

**APPENDIX
QUOTES FROM FDA
ON THE SAFETY OF IMPORTED DRUGS**

1. Letter from William K. Hubbard to the Governor of Wisconsin (3/18/04)

- Drugs made or distributed in other countries are not necessarily subject to our strict regulatory standards, and we are unable to assure that drugs imported from such places are safe and effective.
- The drugs that your citizens will purchase from these pharmacies have not been manufactured, shipped or held within the oversight of the FDA, and Canadian drug regulators have said repeatedly that they will not assure that drugs exported from Canada meet American safety requirements.

**2. Hearing Before the Senate Committee on Commerce, Science and Transportation
(Statement of Dr. Mark B. McClellan) (3/11/04)**

- FDA remains concerned about the public health implications of unapproved prescription drugs from entities seeking to profit by getting around U.S. legal standards for drug safety and effectiveness. Many drugs obtained from foreign sources that either purport to be or appear to be the same as U.S.-approved prescription drugs are, in fact, of unknown quality. Consumers are exposed to a number of potential risks when they purchase drugs from foreign sources or from sources that are not operated by pharmacies properly licensed under state pharmacy laws. These outlets may dispense expired, subpotent, contaminated or counterfeit product, the wrong or a contraindicated product, an incorrect dose, or medication unaccompanied by adequate directions for use. The labeling of the drug may not be in English and therefore important information regarding dosage and side effects may not be available to the consumer. The drugs may not have been packaged and stored under appropriate conditions to prevent against degradation, and there is no assurance that these products were manufactured under current good manufacturing practice standards. When consumers take such medications, they face risks of dangerous drug interactions and/or of suffering adverse events, some of which can be life threatening. More commonly, if the drugs are subpotent or ineffective, they may suffer complications from the illnesses that their prescriptions were intended to treat, without ever knowing the true cause.
- Recent research by the state of Minnesota pointed out significant problems related to purchasing non-FDA approved pharmaceuticals from foreign Internet pharmacies. Even Canadian pharmacies that participate in the Canadian Internet Pharmacy Association were observed engaging in problematic practices during a single, voluntary, pre-announced “visit” by Minnesota State officials. Minnesota state health officials noted dozens of safety problems, such as:
 1. several pharmacies used unsupervised technicians, not trained pharmacists, to enter medication orders and to try to clarify prescription questions;

2. one pharmacy had its pharmacists review 100 new prescriptions or 300 refill prescriptions per hour, a volume so high that it would have been impossible to assure safety;
 3. one pharmacy failed to label its products, instead it shipped the labels unattached in the same shipping container, even to patients who received multiple medications in one shipment; and
 4. drugs requiring refrigeration were being shipped un-refrigerated with no evidence that the products would remain stable.
- At least one of the Canadian pharmacies visited by Minnesota health officials dispensed many drugs that apparently were not even of Canadian origin, and many of the drugs were obtained from prescriptions that had been written and rewritten across multiple Canadian provinces. These types of systematic safety problems, which appear to be a common way of doing business, would generally be clear regulatory violations that would not be tolerated under the comprehensive system of Federal and state regulation of drug safety in the United States.
 - At a time when FDA faces more challenges than ever in keeping America's supply of prescription drugs safe and secure, legislation to liberalize drug importation without providing concomitant enhancements in FDA's authorities and resources to assure the safety of these imports could seriously compromise the safety and effectiveness of our drug supply. The volume of importation that could result from enactment of these bills could overwhelm our already heavily burdened regulatory system. In general, these bills fail to provide FDA with adequate authority or resources to establish and regulate the major new "legal" channels for incoming foreign drugs - manufactured, distributed, labeled, and handled outside of our regulatory system - or even to ensure their safety. Some of these proposals would even limit FDA's existing authorities, which are already being stretched. They would impose unprecedented restrictions on FDA's ability to inspect and test drugs, and FDA's authority to block the distribution of drugs we think are unsafe.
 - [L]egislation allowing pharmacies or consumers to import drugs directly from foreign sources would bypass the protections provided by FDA's drug approval process and by state regulation of firms that dispense drugs within their jurisdictions.
 - [O]ur objections to legislative proposals that would create large, legal channels for drugs to enter our drug supply without assurances of safety are based on concerns that they will create substantial drug safety problems without clear, large-scale, long-term benefits. . . .
 - Today, in part thanks to laws recently passed by Congress to ensure the safety of imported foods from the threat of a bioterrorist attack, we have specific authorities to protect our imported food supply, including authorities to detain such foods, require importers to register with the FDA, require adequate record-keeping and prior notification of incoming shipments. When it comes to beef, we go further to restrict entry points and USDA inspection facilities as well as employ animal health protections as needed to assure safety. And yet, when it comes to drug importation, we do not have these types of authorities.

- While some foreign drug manufacturers submit their products to FDA for approval, the imported drugs arriving through the mail, through private express couriers, or by passengers arriving at ports of entry are often unapproved drugs that may not be subject to any reliable regulatory oversight. FDA cannot assure the safety of drugs purchased from such sources.
- 3. Senate Commerce Committee Holds Hearing on Options for Safe and Effective Prescription Drug Importation FDCH TRANSCRIPTS Congressional Hearings (3/11/04)**
- MCCLELLAN: Under our laws, drugs must be demonstrated to be safe and effective to be legal. No assumptions allowed by law. . . . Other developed countries have similar laws, so when you walk into a drug store in Canada that serves Canadians, you can be very confident that you're getting a product that is safe and effective. But that's very different from buying drugs internationally, outside of our regulatory protections, from storefronts or Web sites that don't serve Canadians but that are designed to make a profit on Americans. . . . As Health Canada and other foreign regulatory authorities have told us, assuring the safety of drugs for Americans is beyond their responsibilities.
 - [W]e have neither the legal authority nor the resources to assure the safety of drugs from outside the federal and state system of regulating drugs, and we've seen many serious safety problems. . . . We've released several reports in the past year with our partners in border security at the Bureau of Customs and Border Protection that found numerous imported drugs that were improperly labeled, improperly stored or, even more worrisome, they were controlled substances or drugs like Accutane that present special risks if they don't have proper physician and pharmacist risk management.
 - We've tried to work with Canadian authorities so that Americans can be assured of notification in the event that their drugs are recalled in Canada, as happened with some important asthma medicines a few months ago, but there is still no such system in place.
 - [Internet pharmacy] Web sites carry legal disclaimers. But FDA can't do that. Legal drugs in this country don't carry "buyer beware" disclaimers, because legal drugs must be demonstrated to be safe and effective. Not only that, but the Canadian Internet pharmacies themselves have said that they cannot reliably provide large supplies of safe and effective drugs to cities or states or many other Americans.
 - On the important subject of drug safety and affordability, I appreciate the views of groups like the AARP, which understand that FDA cannot assure safety under current law and believe that importation should be legalized only if FDA receives the new authorities and resources it needs to assure safety.
 - [T]hanks to bipartisan action by Congress to find effective ways to assure safety, we have enhanced ability to take action to prevent the ability of foods to come into this country that are unsafe. . . . We have nothing like these authorities and resources for assuring that entire new classes of imported drugs are safe, such as drugs that are similar to FDA-approved drugs, while protecting Americans from those who would profit by exploiting any weaknesses in our drug safety and security system.

- [O]ur laws were not designed to assure the safety of imported drugs. In fact, Congress made it explicitly illegal in the Prescription Drug Marketing Act of 1987, a strong bipartisan measure that was passed because there were unsafe prescriptions coming into the country.
4. **Answers for the Record to Questions from Senate Finance Committee Hearing on the Nomination of Mark B. McClellan, to be Administrator of the Centers for Medicare & Medicaid Services (3/8/04)**
- FDA has amassed a great deal of experience with the types, scope and volume of unapproved products entering our borders through the mail, via Federal express, via the Internet. Last year, spot examinations of mail shipments of foreign drugs to U.S. consumers conducted by FDA and U.S. Customs and Border Protection revealed that these shipments often contain dangerous or unapproved drugs that pose potentially serious safety problems. These included unapproved drugs such as anti-azathioprine, an immunosuppressant drug that can cause severe bone marrow depression and can be associated with an increased risk of infection and cancer development; and human growth hormone, a drug that can have serious side effects if used inappropriately or in excessive doses. FDA found over 25 different controlled substances, including diazepam; Xanax; Valium, lorazepam, clonazepam and anabolic steroids. Also found were drugs withdrawn from the U.S. market for safety reasons, improperly packaged drugs shipped loose in sandwich bags or tissue paper, and drugs with labeling not in English.
 - FDA has stated that it cannot assure the American public that drugs imported from foreign countries are the same as products approved by FDA. Consumers are exposed to a number of potential risks when they purchase drugs from foreign sources or from sources that are not operated by pharmacies properly licensed under state pharmacy laws. These outlets may dispense expired, subpotent, contaminated or counterfeit product, the wrong or a contraindicated product, an incorrect dose, or medication unaccompanied by adequate directions for use. The labeling of the drug may not be in English and therefore important information regarding dosage and side effects may not be available to the consumer. The drugs may not have been packaged and stored under appropriate conditions to prevent against degradation, and there is no assurance that these products were manufactured under current good manufacturing practice standards. When consumers take such medications, they face risks of dangerous drug interactions and/or of suffering adverse events, some of which can be life threatening.
 - Patients also are at greater risk because there is no certainty about what they are getting when they purchase some of these drugs. Although some purchasers of drugs from foreign sources may receive genuine product, others may unknowingly buy counterfeit copies that contain only inert ingredients, legitimate drugs that are outdated and have been diverted to unscrupulous resellers, or dangerous sub-potent or super-potent products that were improperly manufactured.
5. **“HHS Announces Task Force on Drug Importation,” HHS Press Release (2/26/04)**
- Secretary Thompson said a fundamental responsibility of HHS, as the nation’s health department, is to protect the integrity and safety of the medicines Americans take. The

Secretary said the department, under the current and previous administration, has not been able to guarantee the safety of imported drugs.

- “The importation of drugs remains a long-standing safety concern for the Department of Health and Human Services, as we currently cannot guarantee the safety of these medicines,” Secretary Thompson said.

6. Letter from William K. Hubbard to the Governor of Minnesota (2/23/04)

- We strongly believe that [Minnesota’s] endorsement of foreign internet “pharmacies” is unsafe, unsound, and ill-considered.
- When you recommend to your citizens that they go outside of our regulatory system and enter into a “buyer beware” gray zone, you assist those who put profits before patient health. Your actions also shine a bright light on a path that can (and, indeed, is) used not only by profiteers masquerading as pharmacists, but by outright criminals who do not pause before actively feeding counterfeit drugs into the marketplace.
- . . . Even Canadian pharmacies that participate in the Canadian Internet Pharmacy Association, which claims to “self-regulate” safety, were observed engaging in dangerous practices on a single voluntary, pre-announced “visit” by Minnesota State officials who have no regulatory authority over the foreign businesses. Even on these single, preannounced visits, your state officials noted dozens of safety problems. . . .
- [A] one-time preannounced “visit” to any Internet pharmacy is no substitute for the comprehensive system for assuring the safety of the prescription drugs used by Americans.
- There are very good reasons why Health Canada (our counterpart across the border) continues to state that they cannot and will not guarantee the safety of drugs exported across the border through Internet pharmacies. Your continued support and active promotion of Minnesota ConnectRX is unwise and, most urgently, unsafe. At a minimum, your statement that you cannot assure the safety of drugs purchased from these sites seems like a questionable way to limit your own liability if and when Americans who visit these websites fail to get the quality care they deserve, or worse.

7. Marc Kaufman, FDA, States at Odds Over Drugs: Minnesota Web Site Points Way to Canadian Pharmacies, The Washington Post (2/22/04)

- “We absolutely do not approve of it, and see it as risky, unsafe behavior,” Peter J. Pitts, FDA associate commissioner for external affairs, said of the Minnesota Web site and Wisconsin's plan [to create a Web site for drug imports]. “We are weighing our enforcement options now and deciding how to proceed.”

**8. Letter from David J. Horowitz to Discount Prescriptions from Canada, Inc.
(2/18/04)**

- Prescription drugs purchased from foreign countries generally are not FDA-approved, do not meet FDA standards, and are not the same as the drugs purchased in the United States. Drugs from foreign countries do not have the same assurance of safety as drugs actually regulated by the FDA. Because drugs from foreign countries have been manufactured, shipped, held and/or repackaged outside of FDA's safety oversight, they could be outdated, contaminated, counterfeit or contain too much or too little of the active ingredient. In addition, foreign dispensers of drugs to Americans may provide patients with incorrect medications, incorrect strengths, medicines that should not be used in people with certain conditions or with other medications, or medications without proper directions for use. These risks are exacerbated by the fact that many of the products that you are soliciting U.S. consumers to buy are indicated for serious medical conditions.

9. Letter from Mark B. McClellan to Diane C. Gorman, Health Canada (2/12/04)

- [W]e have no reason to doubt the safety of Canadian drugs regulated by Health Canada and distributed within the regulated distribution systems in Canada. Rather, it is the practice of cross-border Internet pharmacies in Canada that primarily, or entirely, serve Americans - not Canadians - and the associated gaps between our two drug regulatory systems that remain of great concern to us. . . . As you and I have also discussed, we continue to find numerous safety problems involving prescription drugs being mailed into the United States from Canada outside of effective regulatory oversight. They include:
 - controlled substances and other risky drugs, obtained out of compliance with U.S. law and through pharmacy practices that have been condemned by Canadian practice of pharmacy regulators;
 - prescriptions sent without required patient labeling, and often just with labeling intended for pharmacists, when patients need specific information to use the medication safely and to avoid complications and side effects;
 - drugs that are distributed for use without needed direct medical oversight and monitoring;
 - drugs including complex biologics that are shipped under inadequate conditions to preserve potency; and
 - drugs that have been recalled in Canada, but for which no reliable recall mechanism has been established for U.S. patients who have received these Canadian products.
- [W]hen such widespread violations are present in the vast majority of Internet pharmacies that volunteered to be visited, we believe there is substantial evidence of failure to comply with the drug safety standards that both of our nations wish to uphold for our own citizens.

10. “Recent FDA/U.S. Customs Blitz Exams Continue to Reveal Potentially Dangerous Illegally Imported Drug Shipments,” FDA Press Release (1/27/04)

- The Food and Drug Administration (FDA) and the United States Customs and Border Protection (CBP) agency today announced that their second series of import blitz examinations found 1,728 unapproved drugs, including so-called “foreign versions” of FDA-approved drugs, recalled drugs, drugs requiring special storage conditions, drugs requiring close physician monitoring and drugs containing addictive controlled substances. . . . These findings provide additional evidence of the serious risks posed by the illegal importation of prescription drugs. Unapproved drugs lack assurances of safety, effectiveness, quality and purity. Moreover, FDA cannot assure the safety and efficacy of a drug product the agency has not reviewed and approved and when FDA has not monitored the manufacturing and quality control processes of the facility in which the product was produced.
- Commenting on the findings of the recent blitz operations, FDA Commissioner Mark B. McClellan, M.D., Ph.D. said, “We’re once again alerting consumers of the risks associated with buying medications from foreign sources outside of the safe, regulated systems of the United States and other nations. Americans deserve access to drugs that are safe, effective and affordable. Compromising safety for price is not in the best interest of the American public.”

11. “FDA Takes Actions Against Illegal Drug Import Operations of Expedite-Rx, SPC Global Technologies, and Employer Health Options,” FDA Talk Paper (1/22/04)

- “The FDA is doing its utmost to make safe, effective and affordable drugs available to those who need them,” said FDA Commissioner Mark B. McClellan, M.D., Ph.D., “but we cannot tolerate shady operations that enrich a few while exposing many patients to the risks of dubious imports. United States laws make crystal clear that medications on the U.S. market have to be proven to be safe and effective, and the vast majority of illegal imports fail to meet this standard.”
- There are numerous reasons why imported Canadian and other foreign versions of FDA-approved drugs generally are not up to the U.S. standards and are considered unapproved in the U.S. FDA’s drug approvals are manufacturer-specific and product-specific, and include many requirements relating to the product’s safety, effectiveness and quality. These criteria include manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. Drugs sent to the U.S. by foreign pharmacies rarely meet these standards.
- Because illegally imported drugs are generally manufactured, stored and shipped outside of FDA’s safety oversight, they could be outdated, contaminated, or contain too much or too little of the active ingredient. Foreign drug dispensers also may ship to American patients incorrect medications, incorrect strengths, drugs that should not be used in people with certain conditions, and medicines without proper directions for use.

12. Warning Letter from David J. Horowitz to Expedite-Rx and Employer Health Options, Inc. (1/22/04)

- [P]rescription drugs purchased from foreign countries generally are not FDA-approved, do not meet FDA standards, and are not the same as the drugs purchased in the U.S. Drugs from foreign countries do not have the same assurance of safety as drugs actually regulated by the FDA. Because the medications are not subject to FDA's safety oversight, they could be outdated, contaminated, counterfeit or contain too much or too little of the active ingredient. In addition, foreign dispensers of drugs to American citizens may provide patients with incorrect medications, incorrect strengths, medicines that should not be used in people with certain conditions or with other medications, or medications without proper directions for use. These risks are exacerbated by the fact that many of the products you are soliciting U.S. consumers to buy are indicated for serious medical conditions.

13. Amy Fagan, www.washingtontimes.com (1/2/04)

- "Twice the conclusion was reached that we could not guarantee the safety [of prescription drugs imported from Canada] so therefore [certification] could not occur," said Bill Pierce, spokesman for the Department of Health and Human Services, which includes the FDA. "Nothing has changed since that time," he said, implying that the states and cities will not get their way.

14. CNN Newsnight, Transcript (12/22/03)

- Peter Pitts, FDA: We think that the [Illinois] plan is not well thought out. It's very risky and it provides for illegal, unsafe foreign drugs to come into this country.

15. Ceci Connolly, "Kennedy Endorses Drug Importation: Senator Criticizes FDA, Plans Bill for Limited Program," Washingtonpost.com, (12/19/03)

- William Hubbard, a senior associate commissioner at the FDA, reiterated the agency position that "anything that sends American citizens to a foreign country to buy an unapproved drug is going to be risky."

16. "Buying Medicine from Outside the U.S. is Risky Business," FDA Public Notice (released 12/18/03)

- It's a gamble you can't afford to take. . . . If you buy foreign medicine from an Internet site, from a storefront business that offers to order foreign medicine for you, or during visits outside the United States, you are taking chances with your health. The FDA cannot guarantee the safety of medicine bought from outside the United States. . . . Don't play games with your health.

17. "Hearing on Drug Importation," Hearing before the Senate Committee on Commerce, Science and Transportation (11/20/03) (Statement of John M. Taylor)

- The American public can be confident that . . . medications [purchased from U.S. pharmacies] are safe and effective. FDA cannot, however, offer the same assurance to the

public about the safety and quality of drugs purchased from foreign sources that are outside the regulatory system.

- When it comes to buying drugs internationally, outside our existing regulatory protections, FDA has consistently concluded that the Agency is unable to endorse a “buyer beware” approach.
- All imported drugs are required to meet the same standards as domestic drugs, and thus must not be unapproved, misbranded, or adulterated. Drugs imported by individuals that are unapproved, misbranded, or adulterated, are prohibited by law. This includes drugs that are foreign versions of FDA-approved medications, and drugs that are dispensed without a prescription, because there is no assurance of their safety and effectiveness.
- During a recent drug importation survey at several mail facilities in the United States, FDA found that the vast majority of parcels (88%) contained unapproved drugs that could pose significant safety problems. These packages included drugs that have been withdrawn from the U.S. market for safety reasons; animal drugs sold illegally for human use; drugs improperly packaged in sandwich bags or tissue paper; drugs without English labeling or proper instructions for use; and drugs requiring precise dosing and monitoring by a physician.
- FDA remains concerned about the public health implications of personally imported prescription drugs and the introduction of counterfeit drugs into the stream of commerce. In our experience, many drugs obtained from foreign sources that either purport to be or appear to be the same as U.S.-approved prescription drugs are, in fact, of unknown quality. FDA cannot assure the American public that drugs imported from foreign countries are the same as products approved by FDA. The Agency has long taken the position that consumers are exposed to a number of potential risks when they purchase drugs from foreign sources or from sources that are not operated by pharmacies properly licensed under state pharmacy laws. These outlets may dispense expired, subpotent, contaminated or counterfeit product, the wrong or a contraindicated product, an incorrect dose, or medication unaccompanied by adequate directions for use. The labeling of the drug may not be in English and therefore important information regarding dosage and side effects may not be available to the consumer. The drugs may not have been packaged and stored under appropriate conditions to prevent against degradation, and there is no assurance that these products were manufactured under current good manufacturing practice standards. When consumers take such medications, they face risks of dangerous drug interactions and/or of suffering adverse events, some of which can be life threatening.
- [L]egislation to liberalize drug importation could cause additional drug safety concerns. The volume of importation that could result from enactment of these bills could easily overwhelm our already heavily burdened regulatory system.
- It is difficult for the Agency to reconcile the movement to allow consumers to purchase drugs from foreign sources with widespread understanding that the world has changed, that we now face more security concerns than ever, and that our vigilance over imports entering this country must reflect this reality.

- [I]t simply is not safe to throw open our borders and declare broad new classes of drugs to be “legal.” Despite well-intentioned efforts to design safeguards for this proposed drug import regime, many unsafe drugs will enter if Congress establishes a new, wide “legal” avenue for imports.
- International pharmaceutical peddlers are taking advantage of regulatory gaps to move millions of prescription drugs, including controlled substances, into the United States from Mexico, Canada, and elsewhere. Rogue medical merchants who have dubious or no medical background are selling potentially dangerous drugs to people who never see the prescribing doctor in person or undergo necessary tests. At best, these drugs are of unclear origins and safety. At worst, they are poorly manufactured, improperly repackaged, stored, and labeled, or out-and-out fakes. Weakening import restrictions will only compound these problems.
- It is important to remember why Congress made many drug imports illegal in the first place: FDA did not have the resources or authorities to assure their safety. Moreover, in recent years we have seen many more drugs that require “risk management” programs and regular monitoring to be sure they are used safely and effectively. We have also approved biologic and injectable drugs that have especially complex manufacturing and storage requirements. In both cases, the public health safeguards that FDA has imposed are being undermined by the illegal importation of these products. In addition, regulating controlled substances at our borders is an enduring challenge. These factors strongly argue for maintaining, not loosening, the current standards.
- FDA has long taken the position that consumers are exposed to a number of potential risks when they purchase drugs from foreign sources or from sources that are not operated by pharmacies properly licensed under state pharmacy laws. These outlets may dispense expired, subpotent, contaminated or counterfeit product, the wrong or a contraindicated product, an incorrect dose, or medication unaccompanied by adequate directions for use. The labeling of the drug may not be in English and therefore important information regarding dosage and side effects may not be available to the consumer. The drugs may not have been packaged and stored under appropriate conditions to prevent degradation, and there is no assurance that these products were manufactured under current good manufacturing practice (cGMP) standards. When consumers take such medications, they face risks of dangerous drug interactions and/or of suffering adverse events, some of which can be life threatening. These risks could include potential side effects from inappropriately prescribed medications or side effects due to drug contamination.
- In terms of prioritizing the Agency’s domestic and import compliance workload, products that present a direct health hazard to the user are FDA’s highest priority. Such products include those that have a reasonable potential for causing direct serious adverse effects, or where there is documentation of injury or death. . . . Products that are not themselves hazardous can still present an indirect health hazard in that the consumer may delay or forgo proven medical treatment and the use of approved therapies. These are also a top priority for the Agency. . . .
- While some foreign drug manufacturers submit their products to FDA for approval, the imported drugs arriving through the mail, through private express couriers, or by passengers

arriving at ports of entry are often unapproved new drugs that may not be subject to any reliable regulatory oversight. FDA cannot assure the safety of drugs purchased from such sources.

- [A]t this time the Agency cannot assure the American public that drugs purchased from foreign sources are the same as products approved by FDA, or that they are safe and effective.

18. Mark B. McClellan, Speech Before Drug Information Association (11/18/03)

- [W]hen you go outside of the comprehensive safety systems created within the U.S. and Canadian regulatory umbrellas . . . there are serious safety gaps.
- [M]any Canadian health officials at both the provincial and national level have pointed out real safety concern resulting from improper and illegal prescribing behavior by health professionals, and from non-health professionals engaging in providing what are essentially pharmacy services. The Manitoba College of Physicians & Surgeons recently sanctioned four doctors for such unsafe prescribing practices. Health Canada indicated that it “regards this as a very serious matter due to the inherent risk to Canadians’ health.”
- [T]o the extent that Americans are purchasing Canadian drugs that are supposed to be under Health Canada’s regulation, we are facing new challenges in protecting consumers from product defects.
- Until the many problems I’ve identified with drug safety can be addressed, . . . it’s “buyer beware” when Americans purchase drugs long-distance from for-profit, illegal internet sites or poorly-regulated storefront operations with untrained staff. FDA has said this consistently, for many years, through many different administrations. In an era when powerful medicines can do more than ever before to improve health, but when the risks are greater than ever from unsafe or improperly-used medicines, I don’t think Americans or anyone in the world should have to settle for “buyer beware” drugs.
- . . . Canada’s health care system simply isn’t designed to supply a large volume of safe prescription drugs for Americans. As Canadian drugs and other resources are redirected to the United States, the system here will face increasing strains, with the potential for adverse consequences for the health of Canadians. . . . [T]he [Canadian] National Association of Pharmacy Regulatory Authorities – which consists of all of the provincial pharmacy regulators in the country – said that the export of drugs from Canada to the U.S. for the purpose of economic development was directly in conflict with the public policy objective of Canadians’ access to safe drugs and pharmacy services. . . . In fact, the regulatory authorities believe the situation is so extreme that they urged the Canadian government to ban the exporting of drugs from Canadian pharmacies until the government can implement systems that will ensure the effective regulation of these practices for public safety.

**19. Letter from William K. Hubbard to Special Advocates for Prescription Drugs
(11/6/03)**

- In 1987, in response to instances of unapproved and unsafe foreign medicines entering the United States, Congress enacted legislation to prohibit the importation of unapproved medicines. While the public health threats caused by such medications were significant enough for Congress to act in 1987, the potential threats from unapproved prescription drugs are even greater today. Unapproved and unregulated medicines bought over the Internet can come from *anywhere*. Even medicines that appear to be the same or have the same brand name as those bought in the United States can be dangerously different. We cannot and must not allow the Internet to become the 21st Century's snake oil outlet. (Emphasis in original.)
- Unregulated importation endangers the lives of America's seniors. . . . "Buyer Beware" is bad health care practice and even worse health care policy.
- Your report wrongly assumes regulatory oversight by Canadian health authorities of drugs exported to our citizens, when those authorities have not been willing or able to guarantee the safety of drugs sold to Americans. . . . Your report also assumes the safety of drugs that happen to be imported across the U.S.-Canadian border. While we have often noted that Canadian health authorities set high standards for drugs sold to their citizens, we have also consistently observed that drugs sold outside of the U.S. and Canadian systems (e.g., over the Internet) often do not meet such high standards. Indeed, we have seen concrete examples of drugs sold to Americans by Canadian Internet pharmacies that pose a risk to our citizens. (Footnote omitted.)
- Drugs imported from Canada virtually never have the FDA-approved U.S. labeling, which is designed to inform patients about the drug's proper use and to give them warnings about particular dangers inherent in the drug. As a result, it is unclear how under this plan Illinois would ensure that its citizens get the necessary information and warnings.
- [O]ur surveys of the actual drugs being mailed to American[] patients from Canada have found that very few are in true "unit-of-use" containers. Rather, the drugs tend to be more in the manufacturers' "stock" bottles, which tend to come in specific large volume amounts (e.g., 100 tablets). (Footnote omitted.) These bottles are not intended to be used by individual patients whose prescriptions are for more or less than 100 units; moreover, they do not generally include appropriate labeling and warnings for patients. Thus, medication errors can actually be encouraged, and many patients appear to be getting larger quantities than their doctors are prescribing.

20. "CanaRx Illegally Supplying Prescription Drugs; Company Violates U.S. Law, Puts Americans at Risk," FDA Press Release (11/6/03)

- "The drug safety laws that Congress has charged FDA to enforce require that drugs be proven to be safe and effective to be legal," said Commissioner of Food and Drugs Mark B. McClellan, M.D., Ph.D. "While FDA will continue to do all it can to make safe and affordable drugs available, we are also committed to enforcing the law against those, whether

governmental or private, who endanger Americans by profiting from ‘buyer beware’ schemes to import illegal, unapproved and potentially risky medicines.”

- FDA has long been concerned that medications purchased by U.S. consumers from foreign, unregulated drug outlets pose a growing potential danger. CanaRx and similar companies often state incorrectly to consumers that their products are “FDA approved” or use similar language, which could lead consumers to conclude mistakenly that the prescription drugs sold by the companies have the same assurance of safety and effectiveness as drugs regulated by the FDA. They do not.
- The medications obtained and shipped by operations such as CanaRx are not subject to FDA’s safety oversight. This gap prevents assurance that CanaRx’s medications are safe and effective, are prescribed and distributed properly, and otherwise meet U.S. prescription drug standards. In this case, these risks are heightened by the fact that many of the products CanaRx sells to U.S. consumers are indicated for serious medical conditions. . . . In addition, foreign dispensers of drugs to American consumers may provide patients with incorrect medications, drugs with incorrect strengths, medicines that should not be used by people with certain conditions or with other medications, or medications without proper directions for use.
- [O]f the 1,153 imported drug products examined during a recent “blitz” by FDA and the Bureau of Customs and Border Protection, the overwhelming majority, 1,019 (88%), were illegal because they contained unapproved drugs. Many of these imported drugs could pose clear safety risks to consumers. These drugs arrived from many countries, with 15.8% (161) entering the U.S. from Canada.

21. Letter from David J. Horowitz to CanaRx Services (11/6/03)

- [T]aking as true CanaRx’s assertion that prescriptions processed through it are reviewed by Canadian doctors and filled by Canadian pharmacists, it is nevertheless the case that the drugs then shipped to the United States are generally illegal. As troubling, it appears that neither CanaRx nor the pharmacies that it employees can verify the source of those drugs. Nor are they at all knowledgeable about the manufacture, packing, and labeling of the drugs. This raises FDA’s specific concerns about all illegally imported drugs: that they are unapproved, do not meet FDA standards, and are otherwise less safe than drugs purchased in the United States.
- Claims that drugs supplied by Canadian pharmacies are FDA approved and that “there is no difference” between them and drugs purchased in the United States simply are not true. Unlike FDA-approved drugs purchased in this country, the drugs that CanaRx markets are generally illegal when imported, and their importation circumvents measures designed to protect U.S. citizens. Consequently, FDA remains fundamentally concerned about CanaRx’s misleading claims, which could pose significant health risks to consumers.

22. United States v. Rx Depot, Plaintiff's Proposed Findings of Fact and Conclusions of Law (10/31/03)

- Unapproved prescription drugs, and drugs imported from foreign countries by someone other than the U.S. manufacturer, do not have the same assurance of safety and efficacy as drugs regulated by FDA. Because the drugs are not subject to FDA oversight and are not continuously under the custody of a U.S. manufacturer or authorized distributor, their quality is less predictable than drugs obtained in the United States. For instance, the drugs may be contaminated, counterfeit, or contain erratic amounts of the active ingredient or different excipients. Also, the drugs may have been held under uncertain storage conditions, and therefore be outdated or subpotent. . . . Prescription drugs obtained through Rx Depot frequently are dispensed in greater quantities than are requested by the prescribing physician. Rx Depot advertises the availability of, and causes the importation of, preset quantities of drugs and dispenses these preset quantities regardless of the quantity of the drug the patient's U.S. physician prescribed and without directions to take the drug for only the number of days prescribed by the U.S. physician. . . . American patients could, therefore, take a drug for many days more than their physicians intend without supervision. This practice can be dangerous in instances where drugs have potentially life-threatening side effects with continued use. . . . Prescription drugs obtained through Rx Depot also do not contain the FDA-approved patient package inserts included with certain prescription drugs in the United States. Nor are prescription drugs obtained through Rx Depot shipped in FDA-approved unit-of-use packaging. This type of packaging is used in the United States to help ensure that certain drugs received by customers arrive in designated dosages with the approved patient package insert.

23. Mark B. McClellan, Speech at the National Press Club (10/20/03)

- When it comes to buying drugs internationally, outside of our regulatory protections, beyond the authorities of the Federal and state watchdogs for drug safety, FDA has consistently said for many years that we can't in good faith endorse "buyer beware" approaches to the problem of affordable drugs. Buying long distance from sources we can't regulate is simply not the same as walking into a well-regulated pharmacy under the regulatory umbrella of Canada or another country with a very safe drug supply. People's health is put at risk when doctors and pharmacists, our "learned" intermediaries, are replaced by store fronts and bogus Internet sites that are there for private profit not public health.
- [W]hen Americans import drugs that are not regulated and approved in the United States, it presents real safety risks, risks that are becoming more common. For example, [FDA] recently reported on a "blitz" at four airports over three days, conducted with our border enforcement partners at the Bureau of Customs and Border Protection. We identified more than eleven hundred unapproved drugs coming in from Canada, and many drugs that because of labeling, storage, or other problems presented real safety risks.
- All the evidence suggests that it is not safe to simply declare broad new classes of drugs to be "legal" and to open up our borders - that many more unsafe drugs would take advantage of wide new "legal" import channels.

- Not surprisingly, the Canadian government itself has said repeatedly that it cannot assure the safety of drugs exported to the U.S., even though it is diligent in assuring the safety of drugs purchased through legal channels in Canadian pharmacies.
- Buying between the U.S. and Canadian systems is not the same thing as buying within each system. The U.S. and Canada do not have integrated systems for taking timely action to protect consumers in the event of a safety problem involving an illegally imported drug in the U.S. Protections to assure the appropriateness of a prescription, such as requirements for physician contact and monitoring, may differ. And each country has only limited resources to devote to their existing systems for assuring drug safety for their own populations, let alone to assuring the safety of an expanded scope and volume of drug imports.
- Some people have said: well, maybe it doesn't meet the standards of a legal prescription in the United States or in Canada, but it's cheaper, so it's up to the patient to make sure they use the drug right - to count up the pills, to keep track of the warnings, to make sure the product's not expired, and so on. Now, I do think it's important for patients to be active partners in their health care. But an active partnership is a long way from this sort of "buyer beware" situation.
- [S]tate and local governments and private groups cannot provide reliable safety assurances when they purchase drugs from foreign sources. It's simply not enough to replace a comprehensive Federal and state system for assuring drug safety by picking a company operating outside the US that appears to be legitimate and hoping that their drugs turn out to be safe. In spite of what some say, none of these drugs will have gone through the approval, monitoring, and prescribing process required in the United States.
- This is one reason why Congress made many drug imports illegal in the first place: FDA did not have the resources or authorities to assure their safety, and still doesn't. The safety risks of some drugs are especially great; for example, in recent years, we have seen many more drugs that require "risk management" programs of tight monitoring, biologic and injectable drugs that have especially complex manufacturing and storage requirements, and controlled substances.

24. "FDA/U.S. Customs Import Blitz Exams Reveal Hundreds of Potentially Dangerous Imported Drug Shipments," FDA Press Release (9/29/03)

- A recent series of spot examinations of mail shipments of foreign drugs to U.S. consumers conducted by the Food and Drug Administration (FDA) and U.S. Customs and Border Protection (CBP or Customs) revealed that these shipments often contain dangerous unapproved or counterfeit drugs that pose potentially serious safety problems.
- Although many drugs obtained from foreign sources purport, and may even appear to be, the same as FDA-approved medications, these examinations showed that many are of unknown quality or origin. Of the 1,153 imported drug products examined, the overwhelming majority, 1,019 (88%), were violative because they contained unapproved drugs. Many of these imported drugs could pose clear safety problems.

- “This joint effort with CBP illustrates the real and serious public health risks created by the importation of unapproved drugs,” said Mark B. McClellan, M.D., Ph.D., Commissioner of Food and Drugs. “To protect Americans from unsafe imported drugs, we are working to target our enforcement resources as effectively as possible against those products that pose a threat to the health of consumers and the safety and security of our drug supply.”
- “There is no evidence that unapproved imported drugs are becoming any safer or more reliable,” said Dr. McClellan. “Given FDA’s limited resources and authorities to detect and block potentially unsafe imports, we are concerned about any measures that would increase the flow of these unapproved drugs, or provide easier channels for them to enter the United States.”

25. Mark B. McClellan, Speech Before First International Colloquium on Generic Medicine (9/25/03)

- There is no assurance that [imported “generic”] drugs meet the standards of safety and effectiveness of the United States or Mexico. They may contain incorrect amounts of active ingredients or the wrong ingredients, they may not reach the right blood levels in the body, they may contain toxic impurities, they may not work properly because of improper storage and handling – in short, they may not provide the health benefits that patients should be able to expect from their medicines....

26. “FDA Steps Up Campaign Against Rx Imports; Bill ‘Technically’ Flawed,” The Pink Sheet (9/22/03)

- [At the National Association of Boards of Pharmacy legislative conference September 14 in Washington, D.C.] McClellan maintained that current packaging technologies are inadequate to guarantee the safety of imported products. Importers “rely on one or a few unproven technologies on the drug package system to substitute for a comprehensive system for assuring safety - an approach that in modern times simply cannot provide reliable assurance that the drugs in the package are legitimate and safe.” . . . “An imprint on a box is no substitute for a comprehensive, multi-part system for assuring drug safety from production to patient,” said McClellan.
- “[AARP] correctly pointed out that, in order to keep the drug supply safe, any legislation to allow importation is going to require significantly more resources and more authorities at FDA, to assure drug safety and integrity of our drug supply with a broader range of drug products,” [McClellan] continued.
- “For something as serious as prescription drugs, they would need to monitor the sources and distribution of the drugs involved and make sure they were manufactured reliably and distributed safely.” McClellan said. “They would need to inspect and test the drugs, to make sure they are legitimate products.” . . . “They would need to get help from the Canadian government or its province, to make sure that the prescriptions filled outside the U.S. are legitimate and are filled legally under Canadian law, and the drugs themselves are genuine and are transported, labeled, and used according to appropriate safety and risk management standards.” . . . “If they don’t, they are likely to run into the same safety problems faced by

everyone else attempting to import unapproved illegal drugs,” McClellan said, including receiving drugs that are improperly stored, shipped or dispensed. Imported drugs “may be ineffective or harmful for many other reasons.”

27. Warning Letter from David J. Horowitz to CanaRx Services, Inc. (9/16/03)

- Unapproved foreign drugs do not have the same assurance of safety as drugs subject to FDA oversight. Unapproved drugs have been found to be contaminated, counterfeit, contain different amounts of active ingredients, or contain different ingredients altogether. . . . Without regulation of repackaging, storage conditions, and many other factors, drugs delivered to the American public from foreign countries may be very different from FDA approved drugs with respect to formulation, potency, quality, and labeling, and, therefore, may not be safe and effective.
- For example, the [CanaRx] web site states that “there is no difference” between drugs purchased from the U.S. and from Canada. Such statements are not correct. Prescription drugs purchased from foreign countries generally are not FDA-approved, do not meet FDA standards, and are not the same as the drugs purchased in the United States. Drugs from foreign countries do not have the same assurance of safety as drugs actually regulated by the FDA. Foreign dispensers of drugs to American citizens may provide patients with incorrect medications, incorrect strengths, medicines that should not be used in people with certain conditions or with other medications, or medications without proper directions for use. These risks are exacerbated by the fact that many of the products you are soliciting United States consumers to buy are indicated for serious medical conditions.

28. “FDA Warns CanaRx Services About Its Illegal Internet Website and Mail Operations Obtaining Unapproved and Potentially Risky Drugs from Canada,” FDA Press Release (9/16/03)

- FDA has long been concerned that medications purchased by U.S. consumers from foreign, unregulated drug outlets pose a growing potential danger. CanaRx Services and similar companies often state incorrectly to consumers that their prescriptions are “FDA approved” or use similar language, which could lead consumers to conclude mistakenly that the prescription drugs sold by the companies have the same assurance of safety and effectiveness as drugs actually regulated by the FDA.
- Because the medications obtained and shipped by operations such as CanaRx are not subject to FDA’s safety oversight, they could be outdated, contaminated, counterfeit or contain too much or too little of the active ingredient. In this case, these risks are heightened by the fact that many of the products CanaRx sells to U.S. consumers are indicated for serious medical conditions. . . . In addition, foreign dispensers of drugs to American citizens may provide patients with incorrect medications, incorrect strengths, medicines that should not be used in people with certain conditions or with other medications or medications without proper directions for use.

29. United States v. Rx Depot, Inc., Complaint for Injunction (9/11/03)

- The defendants cause the importation of prescription drugs from Canadian pharmacies, which clearly violates the law and poses significant risks to the public health. Drugs that are imported from foreign countries do not have the same assurance of safety and efficacy as drugs that are regulated by FDA. Because the drugs are not subject to FDA oversight and are not continuously under the custody of a U.S.-manufacturer or authorized distributor, their quality is unpredictable. For instance, they may be contaminated, counterfeit, or contain erratic amounts of the active ingredient or different excipients. Also, the drugs may have been held under uncertain storage conditions, and therefore be outdated or subpotent. . . . In addition, the defendants expose their customers to potentially life-threatening problems by dispensing a greater quantity of drugs than is requested by the prescribing physician. Rx Depot advertises for, and causes the importation of, preset quantities of drugs and dispenses these preset quantities regardless of how much of a drug the patient's U.S. physician prescribed and without directions to take the drug for only the number of days prescribed by the U.S. physician. U.S. patients can, therefore, take a drug for many days more than their physicians intend without supervision. This is particularly dangerous in instances in which the drug can have potentially life-threatening side effects with continued use.

30. United States v. Rx Depot, Inc., Memorandum in Support of Plaintiff's Motion for Preliminary Injunction (9/11/03)

- Defendants cause U.S.-manufactured prescription drugs to be illegally imported into the United States. The defendants also cause foreign-manufactured drugs that have not been approved by the FDA for use in the United States to be unlawfully imported into the United States. . . . These activities pose a significant risk to the public health, as Congress recognized when it outlawed such acts. In passing the Prescription Drug Marketing Act of 1987, Congress found that permitting reimportation of U.S.-manufactured drugs created "an unacceptable risk that counterfeit, adulterated, misbranded, subpotent, or expired drugs will be sold to American consumers."
- When U.S.-manufactured drugs are not continuously under the custody of the U.S. manufacturer or authorized distributor, their quality is unpredictable because storage conditions and packaging differences can significantly impact the safety and effectiveness of prescription drugs. . . . For instance, the drugs could be outdated, or may have been held under uncertain storage conditions (e.g., improper moisture, temperature, or light conditions), such that their safety or effectiveness may have been compromised. Drugs that require refrigerated storage may become subpotent if they are not stored at proper temperatures; too much moisture and light may cause accelerated product degradation.
- [U]napproved drugs from foreign countries do not have the assurance of safety and effectiveness as do drugs that are approved by FDA after going through the new drug application review process. Because unapproved drugs are not subject to FDA's oversight, they are more likely to be contaminated, counterfeit, inherently ineffective, or contain different excipients or different amounts of the active ingredients of similar drugs which have been reviewed and approved by the FDA. . . .

31. Julie Appleby, "Canada's cheap drugs not answer, FDA warns," USATODAY.com (8/27/03)

- "Once you give people the false impression that ordering over the Internet is OK, it opens up a Pandora's box of dangers," says Peter Pitts, the FDA's associate commissioner for external relations.

32. Anna Wilde Matthews, "The FDA Warns Cities, States About Buying Canadian Drugs," The Wall Street Journal On Line (8/27/03)

- "We want to send a very strong message, which is that safety is absolutely crucial, and they need to be aware that these activities are inherently risky," said Peter J. Pitts, associate FDA commissioner for external relations.

33. Letter from William K. Hubbard to California Deputy Attorney General (8/25/03)

- FDA is very concerned about the safety risks associated with the importation of prescription drugs from foreign countries. In our experience, many drugs obtained from foreign sources that purport and appear to be the same as U.S.-approved prescription drugs have been of unknown quality. We cannot provide adequate assurance to the American public For example, an American consumer recently ordered an FDA-approved medication called Neurontin from a website that purported to operate in Canada and ship FDA-approved drugs from Canada into the United States. Nevertheless, the drug the consumer actually received had been manufactured in India, shipped from India, and was not approved by FDA for use in the United States. In another instance, a website that purported to operate in Canada mailed insulin into the United States for use by an American with diabetes. Although the drug originally had been manufactured in the United States, it had not been appropriately refrigerated when shipped back into the country. The failure to refrigerate insulin promotes the degradation of the product and renders it less effective. Unfortunately, however, the failure to refrigerate the product may not change its appearance, so American consumers may have no way of knowing their insulin has been mishandled abroad.
- Congress enacted [the prohibition on reimportation] to create a relatively 'closed' drug distribution system, which helps ensure that the domestic drug supply is safe and effective.

34. Letter from Mark B. McClellan to W.J. "Billy" Tauzin (7/18/03)

- FDA has longstanding concerns the importation of drugs outside of the current safety parameters established by the Federal, Food, Drug and Cosmetic Act (FFDCA).
- [A] growing number of Americans are obtaining their prescription medications from foreign sources, and in doing so expose themselves to a number of risks to their health and safety. Many prescription drugs obtained from foreign sources that either purport to be or appear to be the same as FDA-approved medications are, in fact, of unknown quality. These outlets may dispense expired, subpotent, contaminated or counterfeit product, the wrong or a contraindicated product, an incorrect dose, or drugs unaccompanied by adequate directions for use. The labeling of the drug may not be in English and important information regarding

dosage and side effects may not be available. In addition, the drugs may not have been packaged and stored under proper conditions to avoid degradation.

- H.R. 2427 creates a wide channel for large volumes of unapproved drugs and other products to enter the United States that are potentially injurious to public health and pose a threat to the security of our Nation's drug supply. . . . Secretary Thompson (and former Secretary Shalala in the past) have separately concluded that they could not with currently available technologies assure the safety of such foreign drugs.
- FDA cannot assure the safety of [imported] products. Similarly, Canadian health officials have made clear in public statements that they can provide no assurance as to the safety or authenticity of drug products shipped out of Canada for resale in other countries. In fact, the Agency has specific examples of drugs purchased from Canada that violate safety provisions established by FDA and examples of prescription drug sales from Internet sites that purport to be in Canada, but upon investigation have been found to be located elsewhere and providing drugs that are adulterated, sub-potent or counterfeit.
- [B]ecause [H.R. 2427] does not adequately assure safety standards are met for foreign drugs imported by individuals, does not require more detailed tracking and chain of custody requirements for such products, and does not limit the volume or frequency of such importation, the legislation is particularly problematic as it relates to restricted distribution products that the Agency has placed under Import Alert because of particular risks to patients who might import them. Although these drugs have important benefits for many patients, they also have serious known risks and so are available in the U.S. only under specially crafted safety controls. The controls include: limiting their distribution to specific facilities (such as hospitals); limiting their distribution to physicians with special training or expertise; or requiring certain medical procedures (such as pregnancy testing or blood testing) with their use. There is no reliable way to put these safety controls in place when these drugs are purchased from foreign sources, placing patients who use these drugs when they are received from foreign sources at a much higher risk of harm.
- The sheer volume of importation that could result from enactment of this bill would easily overwhelm our already heavily burdened regulatory system.
- The provisions of H.R. 2427 would erode the ability of the FDA to fulfill its increasingly challenging mission of ensuring the safety and efficacy of the U.S. drug supply. FDA simply cannot support legislation that exposes Americans to greater potential risk of harm from unsafe or ineffective drugs.

35. Warning letter from David J. Horowitz to Canadian Discount Drugs (6/30/03)

- [P]rescription drugs purchased from foreign countries generally are not FDA-approved, do not meet FDA standards, and are not the same as the drugs purchased in the United States. Drugs from foreign countries do not have the same assurance of safety as drugs actually regulated by the FDA. Because the medications are not subject to FDA's safety oversight, they could be outdated, contaminated, counterfeit, or contain too much or too little of the active ingredient. In addition, foreign dispensers of drugs to American citizens may provide

patients with incorrect medications, incorrect strengths, medicines that should not be used in people with certain conditions or with other medications, or medications without proper directions for use. These risks are exacerbated by the fact that many of the products you are soliciting United States consumers to buy are indicated for serious medical conditions [cancer, HIV, and hypertension].

- FDA is also very concerned about the importation of prescription drugs from Canada and other foreign countries because, in our experience, many drugs obtained from foreign sources that purport or appear to be the same as U.S.-approved drugs are, in fact, of unknown quality. Recent examples of counterfeit products entering the U.S. marketplace also raise substantial safety questions about drugs from foreign countries. Moreover, there is a possibility that drugs which come to U.S. consumers through Canada or purport to be from Canada may not actually be Canadian drugs. In short, drugs delivered to the American public from foreign countries may be very different from products approved by FDA and may not be safe and effective. For all of these reasons, FDA believes that operations such as yours expose the public to significant potential health risks.

36. "A System Overwhelmed: The Avalanche of Imported, Counterfeit, and Unapproved Drugs into the U.S.," Hearing Before the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce (6/24/03)

- FDA has long taken the position that consumers are exposed to a number of potential risks when they purchase drugs from foreign sources or from sources that are not operated by pharmacies properly licensed under state pharmacy laws. These outlets may dispense expired, subpotent, contaminated or counterfeit product, the wrong or a contraindicated product, an incorrect dose, or medication unaccompanied by adequate directions for use. The labeling of the drug may not be in English and therefore important information regarding dosage and side effects may not be available to the consumer. The drugs may not have been packaged and stored under appropriate conditions to prevent against degradation, and there is no assurance that these products were manufactured under current good manufacturing practice (cGMP) standards. When consumers take such medications, they face risks of dangerous drug interactions and/or of suffering adverse events, some of which can be life threatening. These risks could include potential side effects from inappropriately prescribed medications or side effects due to drug contamination.
- While some foreign drug manufacturers submit their products to FDA for approval, the imported drugs arriving through the mail, through private express couriers, or by passengers arriving at ports of entry are often unapproved new drugs that may not be subject to any reliable regulatory oversight. FDA cannot assure the safety of drugs purchased from such sources. . . . In sum, at this time the Agency cannot assure the American public that drugs purchased from foreign sources are the same as products approved by FDA, or that they are safe and effective.
- MR. HUBBARD: Generally many of these drugs themselves are not going to immediately hurt you. They are just not going to help you. And the purpose of taking a drug, of course, is to treat an illness, not to just take a placebo or a sugar pill. And many of these drugs in fact are just that, they are subpotent or they are lacking in any active ingredient. You would not

expect an injury from that, but you also would not get the medicinal treatment that the drug was intended for.

37. Letter from Mark B. McClellan to W.J. "Billy" Tauzin and written FDA Response to Concluding Observations Section of Committee on Energy and Commerce Staff Report (6/23/03)

- While some foreign drug manufacturers submit their products to FDA for approval, the imported drugs arriving through the mail, through private express couriers, or by passengers arriving at ports of entry are often unapproved new drugs that may not be subject to any reliable regulatory oversight. FDA cannot assure the safety of drugs purchased from such sources. . . . In FDA's experience, many drugs obtained from foreign sources that either purport to be or appear to be the same as U.S.-approved prescription drugs are, in fact, of unknown quality. Because FDA cannot assure the American consumer that such products are safe and effective, consumers using foreign prescription medications run the risk that such products may be:
 - Expired, subpotent, contaminated or counterfeit drug, the wrong or a contraindicated product, an incorrect dose, or medication unaccompanied by adequate directions for use.
 - Drugs with labeling in a foreign language or where important information regarding dosage and side effects are not available.
 - Drugs that have not been packaged and stored under proper conditions to avoid degradation.
 - Drugs that have not been manufactured using current good manufacturing practice standards.
- [S]ome websites based outside the U.S. may dispense drugs in the absence of a doctor-patient relationship, resulting in prescription products being provided without proper physical examination or medical history. In such instances, patients may be more likely to receive inappropriate medications, may fail to receive needed medical care, or may not be properly made aware of risks of side effects or other drug interactions.
- [T]he Agency simply cannot assure the American public that drugs purchased from foreign sources are the same as products approved by FDA, or that they are safe and effective.
- The Agency acknowledges the significant potential risks associated with imported prescription drugs.

38. "Canadian Prescription Drug Importation: Is There a Safety Issue?" Hearing Before the Subcommittee on Human Rights and Wellness of the House Committee on Government Reform (6/12/03)

- As we have previously testified, the overall quality of drug products that consumers purchase from United States pharmacies is very high. The public can be confident that the drugs they

use are safe and effective. In order to help maintain these high standards, FDA works diligently on many fronts to ensure that consumers receive safe and effective drugs. However, FDA cannot offer the same assurances to the public about the safety of drugs they buy from foreign sources.

- The issue of U.S. consumers purchasing drugs from foreign sources is a significant concern for FDA. A growing number of Americans are obtaining their prescription medications from foreign locations. They often seek out Canadian suppliers, or sources that purport to be Canadian. As we have said in the past, FDA cannot ensure the safety of drugs purchased from foreign sources.
- For public health reasons, FDA remains concerned about the importation of prescription drugs into the U.S. In our experience, many drugs obtained from foreign sources that either purport to be or appear to be the same as U.S.-approved prescription drugs are, in fact, of unknown quality. FDA cannot assure the American public that drugs imported from foreign countries are the same as products approved by FDA.
- FDA has long taken the position that consumers are exposed to a number of risks when they purchase drugs from foreign sources or from sources that are not operated by pharmacies licensed under state pharmacy law. These outlets may dispense expired, subpotent, contaminated or counterfeit product, the wrong or a contraindicated product, an incorrect dose, or medication unaccompanied by adequate directions for use. The labeling of the drug may not be in English and therefore important information regarding dosage and side effects may not be available to the consumer. The drugs may not have been packaged and stored under appropriate conditions to avoid degradation. There is no assurance that these products were manufactured under current good manufacturing practice (cGMP) standards. When consumers take such unsafe or inappropriate medications, they face risks of dangerous drug interactions and other serious health consequences.
- Consumers who buy prescription drugs from foreign countries are at risk of suffering adverse events, some of which can be life threatening.
- FDA is working to address its continued safety concern about increased importation of prescription drugs. However, despite continued efforts to identify ways to assure the safety of imported drugs, FDA for many years has consistently stated that it cannot assure the safety of prescription drugs that are obtained outside its comprehensive regulatory system.
- MR. HUBBARD: All we can do is say to you if Congress wants to let these drugs in, that is Congress' policy decision to make but we believe there will be a diminution of safety and then Congress has to decide whether that diminution of safety, whatever it is, whether 1 percent or 90 percent, is worth the savings that would accrue.

39. "FDA Rx Importation Policy Still Focused On Safeguarding U.S. Drug Supply, McClellan Says," Health News Daily (5/27/03)

- "While we want to remain optimistic about the potential for technology to help in security efforts, clearly there's no reliable way to assure the safety of illegally imported drugs despite

all of our discussions with Canada, so we need to focus our efforts on what policies are available to safeguard the U.S. drug supply,” McClellan told “Health News Daily.” . . . “We understand that many people are doing this because of price issues. However, this is not a solution to that problem. It is both risky and dangerous.”

40. Marc Kaufman, “FDA: Canadian Drug Position Misinterpreted,” Washington Post (5/26/03)

- “The Canadian government is now on record saying they cannot guarantee the safety and effectiveness of drugs not legally exported into the U.S.,” [Peter J. Pitts, FDA’s associate commissioner for external relations] said. “The Canadian position reinforces our position that bringing in any medical products from outside our borders that are not FDA-approved is inherently risky and dangerous.”

41. “MCCLELLAN SAYS ‘REIMPORTATION’ POSSIBLE ONCE TRACKING SYSTEM IN PLACE,” FDA Week (5/23/03)

- “They keep drugs safe within Canada and I think they do a very good job of that,” McClellan told *FDA Week*. “But they stopped short of saying they can assure the safety of drugs exported to the United States. But since we can only assure the safety of drugs within our own regulatory system, there’s a risky gap there.”

42. “Agriculture, Rural Development, and Related Agencies Appropriations For Fiscal Year 2004,” Hearing Before a Subcommittee of the Senate Committee on Appropriations (5/22/03)

- DR. MCCLELLAN: [T]he problem with reimported drugs that come into this country outside our regulatory system is that we can’t provide assurances about the safety or effectiveness of those drugs. . . . [Canada] also clarified in a letter to the Washington Post just yesterday that they can’t assure the safety of imported drugs coming illegally into the United States, that is, coming in outside of our regulatory system. We can’t, either, because they are outside of our regulatory scheme. . . . And so there is a real concern there. We have got to find better ways to make affordable treatments available. Reimportation of illegal drugs, or importation of illegal drugs, since you often can’t tell the difference, is not a safe and effective solution.
- DR. MCCLELLAN: [D]rugs that are not approved by the FDA, that are not legally obtainable in the United States cannot have safety assurances that we would vouch for. We cannot assure that they are safe and effective. . . . Reimportation of illegal drugs is not a cornerstone for a safe and effective public health policy in this country.
- DR. MCCLELLAN: The problem today is that the vast majority of Americans who are buying drugs from outside our regulatory system are not doing what [your constituent who crosses the Canadian border] does. They are buying over the Internet from sites that may be in Canada, that may not. We have seen a lot of the products coming into the country. In many cases, they are not labeled properly. They are the wrong amounts. They don’t come with the risk management and warning information that a doctor and pharmacist in this

country would provide. This is not a safe and effective medical system for providing prescription drugs and we need to do better.

43. “International Prescription Drug Parity: Are Americans Being Protected or Gouged?” Hearing Before the Subcommittee on Human Rights and Wellness of the House Committee on Government Reform (4/3/03)

- Consumers take genuine risks when they purchase drugs from Internet sites that dispense foreign drugs or are not licensed and operated under state pharmacy law. These outlets may dispense expired, subpotent, contaminated or counterfeit product, the wrong or a contraindicated product, an incorrect dose, or medication without adequate directions for use. Unsafe or inappropriate drugs put consumers at risk for dangerous drug interactions and serious health consequences.
- FDA cannot assure U.S. citizens that the prescription medications they are buying over the Internet from foreign countries such as Canada are safe. Many drugs obtained from foreign sources that either purport to be or appear to be the same as U.S. approved prescription drugs are, in fact, of unknown quality. The rise of Internet drugs sales presents substantial safety questions about these products.
- MR. HUBBARD: [W]e have spent countless hours trying to examine processes or procedures that can allow these drugs in safely, and we have simply given our honest appraisal that the ideas that we have come up with and that others have come up with can ameliorate the situation but cannot assure the safety. It will weaken the safety net that has been created, and if Congress wishes to do that because of price controls, that is an issue for the Congress. FDA has not found a magic answer to identify the safe drugs over here and the skeptical drugs over here.

44. “Point, Click, Self-Medicare: A Review of Consumer Safeguards on Internet Pharmacy Sites,” Hearing Before the House Committee on Government Reform (3/27/03)

- Consumers take genuine risks when they purchase drugs from Internet sites that dispense foreign drugs or are not licensed and operated under state pharmacy law. These outlets may dispense expired, subpotent, contaminated or counterfeit product, the wrong or a contraindicated product, an incorrect dose, or medication without adequate directions for use. Unsafe or inappropriate drugs put consumers at risk for dangerous drug interactions and serious health consequences.
- Mr. Hubbard: To answer the question to me, you are absolutely right that there is a great risk that drugs purchased over the Internet from foreign countries could have variability in ingredients and content, they can be contaminated, they might not even be the drug you think you’re getting, so that is a very serious issue and we have been trying to essentially stop those drugs from coming in by taking some enforcement action, by asking foreign governments from where those drugs are coming to step in, and by warning our consumers who buy those drugs that they are taking great risk.

- Mr. Hubbard: . . . [A] big part of the concern is that even if the Canadian drugs today are just fine—and, you know, we don't know, but if this practice were legitimized, Canada could become strictly a trans-shipment point for Third World countries to send drugs to.

45. Warning letter from David J. Horowitz to Rx Depot (3/21/03)

- Rx Depot's web site and documents make misleading assurances to consumers about the safety of the drugs purchased through Rx Depot. For example, flyers provided at your storefront claim that these drugs are 'FDA approved' and '[a]ll meet FDA standards.' Rx Depot's web site claims that the products purchased through Rx Depot, 'are all approved for use by the United States government and are exactly the same as if purchased in the United States.' None of these statements is correct. Prescription drugs purchased from foreign countries generally are not FDA-approved, do not meet FDA standards, and are not the same as the drugs purchased in the United States.
- Drugs from foreign countries do not have the same assurance of safety as drugs actually regulated by the FDA. Because the medications are not subject to FDA's safety oversight, they could be outdated, contaminated, counterfeit, or contain too much or too little of the active ingredient. In addition, foreign dispensers of drugs to American citizens may provide patients with incorrect medications, incorrect strengths, medicines that should not be used in people with certain conditions or with other medications, or medications without proper directions for use. These risks are exacerbated by the fact that many of the products you are soliciting United States consumers to buy are indicated for serious medical conditions [cancer, HIV, and hypertension].
- [M]any drugs obtained from foreign sources that purport or appear to be the same as U.S.-approved drugs are, in fact, of unknown quality. Recent examples of counterfeit products entering the U.S. marketplace also raise substantial safety questions about drugs from foreign countries. Moreover, there is a possibility that drugs which come to U.S. consumers through Canada or purport to be from Canada may not actually be Canadian drugs. In short, drugs delivered to the American public from foreign countries may be very different from products approved by FDA and may not be safe and effective. For all of these reasons, FDA believes that operations such as yours expose the public to significant potential health risks.

46. "FDA Collaborates with Arkansas State Board of Pharmacy in Enforcement Action Against Storefront Obtaining Unapproved Drugs from Canada," FDA Press Release (3/21/03)

- FDA is very concerned that foreign medications purchased by U.S. consumers from unregulated drug outlets pose a growing potential danger. This is particularly true because Rx Depot and similar companies often state incorrectly to consumers that the FDA condones their activities and even that their prescriptions are "FDA approved," which could lead consumers to conclude mistakenly that the prescription drugs sold by the companies have the same assurance of safety as drugs actually regulated by the FDA.
- FDA believes that [internet pharmacy] operations such as this one expose the public to the significant potential risks associated with unregulated imported prescription medications.

Because the medications are not subject to FDA's safety oversight, they could be outdated, contaminated, counterfeit or contain too much or too little of the active ingredient.

- [F]oreign dispensers of drugs to American citizens may provide patients with incorrect medications, incorrect strengths, medicines that should not be used in people with certain conditions or with other medications, or medications without proper directions for use. For example, some prescription medications advertised by Rx Depot have potentially serious side effects, contradictions, and drug/food interactions. Since these medications are not subject to FDA labeling or state board of pharmacy medication information requirements, consumers are at higher risk.

47. "South Florida's Access to Affordable Prescription Drugs: Costs and Benefits of Alternative Solutions," Hearing Before the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce (3/10/03)

- For public health reasons, the FDA remains concerned about the importation of prescription drugs into the United States. In our experience, many drugs obtained from foreign sources that either purport to be or appear to be the same as U.S.-approved prescription drugs are, in fact, of unknown quality.
- FDA has long taken the position that consumers are exposed to a number of risks when they purchase drugs from Internet sites that dispense foreign drugs or are not operated by pharmacies licensed and operated under State pharmacy law. These outlets may dispense expired, some potent [sic], contaminated or counterfeit products. It could dispense the wrong or a contraindicated product, an incorrect dose or medication unaccompanied by adequate directions for use. In addition, FDA cannot provide consumers with any assurance that these products are manufactured under current good manufacturing standards or stored properly. Taking such unsafe or inappropriate medications puts consumers at a risk for dangerous drug interactions and other serious health consequences.
- Another potential problem involves Internet sites that provide prescription drugs without a prescription or by having consumers fill out a questionnaire rather than seeing a doctor.
- Consumers take genuine risks when they purchase drugs from Internet sites that dispense foreign drugs or are not operated by pharmacies licensed and operated under state pharmacy law. These outlets may dispense expired, subpotent, contaminated or counterfeit product, the wrong or a contraindicated product, an incorrect dose, or medication without adequate directions for use. Unsafe or inappropriate drugs put consumers at risk for dangerous drug interactions and serious health consequences.
- In general, FDA has no information to establish where [imported] drugs were actually manufactured and whether cGMP requirements were followed. The labeling of the drug may not be in English and therefore important information regarding dosage and side effects may not be available to the consumer. There is no assurance that the drugs are not counterfeit, contaminated or misbranded. There is also no assurance that the drugs were packaged and stored under appropriate conditions to avoid degradation or contamination.

- FDA cannot assure U.S. citizens that the prescription medications they are buying over the Internet from foreign countries such as Canada are safe. Many drugs obtained from foreign sources that either purport to be or appear to be the same as U.S. approved prescription drugs are, in fact, of unknown quality. The rise of Internet drugs sales presents substantial safety questions about these products.
- There are primarily two types of risks that consumers of [imported] drugs would face. The first risk arises when consumers take drugs of unknown origin or quality. Second is the very significant risk associated with taking many of these drugs without first obtaining a physician's prescription and without the continued oversight of the physician.
- Many of the drugs identified in the Carson [City, California mail facility] pilot [project] are intended to treat conditions that only physicians can properly diagnose. Consumers who bypass physician diagnosis and prescribing may be exposing themselves to risks and toxicities that cannot be justified by offsetting benefits.

48. "Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations For 2004," Hearing Before a Subcommittee of the House Committee on Appropriations, and Written FDA Response to Committee Questions (3/6/03)

- Dr. McClellan: [W]e are very concerned about the safety of drugs that do not go through a closed system full regulatory procedure before they get to patients in this country. There is no guarantee of safety and effectiveness of those kinds of products, and it is a very real concern at FDA.
- Dr. McClellan: There is absolutely no guarantee that [drugs purchased from Canada or Mexico] are up to [FDA's] standard, and one of the reasons why I think action on a prescription drug benefit in Medicare is so important is that the lack of action is contributing to the fact that we have got people now making choices, a conscious choice—they know these drugs aren't as safe. I have tried to be very clear about the fact that there isn't a clear regulatory process, there is no guarantee of safety and effectiveness like there is for the products that we regulate that are produced and distributed within this country. They know the drugs aren't as safe. They are using them, anyway. They are taking a potential risk for their health because they are worried about cost because they don't have good coverage.
- [F]oreign web sites pose added problems because of the possibility that they sell counterfeit products, and contaminated or subpotent medications. FDA has limited ability to take direct enforcement action against these foreign operators on behalf of U.S. citizens.
- FDA has been examining the issue of prescription drug importation or reimportation for some time. We have not been able to devise a mechanism that would allow commercial importation of foreign drugs yet to assure the same level of protections provided to U.S. consumers under the existing system, where all prescription drugs are manufactured by FDA approved facilities and distributed by entities regulated by FDA or by state agencies. The gold standard of drug safety and efficacy that prevails in the United States is due in large part to the closed system of drug distribution. Drugs are manufactured in registered facilities

subject to FDA inspections and intermediate and finished products move through a distribution network regulated by federal and state law before reaching the consumer. In contrast, the foreign distribution network operates without any FDA oversight. Even if FDA were asked to oversee an expensive testing system for imported products, no assurances could be made that such products would meet the same standard of safety and efficacy required of domestic products. FDA remains willing to explore this issue further with the Committee.

- There are sound public health reasons for continuing the current prohibition [on imports]. FDA and the public do not have any assurance that unapproved products are effective or safe, or have been produced under U.S. good manufacturing practices. U.S. made drugs that are reimported may not have been stored under proper conditions, or may not be the real product, because the U.S. does not regulate foreign distributors or pharmacies. Therefore, unapproved drugs and reimported approved medications may be contaminated, subpotent, superpotent, or counterfeit.
- The agency and the U.S. Customs Service continue to work together to address issues of concern in this area. Because FDA lacks resources to inspect all prescription drugs entering the U.S., it is important that we work to develop alternate ways to address this important public health issue.
- FDA is very concerned that medications purchased by U.S. consumers abroad may present health risks. These risks include quality assurance concerns, counterfeit potential, presence of untested substances, risks of unsupervised use, labeling and language issues and lack of information accompanying the medication to permit the consumer to [sic] dangerous side effects of the medication.

49. Letter from William K. Hubbard to the Kullman Firm (2/12/03)

- FDA is very concerned about the importation of prescription drugs from Canada. In our experience, many drugs obtained from foreign sources that purport and appear to be the same as U.S.-approved prescription drugs have been of unknown quality. We cannot provide adequate assurance to the American public that the drug products delivered to consumers in the United States from foreign countries are the same products approved by FDA.
- [M]any drugs obtained from foreign sources that purport and appear to be the same as U.S.-approved prescription drugs have been of unknown quality. FDA approves a drug based on scientific data submitted by the drug sponsor to demonstrate that the drug is safe and effective. We cannot provide adequate assurance to the American public that the drug products delivered to consumers in the United States from foreign countries are the same products approved by FDA.