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Report for Congress

Importing Prescription Drugs

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Summary

In recent years, American consumers, particularly the elderly and uninsured, have discovered they often pay a lot more for pharmaceuticals than citizens in other countries. As prescription drug prices continue to rise, more patients are turning to the Internet, or traveling outside the county, to find cheaper prescription drugs. However, under current law only drug companies can import pharmaceuticals into the United States. Despite this legal restriction, the Food and Drug Administration (FDA) has for years allowed patients to bring a 90-day supply of prescription medications into the country under its so-called "personal use" import policy.

In an earlier effort to deal with the price disparity issue, the 106th Congress passed the Medicine Equity and Drug Safety (MEDS) Act of 2000, legislation that would have allowed pharmacists and drug wholesalers to import less costly FDA-approved drugs from other countries. However, Congress said the Act could not be implemented unless the Secretary of Health and Human Services (HHS) could first guarantee that all drugs imported under the program would be safe and offer significant cost savings for consumers. In time, both the former and current Secretaries said these conditions could not be met, and refused to implement the law. When the Secretaries decided not to implement the MEDS Act, several bills were introduced in the 107th Congress, each taking a somewhat different approach to the drug import issue. One such proposal, offered by Representative Gutknecht, and passed by the House as an amendment to the FY2002 agriculture appropriations bill, would have let persons import small, non-commercial, amounts of prescription drugs for their own use. However, the amendment was later dropped during conference.

Congress is now considering different proposals that would codify FDA's personal use import policy and make it easier for drugs to be imported from outside the country. All of the proposals would let patients bring a 90-day supply of prescription drugs into the country for self-treatment. However, S. 215 (Stabenow) would require these imports to be accompanied by strict "chain of custody" documentation. S. 1229 (Wellstone) would let patients import drugs as long as they were FDA-approved, non-narcotic, and manufactured in registered facilities. Two identical bills, S. 2244 (Dorgan) and H.R. 4614 (Sanders), would waive current prohibitions on drug imports if they are for personal use. Moreover, two of the proposals, S. 215 and S. 2244/H.R. 4614 address the commercial import policy by establishing a program similar to the MEDS Act that would let licensed pharmacists and drug wholesalers import prescription drugs commercially. However, S. 2244/H.R. 4614 would allow drug imports only from Canada.

Supporters of these drug import proposals want Congress to enact legislation that would codify FDA's personal use policy and make it easier to import cheaper drugs from outside the country, particularly from Canadian suppliers. Critics, on the other hand, argue that these proposals could weaken existing import laws and make it easier for unsafe or counterfeit drugs to enter the country. While the Dorgan/Sanders bills would mandate authenticity testing to guard against this, the cost of testing would surely be passed on to consumers, and critics question whether there would be a noticeable reduction in the price of prescription drugs.

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Introduction

In recent years the rising cost of prescription drugs has become an ongoing issue for Congress. International comparisons of pharmaceutical prices have shown that American consumers, particularly the elderly and uninsured, often pay a lot more for their prescriptions than do citizens in other countries. Frequently this price disparity stems from the fact that some countries, particularly those with nationalized health care systems, can negotiate lower prices due to a greater economy of scale. The lower pharmaceutical prices in these countries are often enough incentive for some U.S. citizens to purchase their prescription drugs from Internet or mail-order pharmacies, or when they travel outside the United States, especially to Canada or Mexico. As this practice has become more common in recent years, legislation has been offered in Congress to make it easier for less costly prescription drugs to be imported from foreign suppliers.

Background

Concerned that large quantities of unsafe prescription drugs were being reimported back into the United States in the mid-1980s as "American goods returned," a situation that could threaten the health of American consumers, Congress passed the 1987 Prescription Drug Marketing Act (PDMA).[1] The Act included a provision that, from that time on, made it illegal for anyone other than drug manufacturers to import pharmaceuticals into the United States. Today, section 801(d)(1) of the Federal Food, Drug, and Cosmetic Act states that no "drug ... which 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."

The intent of PDMA was to keep subpotent or adulterated drugs from inadvertently ending up in U.S. pharmacies.[2] To enforce the law, the FDA has adopted regulations that require drug companies to maintain a detailed chain of custody for all pharmaceuticals imported into this country. Today, these rules not only impose strict record keeping requirements, they also require manufacturers to ensure the safety and quality of drugs that are exported, and then reimported back into this country.

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[1] P.L. 100-293.

[2] U.S. Congress. House. Committee on Energy and Commerce. Prescription Drug Marketing Act of 1987. H.Rept. 100-76, 100th Cong., 1st Sess. Washington, GPO, April 30, 1987. p. 7.

When drugs are imported into the United States, whether they are shipped commercially, carried by travelers, or mailed, the U.S. Customs Service and FDA have broad authority to deny products that "appear" to violate U.S. regulatory standards. For regulatory enforcement purposes, FDA separates imported prescription drugs into three broad categories: (1) drugs for commercial distribution; (2) prescription drugs that arrive by mail or common carrier; and (3) prescription drugs that are brought into the country by persons passing through U.S. customs.

FDA's Personal Use Import Policy. As noted above, only drug companies can import drugs legally into the United States. Nevertheless, the FDA for years has maintained a policy that allows patients to bring a small amount (i.e., a 90-day supply) of non-FDA approved drugs into this country for compassionate use. Over the years, the so-called "personal use" import policy has made it easier for patients with life-threatening diseases (such as cancer and AIDS) to bring medicines into this country and be treated by their personal physician.[3] Under the policy, drugs cannot be imported commercially. In addition, patients are supposed to affirm in writing that the drug is for their own use, and provide the name and address of their physician. Today, prescription drugs that enter the country under the import policy are brought in by individuals, or more typically, arrive by mail after being purchased from Internet pharmacies.

When FDA instituted the personal use import policy years ago, it was not supposed to be a way for patients to bring cheaper drugs into this country, nor a means to obtain prescription drugs already available in the United States. Though the policy has not been changed, where it once let patients import drugs for so-called "compassionate" use, today it is used to import drugs for all sorts of medical conditions, or by consumers seeking lower price prescription drugs from other countries.[4] Over the years, advances in technology, economic changes, and lenient enforcement have led to a dramatic increase in the number of drugs being brought into the country. Not surprisingly, monitoring this wave of drug products has become a major problem for Customs Service inspectors.

In 2001, the Customs Service and FDA conducted a 5-week survey in Carson City, California to get a better idea of the number and types of drug products that were entering the United States by mail. According to the agencies, many of the drugs detained during the survey were for treating health conditions that normally require a doctor's diagnosis.[5] This finding raised the concern that patients who obtain prescription drugs without a doctor's prescription may be exposing themselves to serious health risks. During a June 7, 2001 congressional hearing on FDA's drug import policy, an FDA official testified that the agency had recommended that the Secretary of HHS end the practice of allowing drugs to be imported by mail, so long

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[3] U.S. Food and Drug Administration. [http://www.fda.gov/ora/import/pipinfo.htm].

[4] U.S. citizens who want to have their prescriptions filled by Canadian pharmacies must have the prescription confirmed by a Canadian physician before the pharmacy will fill it.

[5] Hubbard, William K., Senior Associate Commissioner for Policy Planning and Legislation, Food and Drug Administration. Testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, June 7, 2001.

as DHHS retained an exception for drugs intended for compassionate use.[6] The large number of drugs entering the country by mail has become an enforcement problem, and the agency is concerned that government inspectors cannot, with any assurance, determine if the products being shipped are safe.

U.S. Drug Approval Requirements

Under the Federal Food, Drug, and Cosmetic Act, drugs must be proven safe and effective before they can be approved by the FDA for marketing. As a first step in this process pharmaceutical companies conduct pre-clinical (i.e., animal) tests to determine if the chemical compound is safe enough to undergo further evaluation in human subjects. If the drug is indeed safe enough to be administered to patients, the company files an investigational new drug (IND) application seeking FDA's permission to begin its clinical trials. When the clinical studies are completed, the drug's safety and efficacy data are submitted in a New Drug Application (NDA) for FDA's review. While the NDA is under review, agency officials sample the ingredients that will be used in the final product, and inspect the production process to be sure it meets current good manufacturing practices (GMPs). Almost simultaneously, the drug's official labeling is reviewed to make sure it is medically accurate and comprehensive. All drugs imported into the United States, whether they were manufactured here or abroad, have to be FDA-approved and be properly labeled. Moreover, imported pharmaceuticals must be accompanied by information telling where they were made, the name and address of the importer, and evidence that they were produced in FDA-inspected facilities. Drugs that do not meet U.S. standards are considered "unapproved" drugs and cannot be legally imported into the country.

Drug Import Legislation: 106th Congress

The Medicine Equity and Drug Safety (MEDS) Act. In an effort to take advantage of the lower prices charged by drug manufacturers in foreign countries, in 2000, the 106th Congress passed the Medicine Equity and Drug Safety (MEDS) Act. Part of a FY2001 agriculture appropriations bill,[7] the MEDS established a 5-year program that would have allowed pharmacists and drug wholesalers to import less costly prescription drugs from overseas suppliers. As an integral part of the program, the Secretary was required to publish regulations only if he/she could guarantee that all imported drugs would be FDA-approved, tested for authenticity, and properly labeled before they could be distributed to retail pharmacies in the United States. Pharmaceuticals imported under the Act could only come from specified countries, and if a pattern of counterfeiting emerged, the agency could suspend importation immediately.

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[6] Ibid.

[7] P.L. 106-387. Added new section 804 to the Federal Food, Drug, and Cosmetic Act.

Congress stipulated, however, that certain conditions had to be met before the MEDS Act could go into effect. More specifically, the Secretary of HHS had to verify that implementation would pose no additional risk to public health and safety, and would lead to a significant reduction in the cost of drugs for U.S. consumers. In late December 2000, then-Secretary Donna Shalala announced that she could not implement the MEDS act because it contained several "serious flaws and loopholes." According to the Secretary the law allowed drug companies to deny U.S. importers legal access to FDA-approved labeling that would be required for reimportation. Second, the Act did not prohibit drug manufacturers from requiring distributors to charge higher prices, limit supply, or treat U.S. importers less favorably than foreign purchasers.[8] And last, the drug import legislation's 5-year "sunset" provision would have had a chilling effect upon private-sector investment in the testing and distribution systems required under the law.[9]

Several months later, her successor, Secretary Tommy G. Thompson, declined to implement the law as well, stating that the safety of prescription drugs could not be adequately guaranteed if drugs were allowed to be re-imported under the MEDS Act.[10] Moreover, the Secretary pointed out that the costs associated with documenting, sampling and testing of imported drugs, as the MEDS Act required, would make it very difficult for consumers to recognize any noticeable price savings.

Drug Import Legislation: 107th Congress

At the start of the 107th Congress, some Members said they were concerned about the Secretary's refusal to implement the MEDS act, and promised to introduce new legislation that would let prescription drugs be imported from outside the country, and simultaneously address some of the issues the Secretary was concerned about, namely, exclusive contracts among manufacturers and importers and labeling ownership.

In the first session, the House passed an amendment, offered by Representative Gutknecht to a FY2002 agriculture appropriations bill (H.R. 2330), that would have given persons — who were not commercial drug importers — the legal right to bring FDA-approved, non-narcotic, prescription drugs into the country for self-treatment. To do this, the amendment would have kept FDA from enforcing the section of the law that only allows drug companies to reimport pharmaceuticals into the United States. However, the Gutknecht amendment was later dropped during final conference on the bill, and never became law.

Thus far, the following bills have been introduced to let cheaper prescription drugs be imported from outside the country. The proposals have one thing in common; they would all codify FDA's current personal use import policy, and in so

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[8] Donna E. Shalala, Secretary of Health and Human Services. Letter to President William J. Clinton, December 26, 2000.

[9] Ibid.

[10] "Secretary Thompson Determines That Safety Problems Make Drug Reimportation Unfeasible," *HHS News*, Press Release July 10, 2001. [http//:www.hhs.gov/news]

doing make it legal for patients to import small amounts of prescription drugs. Two bills, however, would go quite a bit further and establish an import program, much like the MEDS Act, that would let pharmacists and drug wholesalers import prescription drugs through Canadian suppliers on a much larger commercial scale.

The Medication Equity and Drug Saving Act (S. 215). Introduced in January 2001 by Senator Stabenow, the Medication Equity and Drug Saving Act would require the Secretary of HHS to promulgate regulations that would allow persons to bring certain prescription drugs into the United States in their personal baggage, or through the mail. Under the bill, prescription medications could only be imported for self-treatment, and the name of the patient, their doctor, the place of purchase, port of entry, and the cost of the drug would have to be provided. The Secretary would have to evaluate the program in 5 years and report the results to Congress.

The legislation specifies the countries from which drugs could be imported,[11] and allows the Secretary to designate additional countries, unions, or economic areas. It would reconcile the concerns that kept the MEDS Act from being implemented in 2000 and 2001. That is, importers would be allowed to use another company's approved labeling for a fee, and discriminatory pricing agreements between importers and pharmaceutical companies would be outlawed. In addition, it would give the Secretary 30 days to certify to Congress that the program would not pose a "appreciable additional risk to public health" before the rule-making process to implement the program could begin. The Stabenow bill would also eliminate the "sunset" clause that allowed the MEDS Act to run for only 5 years.

The Personal Prescription Drug Import Fairness Act (S. 1229). Introduced by Senator Wellstone in July 2001, the Personal Prescription Drug Import Fairness Act would establish a legal framework for FDA's current "compassionate" use policy, and extend its coverage to drugs for treating any medical condition. The bill would amend the FFDCA and require the Secretary of HHS — in consultation with the U.S. Trade Representative and the Commissioner of Customs — to issue regulations that would allow individuals, either in person or by mail, to bring a 90-day supply of prescription drugs into the country for self treatment. Drugs imported under the measure would have to be FDA-approved, in final dosage form, manufactured in FDA-registered facilities, and come from specified countries.[12] Furthermore, drugs imported for personal use could not be resold in this country.

Under the legislation, imported prescription drugs, whether they were brought in by patients or came by mail, would have to be accompanied by a new import form. The form would have to include the patient's name, address, and telephone number, the name of the dispensing pharmacy, and the place where the drug was manufactured. Also, the name of the patient's doctor, or evidence the drug is to continue treatment that began outside the country, would have to be on the form. The

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[11] Australia, Canada, Israel, Japan, New Zealand, Switzerland, and South Africa.

[12] Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, or the European Union or a country in the European Economic Area (the countries in the European Union and the Free Trade Association).

bill would require the Secretary to maintain records of each prescription drug imported. Also, the Secretary would have to compile a publicly available list of FDA-approved drugs that could be imported for personal use that are made outside the United States, or that, if they are manufactured here, are then exported to a foreign country.

Prescription Drug Price Parity for Americans Act (S. 2244 and H.R. 4614). The Prescription Drug Price Parity for Americans Act, introduced in April 2002 by Senator Dorgan, along with its identical counterpart sponsored by Representative Sanders, would allow U.S. pharmacists and drug wholesalers to import prescription drugs commercially from Canada. While the bills are very similar to the MEDS Act of 2001, they have some important differences. Unlike the MEDS Act, the Dorgan/Sanders legislation would not require the Secretary to first certify that imported drugs would be safe and result in reduced prices for consumers before the law could be implemented. Also, where the MEDS Act would have allowed prescription drugs to be imported from almost any country, the Dorgan/Sanders bills would allow them to be imported only from Canadian suppliers. In turn, Canadian pharmacies and wholesale pharmaceutical suppliers would have to register with the Secretary of HHS.

Like the MEDS Act, both S. 2244 and H.R. 4614 would require the Secretary to adopt regulations requiring importers to document the name of the drug, the quantity of the active ingredient, a description of the dosage form, the date of shipment, the point of origin and destination, and the price paid by the importer. In addition, importers would have to provide documentation from the foreign seller specifying the original source of the drug, the quantity received by the seller from that source, the manufacturer's lot or control number, and the name, address, telephone number, and licence number of the importer.

For drugs shipped directly from the first foreign recipient of the drug, the Dorgan/Sanders bills would require documentation — including quantity and lot numbers — verifying that the drug had been received by the recipient from the manufacturer, and subsequently shipped to the importer. For initial shipments, the proposals would require documentation that each batch of the drug had been statistically sampled and tested for authenticity and degradation; subsequent shipments would need verification that a valid sample of the drug had undergone this testing.

For prescription drugs that are not shipped directly from the first foreign recipient, there would have to be documentation showing that each batch in each shipment entering the United States had also been statistically sampled and tested for authenticity and degradation. Importers and manufacturers would be responsible for the testing, which would have to be performed by qualified labs. Like the MEDS Act, the legislation would require the Secretary to immediately suspend the importation of a specific drug, or the importations by specific importer, if they are found to be counterfeit. While the legislation imposes no penalties in this event; the MEDS Act would have imposed a fine not to exceed $250,000, and up to 10 years in prison.

To counter concerns regarding the proprietorship of drug labeling that arose after the MEDS Act was passed, the Dorgan/Sanders measures would allow importers to use a drug company's FDA approved labeling without charge. In addition, they would make it illegal for drug makers to discriminate against pharmacists or wholesalers, or enter into contracts that would place conditions on the sale or limit supplies of prescription drugs.

The legislation would authorize the Secretary to grant individuals a waiver, either by regulation or on a case-by-case basis, of the law that prohibits the importation of FDA-approved drugs and devices. For drugs imported from Canada, the waivers would let people import a 90-day supply of prescription drugs from registered Canadian pharmacies, as long as the drug was accompanied by a valid prescription. The bills direct the Secretary to use discretion when enforcing the prohibition against persons importing drugs and devices for personal use, particularly in situations where the drug or device poses little risk to the individual. To clarify this point further, the Secretary would be required to publish guidance describing the circumstances in which waivers would be granted to let people bring drugs into the country for personal use.

The Dorgan/Sanders bills would eliminate the "sunset" provision in the MEDS Act that placed a 5-year limitation on the import program. And last, the bills direct the Secretary of HHS to request that the Institute of Medicine of the National Academy of Sciences, to do an evaluation of the entire import program. Further, the General Accounting Office would have to do an analysis of whether the legislation had any effect on the price of prescription drugs sold to consumers at retail.

Issues for Consideration

Reducing Prescription Drug Costs Under the MEDS Act. The MEDS Act would have allowed pharmacists and drug wholesalers to import prescription drugs commercially from foreign suppliers. Enacted as a prelude to the 2000 election, its supporters claimed that the Act would expand access to pharmaceuticals, enhance competition, and lower the cost of prescription drugs for U.S. consumers. However, as previously mentioned, for a variety of reasons the act was never implemented. Nonetheless, some critics question whether the modifications to the MEDS Act, such as those contemplated in the Stabenow (S. 215) and the Dorgan/Sanders measures (S. 2244/H.R. 4614), would actually translate into lower prices for prescription drugs since the proposals make no guarantee that pharmacists and wholesalers will pass any of their savings on to consumers.

While both the Stabenow and Wellstone bills would allow prescription drugs to be imported from most industrialized countries, under Dorgan/Sanders they can only be imported from Canada.[13] At present, it is unknown whether Canadian manufacturing facilities, even those registered with FDA, would be able to supply the variety of drugs that American consumers would likely demand. In fact, heavily prescribed pain-relieving medications, and products that could be riskier for patients

[13] See footnotes 11 and 12.

such as biologics, certain infused and intravenous drugs, and inhalation drugs used during surgery, could not be imported under S. 2244/H.R. 4614.

All three bills, S. 215 and S. 2244/H.R. 4614, would explicitly prohibit drug manufacturers from discriminating against pharmacists and drug wholesalers, either by limiting prices or supplies. However, it has been suggested that drug companies could get around the legislation simply by exporting drugs with characteristics (e.g., color, size, shape, or dosage) different than those marketed in the United States. Since the imported drugs would not look like they were exactly the same as their U.S.-approved counterparts, from a legal and regulatory perspective, they could be deemed "unapproved," and as such, not qualify for import.

Lowering the Cost of Prescription Drugs for Personal Use. The bills would all codify FDA's current "personal use" import policy, in one way or another. Those who favor making the policy permanent contend that, as long as the disparity in drug prices continues, consumers will benefit only if they are able to purchase and import lower priced pharmaceuticals from virtually any country. Given that many foreign counties, including Canada, impose strict government controls on drug prices, it would be difficult to determine a set of circumstances that would completely eliminate the pricing differentials that are currently driving consumer demand for foreign prescription drugs.

Drug Labeling and Testing. As previously noted, the FDA has to approve the labeling of all drugs before they can be marketed. Unlike the Dorgan/Sanders proposals, the Stabenow bill does not require manufacturers to give pharmacists and wholesalers the information necessary to authenticate a drug, have it tested, and verify that it is properly labeled. While S. 215 expects importers to pay a fee for the privilege of using a manufacturer's label, S. 2244/H.R. 4614 mandate that drug companies let importers use their labeling "at no cost." However, since most drug manufacturers consider the formulas, brand names, and even the labeling of their prescription products to be proprietary under U.S. copyright and trademark laws, they might seek some sort of remedy in the courts if they are forced to make this kind of information available to importers.[14] If such litigation occurs, the import program could either be delayed or at least made more difficult to implement.

Product Integrity and Inspections. The purpose of the bills is to make it easier for lower cost prescription drugs to be imported into this country. If this happens, some argue that the legislation may make it easier for adulterated, misbranded, subpotent, or counterfeit drugs to enter the distribution pipeline, and end up in U.S. retail pharmacies. Although the additional bioterrorism funding has allowed the FDA to hire more border inspectors, there is still the concern that opening U.S. borders to drug imports may encourage the transshipment of more counterfeit drugs from neighboring countries, particularly Canada.[15] Also, FDA

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[14] Maintaining that patent holders have the "exclusionary right" to decide whether to sell a product, or even to set conditions for its sale, some feel that the clause in the drug import legislation prohibiting certain contractual agreements may violate the Constitution.

[15] "Dorgan Plans Bill to Allow Reimportation of Drugs From Canada," *Inside FDA Week,* (continued...)

inspectors could be drawn away from other priorities, such as food safety, into the monitoring of more drug records and increased inspections of overseas production facilities and at U.S. borders.[16]

FDA Enforcement Issues and "Personal Use" Imports. As noted, the proposals would all codify FDA's current "personal use" import policy, and make it legal for citizens to import FDA-approved drugs, in final dosage form, from registered manufacturing facilities. As such, very little would change in terms of current policy. Patients bringing prescription drugs into the United States for personal use would still have to fill out an import form providing their name, the address of the pharmacy, the name of their doctor (or evidence that the drug was for a medical condition that began overseas), and where the drug was made.

The bills would all impose additional safety testing for imported drugs. Whether this will insure that every prescription drug imported into the country will meet FDA's high standards for quality, is unknown. However, the Dorgan/Sanders legislation may impart more protection by insisting that dispensing pharmacies, in this case Canadian pharmacies, be registered with the Secretary.

If, as these measures intend, FDA's "personal use" import policy becomes law, the agency has said that even with the additional import records required under the Stabenow and Wellstone bills, it will be unable to guarantee the integrity of all drug products simply because there is no way its inspectors can examine every parcel and determine the quality of its contents. In fact, the agency testified before Congress in 2001 that should any of these bills become the law, it would continue to be "buyer beware" for consumers who decide to import prescription drugs under these circumstances.[17] The success of an expanded import mechanism for pharmaceuticals would, in all likelihood, depend on the ability of consumers to make purchases and obtain approved drugs without undue administrative hardships.

Since FDA inspectors cannot examine every drug product that enters the country via the mail or in personal baggage, and referred to the agency by the U.S. Customs Service, some commentators have stated that it could become increasingly difficult for the agency to keep counterfeit pharmaceuticals out of the country, especially if they look like FDA-approved drugs and appear to comply with U.S. regulations. At a recent Senate hearing on counterfeit medicine before the Special Committee on Aging, FDA testified that even though the Dorgan/Sanders bills attempt to ensure the safety of drugs by requiring authenticity testing, the legislation would not protect

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[15] (...continued)
March 1, 2002, p. 13-14.

[16] "Rx Reimportation Could Divert FDA Inspectors From Food Safety-HHS," *The Green Sheet*, February 25, 2002, p. 3.

[17] Hubbard, William K., Senior Associate Commissioner, Policy, Planning and Legislation, Food and Drug Administration. Letter to the Honorables W. J. "Billy" Tauzin, Chairman, and John Dingell, Ranking Minority Member, Committee on Energy and Commerce, House of Representatives, July 17, 2001.

against the threat of counterfeit drugs because no random sampling plan can protect against such criminal conduct.[18]

The Wellstone bill would require FDA to keep records of all prescription drugs brought into the country for personal use. The agency would also have to compile a list of each and every FDA-approved drug, manufactured domestically or abroad, that could be imported into the country. According to the agency, maintaining such a list, and monitoring the greater volume of pharmaceuticals that would be entering the country, would add enormously to its regulatory responsibilities, without making the imported drugs any more safe.

Lack of Physician Involvement. The FDA is concerned that a growing number of patients today, particularly those who use Internet pharmacies, are buying and using prescription drugs without the traditional safeguard of a doctor's prescription. While the bills would require all patients who bring drugs into the country to do so with a valid doctor's prescription, in situations where prescriptions are purchased or filled via the Internet or mail-order, the traditional doctor-patient relationship of yesteryear may not exist. Since prescription drugs can often cause serious side effects that are known only by doctors and other professional health care providers, those with doubts about provisions expanding Internet or mail-order availability assert that dispensing prescription drugs without professional supervision can have serious health repercussions.

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[18] Hubbard, William K., Senior Associate Commissioner, Policy, Planning and Legislation, Food and Drug Administration. Hearings Before the Senate Special Committee on Aging. *Buyer Beware: Public Health Concerns of Counterfeit Medicine*, July 9, 2002. p. 14.