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John Taylor

The Food and Drug Administration, Rockville, Maryland

Associate Commissioner for Regulatory Affairs

Testimony

Mr. Chairman and Members of the Committee, I am John M. Taylor, Associate Commissioner for Regulatory Affairs at the U.S. Food and Drug Administration (FDA or the Agency). With me is Mr. William K. Hubbard, Associate Commissioner for Policy and Planning at FDA. We appreciate having this opportunity to discuss with you the issues relating to the importation of prescription drugs into the United States and proposals that would legalize the importation of these drugs beyond what is currently allowed by law.

At FDA, our statutory responsibility is to assure the American public that the drug supply is safe, secure, and reliable. For more than 60 years, the Federal Food, Drug, and Cosmetic (FD&C) Act has ensured that Americans can be confident that, when they use an FDA-approved drug, the medicine will be safe and effective and will work as intended in treating their illness and preventing complications. In carrying out this responsibility, FDA also works to do all we can under the law to make medicines accessible and help doctors and patients to use them as effectively as possible, through such steps as expanding access to generic medicines, reducing the time and cost of showing that new medicines are safe and effective, and providing up-to-date information for health professionals and patients to obtain the benefits and avoid the risks associated with powerful medicines. That is the primary mission of the thousands of dedicated staff, including leading health care experts, doctors, economists and scientists who work tirelessly at FDA in public service for the American people. FDA has concerns about unapproved, imported pharmaceuticals whose safety and effectiveness cannot be assured because they are outside the legal structure and regulatory resources provided by Congress. We have also taken steps within the law to improve the availability of affordable medicines and reduce drug costs, without compromising safety. In my testimony today I look forward to having the opportunity to engage in a constructive dialogue about the issue of importing prescription drugs as well as discussing steps to provide greater access to more affordable prescription medications.

REDUCING DRUG COSTS

FDA shares with Congress its great concern for senior citizens and other patients who have difficulty paying for prescription drugs. That is why the Administration worked with Congress to enact the new Medicare prescription drug law. And that is why FDA has made it a priority for its medical and scientific experts to establish and expand programs that promote access to innovative treatments to help Americans live healthier lives and assure that Americans have access to medications and treatments that they can afford.

FDA has taken a number of significant steps to provide greater access to affordable prescription medications, including unprecedented steps to lower drug costs by helping to speed the development and approval of low-cost generic drugs after legitimate patents have expired on branded drugs. Generic drugs typically cost 50 to 70 percent less than their brand-name counterparts. On June 18, 2003, FDA published a final rule to improve access to generic drugs and lower prescription drug costs for millions of Americans. These changes will save Americans over \$35 billion in drug costs over the next 10 years. Elements of this rule were codified as part of the recently enacted Medicare law and, with FDA's technical assistance, the law added additional mechanisms to enhance generic competition in the marketplace.

In addition, last year Congress provided an increase of \$8 million for FDA's generic drug program, the largest infusion of resources into this program ever. This increase in the generic drug budget enables FDA to hire additional expert staff to review generic drug applications more quickly and initiate targeted research to expand the range of generic drugs available to consumers. Improvements in the efficiency of review procedures have led to significant reductions in approval times for generic drugs since 2002, and consequently will save consumers billions more by generally reducing the time for developing generic drugs and making them available.

The Agency has also taken steps to help improve the development process to help lower the high cost of developing new drugs. In particular, FDA is continuing to improve the methods by which assistance and advice is provided to sponsors regarding what we believe are the best approaches to develop new therapies and maximize the prospects for swift FDA approval. These ongoing efforts are designed to provide sponsors with the best possible information and thus increase the efficiency of the development process. We expect that reforms in drug and biologic manufacturing requirements should help reduce manufacturing costs by 20 percent. FDA has identified several priority disease areas, such as cancer, diabetes and obesity, and new technologies including gene therapy, pharmacogenomics and novel drug delivery systems that are good candidates for efforts to clarify regulatory pathways and clinical endpoints.

FDA is also working to prevent adverse events through new rules that would require bar coding for drugs and better ways to track adverse events automatically with the goal of preventing billions of dollars in unnecessary health care costs each year. FDA's final rule requiring bar coding of drug is estimated to have net economic benefits of approximately \$3.5 billion per year. Avoiding such preventable medical complications will also help reduce health care costs, while enhancing quality and safety. In addition, the Agency is striving to promote electronic prescribing, to improve quality and reduce prescription costs as well.

IMPORTATION OF PRESCRIPTION DRUGS

Sixty-five years ago, Congress responded to widespread instances of unsafe drugs by directing FDA to create a system for assuring that Americans have a drug supply they can

trust will not harm them. Over forty years ago, Congress required that legal drugs be proven to be effective as well, because modern medicines – when they are produced, distributed, prescribed, and used properly – should not only be safe but also should prevent the many complications and side effects of diseases. More recently, in 1988, Congress enacted the Prescription Drug Marketing Act (PDMA) to establish additional safeguards to prevent substandard, ineffective, or counterfeit drugs from entering the U.S. Under PDMA, it is illegal for anyone other than the drug’s original manufacturer to re-import a prescription drug into the U.S. that was manufactured in the U.S. This law was enacted with strong bipartisan support because of high-profile cases of unsafe and ineffective drugs entering the U.S. in large volumes. In one instance, over 2 million unapproved and potentially unsafe and ineffective Ovulen-21 “birth control” tablets from Panama were distributed throughout the U.S. In another case, a counterfeit version of Ceclor, a widely used antibiotic at the time, found its way into the U.S. drug distribution from a foreign source. Over the years, FDA’s dedicated professional staff has employed PDMA and other authorities to build a drug safety infrastructure to ensure that Americans enjoy the highest-quality drug supply in the world.

Unfortunately, the drug supply is under unprecedented attack from a variety of increasingly sophisticated threats. This is evident in the recent significant increase in efforts to introduce counterfeit drugs into the U.S. market. FDA has seen its number of counterfeit drug investigations increase four-fold since the late 1990s. Although counterfeiting was once a rare event, we are increasingly seeing large supplies of counterfeit versions of finished drugs being manufactured and distributed by well-funded and elaborately organized networks. At the same time, inadequately regulated foreign Internet sites have also become portals for unsafe and illegal drugs. For example, FDA recently worked with domestic and international authorities to shut down a website that was advertising “FDA-approved” and safe “European” birth control pills and other drugs, but was actually responsible for importing ineffective, counterfeit drugs. Evidence strongly suggests that the volume of these foreign drug importations is increasing steadily, presenting an increasingly difficult challenge for Agency field personnel at ports-of-entry, mail facilities, and international courier hubs, and our laboratory analysts and border and law enforcement partners.

FDA is doing its best to use its limited international authorities to stop the increasing flow of violative drugs into this country, but the task is daunting. Each day, thousands of individual packages containing prescription drugs are imported illegally into the U.S., simply because the sheer volume has grown to exceed the capability of FDA field personnel to properly process. FDA’s Office of Regulatory Affairs has inspectors who work in the field who perform investigational work pertaining to imported prescription drugs, a job that is not limited to inspections at ports-of-entry.

SAFETY CONCERNS RELATING TO IMPORTATION

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.

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. Furthermore, in the case of foreign-based sources, if a consumer has an adverse drug reaction or any other problem, the consumer may have little or no recourse either because the operator of the pharmacy often is not known, or the physical location of the seller is unknown or beyond the consumer's reach. FDA has only limited ability to take action against these foreign operators.

The Agency has responded to the challenge of importation by employing a risk-based enforcement strategy to target our existing enforcement resources effectively in the face of multiple priorities, including homeland security, food safety and counterfeit drugs. However, this system, as it works today, is already overwhelmed by the number of incoming packages, and this presents a significant ongoing challenge for the Agency.

Recent spot examinations of mail shipments of foreign drugs to U.S. consumers revealed that these shipments often contain dangerous or unapproved drugs that pose potentially serious safety problems. In 2003, inspectors found that the majority of the packages examined in these "blitzes" contained illegal, unapproved drugs. Last summer, FDA and Customs conducted blitz examinations on mail shipments at the Miami and New York (JFK) mail facilities in July, and the San Francisco and Carson, California, mail facilities in August. In each location, the agencies examined packages shipped by international mail over a 3-day time span. Of the 1,153 shipments examined, the overwhelming majority (1,019 packages, or 88 percent) contained unapproved drugs. The drugs arrived from many countries. For example, 16 percent entered the U.S. from Canada; 14 percent were from India; 14 percent came from Thailand, and 8 percent were shipped from the Philippines.

A second series of import blitz exams, conducted in November 2003, also revealed potentially dangerous, illegally imported drug shipments. Of the 3,375 products examined, 2,256 or 69 percent were violative. FDA found recalled drugs, drugs requiring special storage conditions and controlled substances. These blitz exams were performed at the Buffalo, Dallas, Chicago and Seattle international mail facilities and, for the first time, the private courier hubs at Memphis and Cincinnati. Canadian parcels appeared most frequently (80 percent of the mail parcels), while 16 percent were from Mexico, and the remaining 4 percent came from Japan, the Netherlands, Taiwan, Thailand and the United Kingdom.

Examples of the potentially hazardous products encountered during the exams include:

- Unapproved drugs such as 1) 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 2) human growth hormone, which can have serious side effects if used inappropriately or in excessive doses.
- Controlled substances – FDA and Customs found over 25 different controlled substances, including Diazepam; Xanax; Codeine; Valium, Lorazepam, Clonazepam and anabolic steroids.
- Drugs withdrawn from the U.S. market for safety reasons such as Buscapina, which appears to be the drug dipyron, removed from the market in 1977 due to reports of association with agranulocytosis -- a sometimes fatal blood disease.
- Improperly packaged drugs shipped loose in sandwich bags, tissue paper or envelopes.
- Animal drugs not approved for human use such as Clenbuterol, a drug approved for the treatment of horses but also known as a substance of abuse in the “body building” community and banned by the International Olympic Committee.
- Potentially recalled drugs -- Serevent Diskus and Flovent Diskus medicines from Canada for the treatment of asthma. Shortly after the blitz, certain lots of the Canadian versions of these drugs were recalled in Canada.
- Drugs requiring risk management and/or restricted distribution programs -- For example, Canadian-manufactured isotretinoin, which in the U.S. is subject to a stringent risk management plan, under which prescribers are required to screen, educate and monitor patients to avoid certain serious risks such as birth defects.
- Drugs with inadequate labeling such as those with missing dosage information or labeling that is not in English.

But its not just FDA that has identified both legal and safety concerns about importation of prescription drugs -- so have many other professional regulators, including state pharmacy boards and most recently courts. On November 6, 2003, Federal District Court

Judge Claire V. Eagan, U.S. District Court for the Northern District of Oklahoma, issued a decision in *United States v. RX Depot, Inc. and RX of Canada LLC*, granting a preliminary injunction to immediately prevent these defendants who operate business that import prescription drugs from Canada, because such unapproved drugs were a clear violation of the FD&C Act. In addition to her unequivocal findings of law, the Judge concluded that these companies could not assure the safety of the drugs they have been importing and, as a result, in violating the law, have put Americans at serious risk. The Judge concluded that “unapproved prescription drugs and drugs imported from foreign countries by someone other than the U.S. manufacturer does not have the same assurance of safety and efficacy as drugs regulated by the Food and Drug Administration.” She continues: “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.”

RECENT STATE ACTIONS

Despite this ruling and the concerns raised by the Agency, recently, several governors and mayors have proposed to create systems whereby their employees and/or constituents could be directed to Canadian pharmacies for purchasing Canadian drugs. FDA has spoken with a number of such officials about our concerns, and many have declined to proceed and have turned to other legal, proven ways to safely reduce drug costs. However, some states and localities, including the state of Minnesota and the state of Wisconsin have proceeded to establish state-run websites linking citizens to entities dispensing drugs purportedly from Canada.

Recent research by the state of Minnesota pointed out significant problems related to purchasing non-FDA approved pharmaceuticals from foreign Internet pharmacies. Minnesota State health officials observed even Canadian pharmacies that participate in the Canadian Internet Pharmacy Association engaging in problematic practices during a single, voluntary, pre-announced “visit.” The 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 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 U.S.

Similar findings occurred when representatives of New Hampshire Gov. Craig Benson visited the Canadian Internet pharmacy known as CanadaDrugs.com, located in Winnipeg, Manitoba. The “terms of service” for CanadaDrugs.com requires purchasers to agree that they “will not be liable for damages arising from personal injury or death” from the use of drugs sold by the pharmacy. Under this practice, the consumer has no recourse for injuries arising from the use of drugs from this shipper. Additionally, the website allows patients to send in their prescriptions by fax, when the practice is illegal under the law in New Hampshire and other states. CanadaDrugs.com is “accredited” only by the Internet and Mail order Pharmacy Accreditation Commission, which is a voluntary body with no legal standing and no Federal or state regulatory or enforcement authority.

DRUG COUNTERFEITING

Counterfeiting of prescription drugs is a growing global concern. In fact, counterfeiting of drugs is commonplace in many countries. In the U.S., Federal and state authorities have kept counterfeiting of drugs to a minimum because of our extensive system of laws, regulations and enforcement. As a result, Americans have a high degree of confidence in the drugs they obtain from their local pharmacy. In recent years, however, FDA has seen growing evidence of efforts by increasingly well-organized counterfeiters, backed by increasingly sophisticated technologies and criminal operations, intent on profiting from drug counterfeiting at the expense of American patients.

To respond to this emerging threat, FDA convened a Counterfeit Drug Task Force that received extensive comment and ideas from security experts, Federal and state law enforcement officials, technology developers, manufacturers, wholesalers, retailers, consumer groups, and the general public. Based on these comments, on February 18, 2004, FDA issued a report that contains specific steps that can be taken now and in the future to protect consumers from counterfeit drugs and secure the U.S. drug supply chain.

The report’s framework describes how to strengthen our drug safety assurances against modern counterfeit threats through a multilayered strategy that includes modern anti-counterfeiting technologies. Promising developments such as “track and trace” technologies that cannot be faked like a paper drug pedigree, and verification technologies built not only into tamper-resistant drug packaging but also into the drugs themselves will make our job of verifying the legitimacy of drug products much easier. FDA is working to speed the availability of these anti-counterfeiting technologies, but these technologies have not yet been proven, and they are intended to complement and reinforce an underlying system for assuring the safety and effectiveness of prescription drugs.

Thus, anti-counterfeiting technologies hold great promise for strengthening our legal drug distribution system, but to be effective they must be used in conjunction with effective

legal authorities.

INTERNATIONAL DRUG PRICES

As millions of Americans without good prescription drug coverage experience every day, the “list prices” they face for patented drugs when they walk into a drug store in the United States can be much higher than the price of drugs sold abroad. But these price differences do not result from a comparative advantage in the production of such goods abroad. Foreign “list” prices are lower in part because of price controls in foreign countries. While drug prices in the U.S. can be much lower than “list” for Americans with good drug insurance, in Canada, the Patented Medicine Price Review Board (PMPRB) limits both initial prices and price increases of patented medicines through a variety of “tests.” Price controls at the provincial level also constrain prices.

Studies of patented drug prices often ignore how competition in the U.S. today, building on the measures described above to improve access and competition in generic drugs, effectively lowers generic drug prices so that many are far lower than drug prices abroad. Generic drugs comprise over half of all U.S. prescriptions, a much higher percentage than in most other countries. Furthermore, low generic prices are fully compatible with strong incentives for research and development of new drug products, because generics are allowed in the U.S. only after patents expire. The U.S. policy has meant that patent law and competition, not price controls, are the primary mechanism by which to affect incentives for innovation.

Competition in the U.S. has provided U.S. consumers with some of the lowest priced generic drugs in the world. For example, recent studies examined the prices for seven drugs that are the biggest selling chronic-use drugs for which the first U.S. entry of a generic version occurred in the last ten years (alprazolam, clonazepam, enalapril, fluoxetine, lisinopril, metformin, and metoprolol). Five of the seven U.S. generic drugs were found to be significantly cheaper than the generic version of the same drug available in Canada. Five of the same seven generics were also more expensive in Australia than in the U.S., with some prices being many times greater than the comparable U.S. price.

Many countries could do more to encourage innovation in health care by changing the way their dollars are being spent, to get more value for their citizens. First, most countries need more competition when it comes to generic drugs, which should be made available quickly and used more widely and at lower prices as soon as legitimate drug patents expire. Regulation of generics should not restrict prices and choices; it should focus on promoting free and fair generic drug competition, including lower prices for patients that use generic drugs. The bottom line is that it can be possible to redirect billions of dollars in drug spending, through greater use of less expensive generic drugs, permitting greater financial rewards for developing and providing access to valuable new drugs quickly. This approach encourages innovation without spending more money. If the savings from more competitive generic prices and wider use of generic drugs are applied to providing better rewards for innovative new drugs, this approach could reduce the inequities in new

drug prices across countries, while improving global incentives to develop better drugs.

The international community has started making progress toward greater fairness in drug pricing, with the potential to reduce the excessive burden on American consumers, who currently pay about half of all drug costs worldwide. For example, an agreement under TRIPS last year will help make very low-cost medicines available to developing countries for urgent public health threats, such as AIDS. In conjunction with this agreement, many developed nations agreed not to “re-import” these low cost medicines, in recognition of the fact that the price of medicines in a country should reflect that country’s ability to pay. The United Kingdom and France are also taking steps toward increasing payments for innovative new medicines. The fact that significant savings are possible in other developed countries from greater use and more competition involving generic drugs means that it is possible to achieve fairer new drug prices worldwide with less burden on American consumers, without other countries having to spend more.

IMPORTATION PROPOSALS

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 compromise the safety and effectiveness of our drug supply. Depending upon the specifics of the legislation, the volume of importation that could result from enactment of these bills could overwhelm our regulatory system. Many of 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. 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.

Today, FDA drug approvals are manufacturer-specific, product-specific, and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. Under section 801 of the FD&C Act, only manufacturers may import drugs into the U.S. The drugs must be produced in FDA inspected facilities. These facilities and the drugs produced in them are currently covered by the U.S. regulatory system, and it is legal to import these drugs. It is important that in considering legislation to allow expanded importation of drugs by persons other than the manufacturer, Congress should not bypass the protections provided by FDA’s drug approval process and by state regulation of firms that dispense drugs within their jurisdictions.

We want to be clear that our 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. FDA has particularly raised concerns about legislative

proposals that would create such channels by weakening our existing safety protections rather than providing the necessary resources or additional authorities to enable the Agency to assure drug safety and security. Furthermore, our economic experts as well as many others have raised concerns about the limitations of potential longer-term benefits and savings that could be realized from imported drugs. The Congressional Budget Office has estimated that the savings from even a broad, multiple-country importation proposal would be only about one percent, while savings from importing drugs from Canada only would be “negligible.” Even the Canadian Internet pharmacy operators have said that they cannot provide safe drugs for Americans on a large scale. These are important concerns, but that does not mean that we are opposed to undertaking a thorough effort to determine whether and how importation could be accomplished safely. But this cannot be accomplished by fiat or with a presumption of safety.

Some Members of Congress are working on the difficult challenge of identifying the resources and authorities necessary to assure safety for certain types of imported drugs. This is a much more constructive approach than simply declaring imported drugs to be legal or restricting FDA’s authorities to keep the U.S. drug supply safe. To help determine whether and what specific authorities and resources would provide for the safe importation of drugs, the conference report of the new Medicare law gave the Secretary of Health and Human Services specified requirements for a study of drug importation. Among these requirements, the conference report asked the Secretary to “identify the limitations, including limitations in resources and in current legal authorities, that may inhibit the Secretary’s ability to certify the safety of imported drugs” and to “estimate agency resources, including additional field personnel, needed to adequately inspect the current amount of pharmaceuticals entering the country.”

MEDICARE IMPORTATION STUDY AND TASK FORCE

Last year, when Congress enacted the Medicare Modernization Act, it recognized these safety issues and included language that required that the Secretary certify the safety of prescription drugs prior to authorizing their importation. At the same time, Congress directed the Department to conduct a comprehensive study and prepare a report to Congress on whether and how importation could be accomplished in a manner that assures safety. The Department is currently working on that analysis and has created an intergovernmental task force to steer this effort to completion by the Congressional deadline later this year.

The taskforce includes representatives from FDA, the Centers for Medicare and Medicaid Services, Customs and Border Protection, and the Drug Enforcement Administration. The taskforce has brought together a wide variety of health care stakeholders to discuss the risks, benefits and other key implications of importing drugs into the U.S., and to offer recommendations to the Secretary on how to best address this issue in order to advance the public health. The statutory language and the conference report provide detailed, comprehensive requirements for the importation study.

As an integral part of the study process, the task force held a series of six meetings to

gather information and viewpoints from consumer groups, health care professionals, health care purchasers, industry representatives and international trade experts, and a public docket for comments was opened as well. This process affords Congress and the Administration an opportunity to fully address the complex public health, economic and legal questions in order to make appropriate and effective recommendations about importation of prescription drugs and the associated fundamental changes to the FD&C Act and in safety resources that may be required.

CONCLUSION

The standards for drug review and approval in the U.S. are the best in the world, and the safety of our drug supply mirrors these high standards. The employees of FDA constantly strive to maintain these high standards. However, a growing number of Americans are obtaining prescription medications from foreign sources. U.S. consumers often seek out Canadian suppliers, sources that purport to be Canadian, or other foreign sources that they believe to be reliable. Often, the imported drugs arriving through the mail, through private express couriers, or by passengers arriving at ports-of-entry are unapproved drugs that may not be subject to any reliable regulatory oversight. FDA cannot assure the safety of drugs purchased from such sources.

The vigilance of FDA and Customs inspectors is an important tool in detecting imported products that violate the FD&C Act. Given the available resources and competing priorities facing these agencies, however, experience shows that inspectors are unable to visually examine many of the parcels containing prescription drug products that arrive through the mail and private courier services each day. The growing volume of unapproved imported drugs, which often are generated from sales via the Internet, presents a formidable challenge.

FDA firmly believes that we can and should do a much better job of making safe and innovative drugs more affordable in the United States, but to succeed we need to find safe and affordable solutions that, when implemented, do not put consumers at risk. We appreciate and support the bipartisan commitment to making drugs more affordable for seniors and other consumers and are working hard to achieve the goals of safety and affordability. We believe that Americans should not have to settle for less.

We all agree more needs to be done to continue to address the high cost of prescription medicines. But we must be cautious and deliberate as we consider proposals to accomplish this goal. FDA would urge that Congress ensure that any changes to our drug regulation system do not require American citizens to give up the “gold standard” in drug safety that has become a hallmark in this country. FDA’s scientists, doctors, health care experts and regulators must be empowered to protect us from bad medicine. We owe it to patients today and tomorrow to make our medical future brighter, healthier and more affordable.

Thank you for the opportunity to testify. I look forward to responding to any questions you may have.