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HHS Task Force Report on Prescription Drug Importation

Introduction and Background

In response to the importation of counterfeit and improperly handled and stored drugs, Congress passed the Prescription Drug Marketing Act ("PDMA") of 1987. Among other things, the PDMA amended the Federal Food Drug and Cosmetic Act to include a provision prohibiting anyone except a drug’s manufacturer from importing into the United States a prescription drug originally manufactured in the United States and then exported.

Responding to the growing controversies and debates regarding drug importation policy in the United States, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("MMA") required the Secretary of Health and Human Services ("HHS") to conduct a study on the importation of prescription drugs into the United States. On December 21, 2004, the HHS Task Force on Drug Importation, chaired by Surgeon General, Richard H. Carmona, issued its report to Congress.

Categories of Imported Drugs

Under existing law, FDA recognizes two types of legally imported drugs: 1) Drugs originating in foreign, FDA-inspected facilities, manufactured in compliance with FDA approvals for the U.S. market, and 2) U.S.-approved drugs manufactured in the United States, sent abroad and (re)imported into the United States by the original manufacturer under controlled conditions and in compliance with the Food Drug and Cosmetic Act.

FDA has designated another category of imported drugs as those manufactured in a foreign facility where U.S. approved versions of the same drug also are manufactured. Although such manufacturing process may have been inspected by FDA, the Agency regards the foreign version of a drug to be different in certain respects from the U.S.-approved version. Notwithstanding significant similarities between the two versions, FDA’s position is because of the potential differences and the fact only the U.S.-approved drugs have been shown to meet U.S. standards enforced by FDA, the foreign version is not necessarily considered equivalent to the U.S.-approved version.

Another category of imported drugs is those unapproved in the United States and produced in foreign facilities not inspected by FDA. Such drugs are not formally regulated within the U.S. drug approval and monitoring system, and FDA has little, if any, information about the specifications and conditions under which they are manufactured and distributed.

The Task Force Report In Summary

The report consists of ten chapters and makes eight key findings.

Chapters

Chapter 1. Scope, volume, and safety of unapproved drugs entering the United States. The Task Force found the number of such drugs to be very large: 5 million shipments, comprising about 12 million prescription drug products, valued at approximately $700 million entered the United States from Canada alone in 2003. These purchases were done largely by internet sales.
and travel to Canada by American consumers. The report estimates an equivalent amount of prescription drugs is currently entering the United States from the rest of the world, mostly through the mail and courier services.

Chapter 2. Existing limits on resources and authorities. The report concludes many of the prescription drugs imported into the United States by individual citizens, via mail and courier services, fail to comply with some or all of the U.S. standards determining whether a drug is “safe and effective.” The Task Force determined it would be extraordinarily difficult to ensure drugs personally imported by individuals could meet the necessary standards of safety and efficacy, especially if done in the same or increased numbers by consumers. The Task Force suggested a commercial importation program could be feasible but would require new legal authorities, substantial additional resources and significant restrictions on the types of drugs that could be imported, thereby increasing the costs of imported drugs.

Chapter 3. Impact of importation on the pharmaceutical distribution system. The Task Force noted the drug distribution network for legal prescription drugs in the United States is a “closed” system involving manufacturers, wholesalers, and pharmacists who distribute and dispense drug products from the manufacturer to the ultimate consumer. The Task Force decided legalized importation of drugs in a way that creates an opening in the “closed” system would result in some increase in risk, as weaknesses in the oversight of drug regulation and distribution have been exploited. In particular, the Task Force concluded legalizing importation would increase the opportunity for counterfeit and other substandard drugs to be introduced into the U.S. drug distribution system.

Chapter 4. The role of new technologies. A number of anti-counterfeiting technologies are showing potential for effectively assuring authenticity of drugs and for combating counterfeiting of drugs. Examples cited by the Task Force are: holograms, color shifting inks and watermarks currently employed for U.S. currency. Technologies such as radio-frequency identification (“RFID”) and sophisticated bar coding, the Task Force noted, may also provide effective monitoring of a drug’s movement from a manufacturer through the distribution chain. The Task Force concluded these new and emerging technologies are promising, but currently cannot be adequately relied upon to assure safety, efficacy and integrity in a global market place to import prescription drugs safely into the United States.

Chapter 5. FDA resources associated with drug importation activities. The Task Force heard from FDA managers who repeatedly complained the large number of personal drug shipments coming into international mail and courier facilities is overwhelming the available FDA staff. Of the approximately 3,800 FDA field staff, 450 are involved in investigative import activities. The Task Force found FDA lacks sufficient resources to ensure adequate inspection of personal shipments of prescription drugs entering the United States at current levels. The Task Force concluded if importation were to be legalized, FDA would need a meaningful investment, among other things, in new information technology and personnel, as well as appropriate standards to ensure adequate inspection of commercial quantities of drug products.

Chapter 6. Roles of foreign health agencies. The Task Force determined because foreign governments give priority to ensuring the safety of drugs used by their citizens, such governments have little incentive and limited resources to ensure the safety of drugs exported from their countries, particularly when those drugs are transshipped or originally not intended for import into the United States. According to the Task Force, no country expressed any interest or willingness to ensure the safety and effectiveness of drugs exported from their country in any expansion of legal U.S. importation. The Task Force received few comments by foreign governments, none of which outlined a specific strategy for new steps to collaborate with the United States on oversight of importation of drugs.
Chapter 7. Effects of importation on prices and consumer savings. Based on an analysis of data on drug prices and volumes, the Task Force found total savings to consumers from legalized importation under a commercial system would be a small percentage (estimated at 1 percent to 2 percent) relative to total drug spending in the United States. The report found generic drugs often are cheaper in the United States when compared to international prices for similar drugs. The Task Force found prices paid by foreigners for generic drugs, on average, are fifty percent greater than in the United States. In this regard, the Task Force disclosed there is evidence greater use of U.S.-approved generic drugs by United States citizens could reduce drug spending by billions of dollars annually. The Task Force also determined potential quantity constraints imposed by manufacturers or foreign governments would limit the eligible supply and cost saving benefits to U.S. consumers in the event prescription drugs were eligible for importation from the same company at the lower price than in the United States.

Chapter 8. Impact of importation on research and development and consumer welfare. According to the Task Force, one of the most frequently debated issues associated with drug importation is whether legalization of importation would reduce research and development, including spending on discovery, development and launching of new drugs. Based on an empirical analysis of drug data and review of previous studies, the Task Force found, by shifting sales to countries with price controls for new drugs, importation of those drugs would reduce overall U.S. pharmaceutical industry revenues. The Task Force further found revenues would likely fall without a reduction in the cost to produce new medicines, profits would likely fall, as well as spending on research and development. The Task Force concluded legalized importation would likely adversely affect incentives for research and development, slowing the flow of new drugs. The Task Force estimated, as a result of reduced research and development spending, importation could result in four to eighteen fewer new drugs being introduced per decade, at a substantial cost to society. The Task Force found if there were a reduction in innovative new drugs, foregone consumer benefits associated with loss or delay in new therapies may significantly offset any anticipated savings from legalized importation.

Chapter 9. Impact of drug importation on intellectual property rights. Acknowledging a more exhaustive legal analysis of the implications of allowing importation of patented pharmaceuticals would require further study, the Task Force determined importation could impact the intellectual property rights of pharmaceutical products developers. Further, the Task Force found importation could be subject to challenge under domestic law, including possibly the U.S. Constitution and international intellectual property rules.

Chapter 10. Liability issues related to importation. The Task Force report noted allowing prescription drug importation would have uncertain effects on the litigation exposure of manufacturers, distributors, doctors and pharmacists. The Task Force theorized entities in the pharmaceutical distribution chain may take additional costly defensive actions in order to deal with what the Task Force believed to be likely increased risks. The Task Force further projected perhaps the largest source of additional liability and/or litigation risk with drug importations would be an increase in the number of injuries and poor disease outcomes if imported drugs were, as a class, less safe and effective.

Summary of Key Findings

Among the key findings of the Task Force are: 1) The current system of drug regulation in the United States has been very effective in protecting public safety, and should be modified only with great care. 2) There are significant risks associated with the way individuals are currently importing drugs. 3) It would be extraordinarily difficult and costly to implement “personal” importation in a way that ensures safety and effectiveness of the imported drugs. 4) Overall national savings from legalized commercial importation will likely be a small percentage of total drug spending, and implementing such a program would incur significant cost and require significant additional authorities. 5) Public expectation that most imported drugs are less
expensive than U.S. drugs is generally not true. 6) Legalized importation will likely adversely affect the future development of new drugs for American consumers. 7) The effects of legalized importation on intellectual property rights are uncertain but likely to be significant. 8) Legalized importation raises liability concerns for consumers, manufacturers, distributors, pharmacies and other entities.

**Importation Issues to be Addressed**

The cover letter, signed by Secretary Thompson of the Department of Health and Human Services and Secretary Evans of the Commerce Department transmitting both the commerce report, “Foreign Drug Price Controls: Their Effects on R&D, Innovation and Consumer Welfare and the Department of Health and Human Services’ “Report on Prescription Drug Importation,” outlined specific issues to be addressed by Congress when considering any importation program. The issues identified are:

- Ensure the integrity of the distribution system by requiring drug pedigrees, adequate documentation and limiting ports of entry and distribution channels. Allow commercial importation only from licensed foreign wholesalers to authorized U.S. sellers.
- Personal shipments, via the mail and courier services, must be eliminated, even though anticipated to be extra-ordinarily costly, on the order of $3 billion a year, based on estimates of the current volume.
- Importation should be limited to prescription drugs most likely to yield savings, namely high-volume products for which a U.S.-approved generic equivalent is not available. Importation of such drugs would be allowed only from countries for which the United States has a high degree of confidence in the comparability of drug regulatory systems. Canada is the only country from which importation could be considered at this point. Controlled substances, drugs requiring refrigeration during shipping and drugs or classes of drugs that pose increased safety risks would be excluded.
- Any imported prescription drugs must be dispensed pursuant to a valid U.S. prescription, pursuant to advice from a trusted medical professional.
- All packaging, labels and full and adequate information regarding, among other things, a source of drugs must be provided to purchasers of imported drugs.
- Any importation program must ensure effective oversight and adequate government resources to protect American consumers.
- The import program must include streamlined inspection procedures and ensure appropriate remedial steps can be taken in the event of adverse events associated with imported drugs.
- The program must avoid anti-competitive provisions such as so-called “forced sale” provisions and other types of price controls.

The report will likely provoke further lively debate and analysis as Congress deals with the continuing and challenging issue of drug importation.

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