practices are utilized in their development?
- D. Clearly, FDA would need resources to implement a drug importation program. Are there other federal agencies that should be considered for funding (Customs, USPS)? Are there non-Federal entities that may need new resources for an importation program?

- E. In addition to funds to implement a new program, are there other activities that the Task Force should consider too build in to its recommendations? For example, testing/demonstrations of particular aspects of importation, or a comprehensive evaluation of a new program?

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.

- ?? What kinds of protections from unapproved competitors would be available for generic manufacturers that have undergone the FDA abbreviated new drug application process? If foreign pharmacies export generics that are approved in their own countries but not in the U.S., will that undermine the incentive for generic companies to seek U.S. 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.

- A. What is the evidence on the feasibility of imposing anti-counterfeiting technologies for drugs not subject to current U.S. regulatory requirements, and the ability of these technologies to prevent counterfeit or otherwise unsafe drugs from entering the U.S. drug supply along with legitimate drugs?
- B. How quickly could the technologies and other steps included in the FDA's recent initiative on securing the current legal drug distribution system against counterfeits be expanded to help assure the security of additional types of imported drugs?
- C. What are the costs associated with implementing these new technologies? What would be the cost to entities within the U.S. pharmaceutical distribution system of any new regulations?

LIABILITIES, OTHER COSTS, AND IMPACTS ON INNOVATION

VIII. Assess the potential short- and long-term impacts on drug prices and prices for consumers associated with importing drugs from other countries.

- A. What are the likely new costs that would be borne by entities within the distribution chain to utilize anti-counterfeiting technologies and undertake other steps that may be required to provide assurances of import security?
- B. What is the evidence on savings for patients from existing parallel importation programs? In legalized systems of parallel importation, to

what extent do international differences in drug prices translate into price differences for consumers, or are a substantial part of the price differences “captured” by middlemen or arbitrageurs?

IX. Assess the impact on drug research and development, and the associated impact on consumers and patients, if importation were permitted.

?? What would be the impact on research and development of drugs and the associated impact on consumers and patients, if changes in importation laws were to be implemented?

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

?? What, if any, liability concerns would exist for entities in the U.S. drug distribution system if importation of drugs from another country were permitted?

ROLE OF NEW TECHNOLOGIES

XI. Analyze whether anti-counterfeiting technologies could improve the safety of products in the domestic market as well as those products that may be imported.

?? Identify the magnitude of the counterfeit drug problem currently existent in the U.S. To what extent is the development of Internet pharmacies contributing to that problem?