

**EXAMINATION AND ASSESSMENT OF  
PRESCRIPTION DRUG IMPORTATION FROM  
FOREIGN SOURCES TO THE UNITED STATES**

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**GIULIANI**  
P A R T N E R S

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## **INTRODUCTION**

Prescription medicines are a key component to this nation's healthcare system. As new medicines are developed, people are living longer, healthier lives. And because it is literally a matter of life and death, every effort must be made to protect this nation's medicine supply. To that end, a comprehensive system has been implemented at the federal and state levels to ensure that the medicines that are approved are safe and effective and that the processes for their manufacture, distribution and sale are as tightly controlled as possible in order to keep them safe and effective. And while the United States does have an excellent system, often referred to as the "gold standard," some weaknesses do exist and they, in turn, create vulnerabilities that can be exploited. Common sense dictates that when weaknesses are identified in critical systems, those weaknesses should be addressed before possible harm results. Unfortunately, the current debate regarding the importation of prescription drugs from foreign sources has diverted attention from where it should be; attention is not appropriately focused on addressing the problems that currently challenge those who are responsible for keeping America's medicines safe and minimizing the risk for potential harm.

Giuliani Partners LLC was retained by the Pharmaceutical Researchers and Manufacturers of America (PhRMA) to evaluate the risks associated with the importation of non-FDA approved medicines from foreign sources. After conducting a preliminary, independent review of these issues, in May 2004 an Interim Report, entitled an "Examination and Assessment of Prescription Drug Importation from Foreign Sources to the United States," was submitted to the Health and Human Services Task Force. It was also submitted to two Congressional committees studying the issues associated with importation – the Senate Judiciary Committee and the United States Senate Permanent Subcommittee on Investigations of the Committee on Governmental Affairs. That report found that counterfeit, diluted or adulterated drugs are already entering the United States and that the existing pharmaceutical system is vulnerable to significant exploitation by drug traffickers, organized criminals and terrorists. The serious problems identified in the existing system should be addressed first before any type of importation is authorized.

After the issuance of the Interim Report, Giuliani Partners continued its review of the safety issues associated with the importation of non-FDA approved medicines from foreign sources. This report summarizes the preliminary findings outlined in the Interim Report, includes new information and offers several recommendations to address some of the issues identified. Based upon what has been learned, there is real reason for serious concern regarding the safety of the nation's medicine supply if commercial importation is permitted. To do so would be fraught with risk and could seriously compromise a system that is already weakened. Efforts should be dedicated to addressing the issues within the existing system first while at the same time finding alternative ways to provide safe, effective and affordable medicines to those who need them.

## **EXECUTIVE SUMMARY**

Much of the reason for the focus on importation of prescription medicines from foreign sources stems from the sometimes significant differences in the cost of such medicines in the United States versus foreign countries. Ensuring that all Americans have access to safe, effective and affordable prescription medicines must be a priority. However, based upon the findings in this review, safety will surely be compromised if current efforts to broadly legalize importation are successful. The United States cannot afford to go forward with such a program unless it has determined with absolute certainty that the nation's medicine supply is adequately protected. The press for legislative action to open the borders should be halted until the issues presented can be sufficiently resolved. To do otherwise would create serious risk to the nation's medicine supply.

At the conclusion of the preliminary review, a number of things quickly became evident:

- There are significant risks associated with the importation of medicines from foreign sources.
- Loopholes and problems in the existing drug distribution system need to be addressed.
- An importation system that can assure that medicines being imported are safe and effective does not appear to exist.
- Most surprisingly, the nation's medicine supply is vulnerable to exploitation by organized criminals, drug traffickers and terrorists.

We should not contemplate opening our borders to threats to our medicine supply when in all other aspects we are searching for ways to tighten the security of our borders.

The review also revealed that access to safe, effective and affordable medicines for all Americans is a critical issue and that, due to price controls in other countries, Americans do pay more for many of their prescription medicines. These matters related to affordability and access should be addressed. However, if the health and safety of Americans are truly paramount, then importation of prescription drugs is not the answer. Shortcomings in the existing system related to safety should be addressed and the medical and healthcare professions, as well as consumers, must be educated about various options that currently exist to access more affordable medicines.

This report and the preceding Interim Report discuss a number of findings regarding the safety issues associated with the importation of non-FDA approved medicines from foreign sources. In addition, this document briefly summarizes the law

regarding importation, and the findings of the report recently issued by the Health and Human Services Task Force on Drug Importation. Further, although not the primary focus of this review, in light of the fact that the price of prescription medicines in the United States is an incentive for people to turn to foreign sources, this report briefly discusses several studies regarding the economic implications of such a program.

Those findings can be summarized as follows:

- **Importation is illegal.** The law currently prohibits the importation of prescription drugs from foreign sources unless done by the manufacturer from an FDA-approved facility.
- **Unapproved drugs have already compromised the system.** Non-FDA-approved drugs are already getting into the United States, as evidenced by inspections at various airport mail facilities. Random inspections found that 86% to 88% of the suspected drug parcels examined contained non-FDA approved medicines from such countries as Pakistan, Mexico, Brazil, the Netherlands and Canada. In addition, the World Health Organization, the FDA and pharmaceutical companies indicate that the number of counterfeit drug cases is on the rise. By expanding the sources for drugs, it will be harder to ensure authenticity and chain of custody. The risk to patient/consumers of receiving some of that counterfeit product increases proportionally.
- **There are problems with the existing system.** The weaknesses in the current drug distribution system are well documented. For example, no uniform mechanism, i.e., pedigree of chain of custody, has been implemented to track medicines from the point of manufacture to the point of sale. There are reported issues with the “secondary” drug distribution market and those responsible for oversight of the system do not have sufficient resources to conduct adequate inspections or effectively monitor the system.
- **Troubling questions are raised about remedies proposed in pending importation legislation.** Saying that a commercial importation program is safe does not make it so. Many of the safety features being discussed in the context of pending importation legislation are not necessarily reliable. For example, meaningful ways to “track and trace” medicines electronically, while being used successfully in a few places in the system, are still a few years away from system wide implementation. Further, it is estimated that the FDA resources required to implement a safe system will cost billions. Even if the resources were available, it is questioned whether the FDA would have the necessary authority to perform the required inspections in other countries. We cannot and should not rely on other countries to perform these tasks for us. As was stated in the HHS Task Force Report and by Canada as well, foreign governments are primarily

concerned with the safety and effectiveness of the drugs sold to their own citizens, not necessarily those that are being exported to other countries.

- **The Internet mail-order pharmacy business has exposed a number of safety concerns.** Given that Internet pharmacies are not regulated, ordering prescription drugs in this manner is fraught with risk unless the consumer/patient is able to verify that he or she is dealing with a legitimate pharmacy. Many Internet pharmacies seek to avoid liability by requiring patients to sign waivers.
- **Importation could have significant implications for Canada.** That country does not have supply sufficient to provide for its residents and Americans as well. The Canadian Minister of Health has stated that Canada cannot be the drugstore for the United States and that the Canadian government is contemplating measures to limit Canadian Internet pharmacy sales.
- **Drugs are already coming from foreign sources.** Several of the large Canadian Internet pharmacies have stated publicly that they are already filling prescriptions with drugs from foreign countries and that if the Canadian government does limit their business, they will move their operations to Europe. Patients cannot assume that the drugs they receive from such sources are identical to what they would get in the United States.
- **We must learn from experience regarding the actions of organized criminals, drug traffickers and terrorists.** The present system of importation, inspection and distribution is vulnerable to exploitation and abuse by drug traffickers, organized criminals and terrorists. Several credible sources have identified links between counterfeit goods, including pharmaceuticals, and organized criminals and terrorist groups. Based upon what was learned about the existing system, it is not difficult to imagine a scenario in which terrorist groups could use this system to either finance their operations or, worse, as a vehicle of attack.
- **Savings to consumers may not necessarily be achieved in the long run.** Although not the primary focus of this review, several studies that examined the economic implications of parallel trade, price control and/or commercial importation schemes, were reviewed. They raise troubling issues. Generally, no data could be located to support the contention that there is any economic benefit of legalized importation to consumers in the United States in the long run. Such programs will likely have a negative impact on the investment in research and development by pharmaceutical companies, which in turn could lead to the development of fewer new and innovative medicines. Two other studies examined the economic implications of such programs in the states of Michigan and Massachusetts and both studies projected job loss and reductions in personal income.

In order to appreciate more fully the implications of authorizing a commercial importation program in the United States, a few points perhaps merit some clarification. Generally speaking, under the importation schemes currently being discussed, prescription drugs would be purchased from certain foreign countries, such as Canada or the countries that are part of the European Union (EU). Many, if not all of those countries have systems in place to regulate the price of prescription medicines in their respective countries and those prices do vary. Since these price differentials exist, prescription drugs are traded among those countries comprising the EU. The practice is referred to as “parallel trading.” In essence, licensed traders buy medicines in one country where the prices are lower and then sell them in another country at a higher price. Because there are costs associated with this process, e.g., related to transportation, repackaging and distribution, there are mark ups in the price of the medicines.

In order to give a frame of reference regarding the volume of drugs that are being parallel traded, a document published by the Social Market Foundation, which cites the European Association of Euro-Pharmaceutical Companies that estimated that 140 million packs of medicines were parallel traded in 2002 within the EU Internal market and that 70% of that trade is in the United Kingdom. Since commercial importation into the United States would appear to take on similar characteristics to parallel trading, increases in foreign drug prices can be anticipated thereby reducing the overall savings. Another aspect of this process is troubling. The more often prescription drugs change hands, the more difficult it becomes to verify custody at each step and the easier it becomes to tamper with the product or introduce counterfeit drugs into the supply.

Several recommendations are also included. Based upon what was learned during this review, a number of steps should be considered to ensure that every possible effort is made to protect this nation’s medicine supply. The questions and threats related to the safety of imported medicines are real and should not be dismissed. Accordingly, the following recommendations are offered:

- **Fix the existing system.** The safety of this nation’s medicine supply cannot be assured without investing significant resources into an already overburdened system. The vulnerabilities in the current system should be addressed in order to maintain the “gold standard.” The FDA, Customs and Border Protection and other regulatory entities should be provided with the authority and the resources necessary to ensure that the “gold standard” is not compromised further. In addition, other systemic issues should be addressed, including the implementation of an effective pedigree system.
- **DHS should conduct a threat and vulnerability assessment.** Given the critical role that medicines play in the overall healthcare of the people of this country, a

threat and vulnerability assessment of the nation's medicine supply should be conducted by the Department of Homeland Security.

- **Conduct an education campaign regarding access to cheaper, safer medicines.** At the same time as efforts are underway to address the safety issues associated with the current system, doctors, healthcare professionals and consumers need to be better educated regarding the options available to access cheaper medicines, such as drug discount cards or other patient assistance programs.
- **New efforts should be undertaken to track potential problems with drugs obtained from foreign sources.** There is a need to assess the extent to which people are being harmed as a result of importing drugs from foreign sources. Currently, there is no formal mechanism in place to quantify the problem. Efforts should be undertaken by the healthcare and medical profession to identify the problem. For example, consideration should be given to modifying emergency room, medical examiner and doctor protocols, urging that the following types of questions be asked: from where are the prescription medicines being purchased and are they available to be tested? Additionally, consideration should be given to modifying the FDA's "MedWatch" system, which tracks adverse events involving FDA-approved products, in order to capture additional information related to this issue.
- **Better educate consumers about risks associated with drugs from foreign sources.** Consumers must be made more aware of the risks associated with importing medicines from foreign sources. Not only is there a potential risk from the compromised quality of product they may be receiving, but also there may be serious health implications if their doctors and/or pharmacists are not aware of all of the medicines they are taking. In addition, because current legislative proposals concerning importation extend beyond Canada, for example proposing importation from 25 or more countries, a study should be undertaken, similar to that which was conducted by the HHS Task Force regarding Canada, to assess the feasibility and the risks associated with a broader program. Patient safety requires no less.
- **Create greater access to more affordably priced medicines.** Access to safe, effective and affordable medicines is a significant issue for many Americans, particularly the uninsured and the underinsured, and it should be addressed; but importation is not the answer. As a mechanism to reduce reliance on importation to create greater access at more affordable prices, there needs to be a candid discussion among the pharmaceutical companies, the health care industry, governments and international trade organizations, consumer groups and other

interested parties regarding the cost and accessibility of prescription medicines in the United States and abroad.

Importation from foreign sources clearly invites greater risk to a system that is already compromised. We need to take appropriate steps to address the problems that currently challenge those responsible for ensuring the safety of the nation's medicine supply – close the loopholes, get the resources to those who need them, give developing technologies like those that are capable of ensuring that each pill is authentic and traceable, a chance to be implemented system wide and, in the meantime, find other ways to bring safe and affordable medicines to those who need them. Simply put, patient safety must come first.

Most importantly, it is hoped that this report will raise the level of concern with regard to the risks our medicine supply faces already. Repeatedly, Congress has recognized the need for a regulatory system to ensure Americans receive safe and effective medicines and that the nation's medicine supply is adequately protected - from the earliest stages of development through the approval process to the distribution and sale to patients and consumers. The risks associated with importation of medicines from foreign sources are well documented. Until the existing issues are addressed, it seems illogical to disregard the warnings and open an already vulnerable system to potentially harmful medicines. Under the present circumstances, why would Congress now deviate from its past practice and contemplate introducing a system that cannot, with certainty, guarantee the safety of the nation's medicine supply. That is not to say that the issue of access to safe and affordable medicines should not be addressed; it must be.

## **THE BACKDROP**

### ***THE LAW***

Millions of Americans are engaged in the importation of non-FDA approved medicines from foreign countries and may not fully appreciate that certain aspects of their conduct may be against the law. Historically, the federal regulation of the prescription drug industry began in 1938 when Congress passed the Food Drug and Cosmetic Act (FDCA). Its key provision required that all drugs be cleared for safety by the FDA prior to distribution. It was passed in response to the disaster involving the elixir sulfanilamide in 1937, which killed 107 people when antifreeze was used as a solvent for the drug.

The FDCA makes it illegal to distribute or import an unapproved drug. The Prescription Drug Marketing Act (PDMA) of 1987, passed in response to a concern about counterfeit medicines being diverted into the market, made it illegal for anyone other than the original manufacturer to re-import an approved drug that was manufactured in the United States and then shipped overseas. As a result of these laws and other steps taken

by Congress, an extensive system of regulation currently governs the manufacture, distribution and sale of prescription drugs in the United States and, with limited exception, ensures that the American medicine supply is safe and effective. This system, often referred to as the “gold standard,” essentially establishes a closed system of drug distribution – meaning that, among other things, any medicines distributed in the United States must be FDA-approved.

Notwithstanding this prohibition against importation, the FDA exercises its discretion with regard to the importation of certain unapproved drugs by individuals. Referred to as the “personal use exemption,” the FDA, in its Regulatory Procedures Manual, indicates that “FDA personnel may use their discretion to allow the entry of shipments of violative FDA regulated products when the quantity and purpose are clearly for personal use and the product does not present an unreasonable risk to the user.” The personal use exemption was intended for drugs that had not been approved for use in the U.S. but were being used to treat a serious condition for which other treatments were not available. It does not apply to the importation of drugs available in the United States, the importation of unapproved foreign versions of drugs available in the United States, or to the re-importation of approved drugs in violation of the PDMA.

Congress has passed other laws since the PDMA which demonstrate its acknowledgment that this nation’s medicine supply must be protected. In 2000, Congress enacted the Medicine Equity and Drug Safety Act, certain provisions of which were subsequently amended by the Medicare Prescription Drug Improvement and Modernization Act of 2003. Each of these laws contains provisions that would authorize the importation of medicines from foreign sources provided the Secretary of Health and Human Services (HHS) certifies that such action will pose no additional risk to the public’s health and safety and will result in significant cost savings to the consumer. Since the enactment of these laws, neither the Secretary of HHS under the Clinton administration nor the successors under the Bush administration ever made such a certification.

States have also enacted laws and implemented regulations to provide additional safeguards for the nation’s medicine supply. For example, most states have established licensing systems for distributors, pharmacists, and pharmacies. Current importation practices circumvent these laws and regulations adopted by the appropriate state Boards of Pharmacy.

Notwithstanding the above-referenced legal restrictions, the report prepared by the United States Department of Health and Human Services Drug Task Force which will be discussed in greater detail below estimated that two million Americans purchased approximately \$700 million worth of prescription drugs from Canada in 2003. The report estimates that similar amounts were purchased from other foreign countries, primarily coming in the mail. Further, a number of states and municipalities continue to promote

purchasing from Canada and other foreign sources. A recent news story reported that 28 states and the District of Columbia considered drug importation measures last year.

Examples include:

- The State of Rhode Island, which passed a law permitting the purchase of drugs from Canada by giving the State Board of Pharmacy the authority to license Canadian pharmacies in the same manner that it licenses other out-of-state mail order pharmacies;
- The Governor of Oklahoma, who recently proposed a plan to be submitted to the State's legislature that would allow state residents to buy lower-cost prescription drugs from Canada and other nations;
- Five states - Illinois, Wisconsin, Kansas, Missouri and Vermont - through a website, I-SaveRX.net, have joined together with CanaRX, a pharmacy benefits manager, to facilitate the purchase of prescription drugs from Canada, Ireland and the United Kingdom; and
- Montgomery County in Maryland which passed a local law permitting importation of prescription drugs from Canada.

Thus far, the FDA has been reluctant to take formal action against any state or municipality that has instituted such programs. Instead, it has sent letters to those entities advising them of the safety risks associated with importing medicines from foreign sources and outlining how such programs may violate federal law.

### ***SUMMARY OF INTERIM REPORT***

As noted above, Giuliani Partners issued an Interim Report in May 2004 to the Health and Human Services Task Force and stated that, based upon what had been learned to that point, there are already safety risks associated with the importation of non-FDA approved medicines from foreign sources. In addition, under the current distribution and regulatory system, those risks are likely to increase if importation is legalized. It would be extremely difficult to assure the safety of America's medicine supply under such a program. The following is a summary of the findings from that report, a copy of which is attached to this report as Attachment A.

#### ***Non-FDA Approved Drugs Are Already Coming into the U.S.***

- FDA random inspections at several mail facilities revealed that 86% – 88% of the packages examined contained non-FDA approved drugs.

- During a visit to the JFK Airport Mail Facility, controlled substances, injectables, and medicines with sensitive storage requirements delivered from the Netherlands, Brazil, and Pakistan were discovered.
- The FDA, the World Health Organization and pharmaceutical companies report that counterfeit cases are on the rise.
- Although difficult to assess and monitor, there are a number of reported incidents of adverse effects involving people who took medicines with questionable origins.

#### ***Weaknesses Exist In The Current System***

- The volume of parcels coming into this country (estimated to be greater than 10 million annually) coupled with insufficient resources (the FDA has only approximately 100 investigators to handle this nationwide) makes meaningful inspection by the FDA almost impossible.
- At the JFK Airport Mail Facility, only 1%-2% of the 40,000 packages received daily are inspected.
- There is no uniform mechanism, i.e., a chain of custody or “pedigree,” to track the medicine from point of manufacture to point of sale.
- Wholesalers and distributors are regulated by the states with no uniform interstate standards (there are reportedly more than 6000 secondary wholesalers).
- A Florida Grand Jury report released in February 2003 found an overwhelming need for tighter regulation and oversight of the pharmaceutical distribution system. More specifically, the report concluded that oversight of the distribution system is lax, product quality is compromised, health risks are significant, funding for oversight agencies is inadequate, and incentives for counterfeiting and diversion are considerable.
- There are challenges associated with the oversight and enforcement of current laws with regard to ensuring that medicines being purchased or sold in this country are FDA-approved.

#### ***Internet Pharmacies Are Not Regulated***

- When placing orders over the Internet, there is no way to ensure product quality or origin.

- Many Internet pharmacies do not employ doctors; some do not require prescriptions and many require patients to sign waivers in order to have their prescriptions filled.

***Importation Would Appear to Have Significant Implications for Canada***

- The Canadian government made it clear in correspondence to The Washington Post that it would not be responsible for the safety and quality of prescription drugs exported from Canada into the United States or any other country.
- Canada does not have the infrastructure and sufficient supply to provide for its residents and Americans as well. In fact, Canadian pharmacists report difficulties in sourcing the supply of medicines.
  - The United States fills 3.1 billion prescriptions annually versus 300 million in Canada (US population – 293 million versus Canada – 32.5 million).

***There is a Potential for Exploitation by Narcotics Traffickers, Organized Criminals and Terrorists***

- Although much has been done since September 11, 2001 to protect America's borders, there has not been enough focus on providing additional security for the nation's medicine supply system and it remains vulnerable as a potential target.
- Various studies have documented the links between counterfeit products and terrorist organizations, which engage in such activity to finance their operations.

***THE HHS TASK FORCE REPORT***

Since the issuance of the Interim Report mentioned above, a comprehensive report was issued by the United States Surgeon General regarding the importation of prescription drugs from Canada. The Surgeon General and other experts concluded that the safety and effectiveness of America's medicine supply could not be ensured if drugs are imported from foreign sources. The Medicare Prescription Drug Improvement and Modernization Act passed in December 2003 required the Secretary of Health and Human Services to convene a Task Force on Drug Importation to explore how drug importation might be conducted safely and what would be its potential impact on the health of American patients, medical costs, and the development of new medicines. In its report, the Task Force recognized that access to drugs that are safe and effective as well as affordable is a critical policy goal and there is a "difficult balance" between the need for affordable prescription drugs and the concerns over potential safety hazards that many imported drugs pose. The Task Force also acknowledged that "safety should not be

sacrificed for affordability.” In December 2004, the Task Force issued its report<sup>1</sup> and in its Executive Summary identified the key findings as follows:

- The current system of drug regulation has been effective but is facing new threats; it should be modified “only with great care” to ensure continued high standards of safety and effectiveness of the US drug supply.
- There are significant risks associated with the way individuals are currently importing drugs.
- It would be extraordinarily difficult and costly for personal importation to be implemented in a way that ensures the safety and effectiveness of the imported drugs.
- Overall national savings from legalized commercial importation will likely be a small percentage of total drug spending and developing and implementing such a program would incur significant costs and require significant additional authorities.
- The public expectation that most imported drugs are less expensive than American drugs is not generally true.
- Legalized importation will likely adversely affect the future development of new drugs for American consumers.
- The effects of legalized importation on intellectual property rights are uncertain but likely to be significant.
- Legalized importation raises liability concerns for consumers, manufacturers, distributors, pharmacies, and other entities.

The work of the Surgeon General and the HHS Task Force is comprehensive and well documented. Its findings, which are thoughtful and well supported, should not be ignored by those engaged in the debate regarding importation.

### **FOLLOW UP TO THE INTERIM REPORT**

After issuance of the Interim Report, Giuliani Partners continued its review of the safety issues associated with the importation of non-FDA approved medicines from foreign sources. This section outlines additional information regarding issues discussed

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<sup>1</sup> “Report on Prescription Drug Importation,” HHS Task Force on Drug Importation, U.S. Department of Health & Human Services, December, 2004.

in the first report as well as new findings. Research conducted since the issuance of the Interim Report reinforces safety concerns, and the volume of evidence supporting a position against importation of medicines from foreign sources continues to mount.

***More About Internet Pharmacies***

The information learned during this review strongly indicates that the purchase of prescription drugs over the Internet can be fraught with risk. That is not to say that all Internet pharmacies are bad; some are legitimate. Unless consumers have the ability to verify that they are dealing with a legitimate pharmacy that dispenses FDA-approved medicines, they are potentially putting themselves in harm's way. The facts are overwhelming; for example, although there are some pharmacies that have a sound Internet business, there are hundreds of "rogue" or very questionable Internet sites that are not what they purport to be. Internet sites claiming to be based in Canada may actually be located someplace else. One news report cited an example involving the drug Accutane, which is used to treat acne and requires careful doctor monitoring. It was ordered over the Internet without a prescription; it was shipped from Pakistan, the instructions were in Greek and the foil blister pack was broken on arrival. Other examples from the FDA set forth below (see page 17) further illustrate this point.

In addition, Internet pharmacies may utilize questionable business practices. In evaluating eight different Canadian pharmacies being evaluated for participation in the Minnesota Governor's prescription drug website, the Minnesota Board of Pharmacy prepared a report which noted that four of the eight pharmacies visited did not provide "acceptable pharmacy services." (It should be noted that none of these pharmacies was selected to participate in the Governor's program.) The report also included a number of observations indicating that safety standards among the pharmacies were not uniform and that quality control appeared to be an issue for several of the pharmacies. If what has been learned to date regarding personal importation using the Internet is any indication of what is to come if commercial importation is authorized, then this nation's medicine supply could be subject to compromise.

The following highlights additional findings regarding the Internet sale of prescription drugs.

- State programs facilitating the importation of drugs from Canada have not been without incident. In Wisconsin, a state-sponsored website facilitates the purchase of drugs from three mail order pharmacies in Canada. A report issued in August 2004 by the Pharmacy Society of Wisconsin noted that analyses of reports provided to the state from the Canadian pharmacies indicated that some of the drugs being imported did not comply with the requirements of the program. For example, some were improperly shipped (e.g., no refrigeration) and others were unapproved generics. One news report quoted the executive director of the

Society as saying that “almost a third of the drugs the Canadian pharmacies have dispensed were not (FDA) approved...” In addition, during the summer of 2004 the FDA conducted its own review of the packages coming from the Internet pharmacies participating in the Wisconsin program. Over a five-day period, the FDA found that almost 70% of the packages sent to Wisconsin consumers contained drugs that violated the agreement between the State and the Canadian Internet pharmacies.

- During the summer of 2004, the Government Accounting Office (GAO) issued two reports concerning this issue; both were presented to the Chairman of Permanent Subcommittee on Investigations, Committee on Government Affairs, U.S. Senate.
  - The first report, issued in June and entitled “Internet Pharmacies – Some Pose Risk for Consumers,” detailed the findings from a study wherein the GAO placed orders over the Internet for a number of different drugs. It placed 90 orders for 13 distinct drugs with a mix of pharmacies, some U.S.-based sites, some Canadian-based sites and some “other foreign” sites. The GAO received 68 samples of 11 distinct drugs. Many of the problems identified were among drug samples received from the “other foreign” sites. The problems included the following: generally no prescription was required to order, many of the drugs were not properly labeled, many were not properly packaged or shipped, many were non-FDA approved drugs and two samples were counterfeit, having a lesser amount of the required active ingredient, and two samples had “significantly different chemical compositions” than the products ordered. Further, 16 of the 18 samples from the Canadian pharmacies were unapproved for sale in the U.S. for labeling and packaging reasons. This report suggests that as more and more Canadian Internet pharmacies seek to move their operations to Europe or other foreign countries and/or fill their prescriptions with drugs from foreign sources, the risks of receiving non-FDA approved or counterfeit drugs increases.
  - The second report, issued in July 2004 and entitled “Prescription Drugs – Preliminary Observations on Efforts to Enforce the Prohibitions on Personal Importation,” identified problems encountered by the FDA, Customs and Border Protection and other federal agencies in monitoring the purchase of drugs over the Internet and shipped through the mail. The report acknowledges that the volume of non-FDA approved drugs coming into the U.S. is very large and increasing, that the authorities do not have the requisite resources to inspect a significant number of shipments coming into the country and that the ability to inspect the packages is hindered by the cumbersome processing requirements. As a result, tens of

thousands of shipments have been delivered to consumers even though they may contain drugs that pose health risks. This report also discussed the results of an analysis done by a Customs and Border Protection (CBP) laboratory in which 180 drugs coming through the mail were intercepted by CBP and the FDA. Of these, 5% of the drugs contained no active ingredient, 28% contained controlled substances that were prohibited for import and 68% were non-FDA approved.

- The FDA continued in its efforts to identify risks associated with the purchase of drugs over the Internet. In July 2004 the FDA, in a news release, delivered the results of analyses it had performed on “Canadian generic” versions of Viagra, Lipitor and Ambien that had been purchased from a website (since none of the drugs has a U.S. approved generic, all were unapproved). One, Ambien, was “super-potent,” containing too much active ingredient, another, the “generic” Lipitor, was sub-potent, containing on average only 57% of the active ingredient stated on the label and the last, the “generic” Viagra, contained too little of the active ingredient and had an unacceptable level of impurities. Additionally, at a Senate hearing in July 2004, the FDA cited three examples that are illustrative of the point that a consumer cannot be assured of the veracity of the statements contained on the websites from which purchases are being made (the FDA had conducted a survey of Internet sites that appeared to be Canadian and analyzed a random sample of 106 sites): one Internet site advertised as being located in British Columbia, but the registrant was actually in the Czech Republic; another said it was located in Winnipeg, but the registrant was in Ho Chi Minh City, Viet Nam; and yet another purporting to be located in Canada, was registered in China, the drug ordered came in a package with a Dallas postmark and a Miami return address, the credit card was billed to St. Kitts and the phone number was in Belize.
- In testimony before the Senate Committee on Governmental Affairs on July 22, 2004, DEA Administrator Karen Tandy stated that “rogue Internet pharmacies pose a significant threat to lives and health across the country” and that in an “import blitz” conducted at international mail facilities by a task force comprised of several federal agencies, of 325 packages sampled, 132 contained controlled substances that had illegally arrived from Spain, India, the Netherlands, Belgium, Romania, Slovenia, Mexico, Argentina, and Brazil.
- The U.S. Department of Justice recently issued a press release regarding the conviction and sentencing of a California man for his role in operating one of the largest Internet pharmacy schemes ever prosecuted. The man operated an Internet pharmacy that did not require prescriptions in order to purchase drugs. Customers merely had to fill out a questionnaire and pay \$35 for a doctor’s consultation; however there was no doctor involved in the operation. The drugs were labeled

as “generic” even though some had no approved generic equivalent and contained active ingredients for Viagra, Cialis, Levitra and other drugs. It was reported that the drugs were manufactured in Mexico and contained ingredients that were shipped from China and India. As part of this press release, Michael Garcia, Assistant Secretary for U.S. Immigration and Customs Enforcement of the Department of Homeland Security, stated “The reality is, the quality and content of drugs sold over the Internet is a big question mark.” In the same press release, another federal law enforcement official commented “illegal pharmaceutical distribution is a growing problem...”

- An article in the [Sarasota Herald-Tribune](#) recently reported that a mail order pharmacy, Canada Pharmacy Direct Inc., operating in that city was sending authorization forms to its customers seeking their approval to import drugs from Europe, New Zealand, and Australia. The same article recounted a story of a man who had ordered an anti-depressant from Canada that was shipped from Vanuatu, an island in the South Pacific. Reportedly, the box’s label also mentioned both Australia and New Zealand. The medicine was ordered through a business in New Jersey.
- As was indicated by the information learned by the FDA, many of the websites claiming to be Canadian Internet pharmacies contain false or misleading information and may be conducting their operations using questionable business practices. Giuliani Partners learned from one independent review of a number of websites that claimed to be Canadian pharmacies that several were not what they claimed to be. Six websites in the Ontario region were randomly selected and the registered business addresses were visited. Surprisingly, each location turned out to be a private residence, one of which appeared to be a “call center” or location used solely for taking orders, given the equipment that was present within and around the residence. It remains unclear where the actual business was being conducted and where the drugs were coming from to fill the orders being placed.

It bears repeating, given all of the issues that were identified in the Interim Report and the information presented in this document regarding the purchase of prescription drugs over the Internet, significant safety concerns are evident. Consumers should be made more aware of the risks they are undertaking when they go online to make such purchases. As was stated in the HHS Task Force report: “Safety should not be sacrificed for affordability.”

### ***More About Counterfeits***

As was noted in the Interim Report, counterfeit drugs continue to be found within the United States medicine supply as well as in other foreign countries. A [U.S. News and World Report](#) article on this subject stated that the drug market “safety net is increasingly

full of holes.” Before any expansion of our drug distribution system is seriously contemplated, more should be done to identify such products and tighten the country’s supply chain in order to prevent counterfeits from reaching pharmacy shelves. The following highlights additional information regarding counterfeit drugs.

- Notable cases of counterfeit drugs continue to compromise America’s drug distribution system. Most recently, in an FDA Talk Paper issued in July 2004, the agency warned the public about counterfeit versions of the drugs Zocor (simvastatin) that contained no active ingredient and Carisoprodol, which had a different potency from the authentic version, being imported from Mexico by some Americans. Another case involved counterfeit Viagra that was found in two pharmacies in California in June 2004. The bad product was originally discovered by a patient, who notified Pfizer after becoming suspicious of the packaging. The second incident was discovered by a pharmacist who was alerted to the first case.
- For the first time in many years, England reported the discovery of several cases of counterfeit medicines. In late August 2004 the United Kingdom Medicines and Healthcare Products Regulatory Agency (MHPA) issued a warning about counterfeit Cialis, which had been found in circulation; one week later, the MHPA issued another drug alert and recall of an obesity drug, Redistill. In addition, a University of London study that analyzed samples of Viagra sold on the Internet and estimated that around half of the Viagra sold on the Internet could be counterfeit. As will be discussed later, this becomes important because many of the Canadian Internet pharmacies have publicly stated that they are sourcing some of their supply from England and other foreign countries.
- A news article reported that two Florida men recently plead guilty to federal conspiracy charges for admittedly running a large Internet pharmacy that sold counterfeit Viagra made by a San Diego based operation. It was reported that at least some of the pills were being manufactured in India.

### ***More About Canada***

Recent events concerning the implications of the “cross border drug trade” on Canada’s medicine supply have received a great deal of media attention in the last few months. For the first time since mail order pharmacies began selling drugs to Americans from Canada, the Canadian government is publicly expressing its concerns about the impact of this business on the Canadian drug supply. Additionally, the Canadian government is considering taking steps to protect its supply. Given the apparent reluctance on the part of the Canadian government to continue to support this business, the importation of prescription drugs from Canada may not remain a viable option for those seeking to open the borders of the United States to drugs from that country.

Canada does not have the medicine supply or the infrastructure in its current pharmaceutical drug distribution system to supply the United States with its prescription medicine needs. This fact coupled with the information set forth below leads to the more obvious conclusion that the United States should address the issues associated with the access to safe and affordable medicines within its own borders. The following is a summary of the more significant recent events in Canada:

- The Canadian Minister of Health stated in a speech given at the Harvard Medical School on November 10, 2004 that "...Canada cannot be the drugstore of the United States." He also stated that it was difficult for him to appreciate how a small country like Canada could satisfy the prescription drug needs of America without putting the Canadian supply "at serious risk." Such statements were a marked departure for the Canadian government. Prior to this, the government had been relatively silent on the issue, stating that it was monitoring the situation. These statements were also unusual because in Canada, healthcare is a provincial responsibility and the federal government does not typically get involved in provincial affairs.
- As a follow-up to his remarks at Harvard, the Canadian Minister of Health has indicated that he and the Canadian government are considering proposals to make it illegal for pharmacists to fill prescriptions for patients who have not been seen in person by a Canadian doctor; to prevent filling of prescriptions for foreigners who are not in Canada and to ban certain drugs from being exported.
- The Canadian Pharmacists Association released the findings of a study entitled "Administrative Burden on Canadian Pharmacists Due to Drug Shortages" in November 2004. Of the 218 community pharmacists that responded to the survey, 80% indicated that they had difficulty filling prescriptions and that drug shortages had become more frequent during the preceding 12 months. While the study acknowledged that there may be a number of variables causing a drug shortage, the cross border drug trade was identified as a possible factor.
- Canadian doctors are being penalized for inappropriately signing prescriptions for U.S. patients. One doctor from Surrey, British Columbia was suspended by the British Columbia College of Physicians and Surgeons for two years after admitting that he signed thousands of prescriptions for U.S. patients without first seeing them. Although it is not illegal for doctors to sign prescriptions for patients they have not personally examined, it is reported that most of Canada's 10 provinces and two territories have adopted professional standards, through the appropriate regulatory bodies, precluding such activity. Another doctor from Toronto who also co-signed thousands of prescriptions for an Internet pharmacy without first seeing the patients was recently found guilty of professional misconduct by the College of Physicians and Surgeons of Ontario.

- Most significantly, Canadian Internet pharmacies have publicly stated that they are moving their business to Europe; Examples include:
  - Internet pharmacist Darren Jorgenson, founder and chairman of canadameds.com said he “is dispensing drugs to Americans from almost 30 different countries including England, Malta, Australia, New Zealand, and Chile. It doesn’t matter to Americans.” In a more recent news article, Mr. Jorgenson stated that 50% of the prescriptions being filled by his pharmacy were coming from international pharmacies, primarily in Israel, Britain, Ireland and Germany. He also said they were ready to fill all of their prescriptions in this manner if the changes are made to the Canadian law. In fact, his website states “Not just from Canada anymore! Choose your country and your savings.”
  - Another mail order pharmacy, TheCanadaPharmacy.com, was offering drugs from British pharmacies as early as last spring and was looking to add inventory from Australia, New Zealand, Israel and Chile. Similarly, news reports state that Mediplan Health Consulting Inc. of Manitoba is filling prescriptions with drugs from the British Commonwealth.
  - Another Canadian pharmacy, CanadaRX, has set up a distribution warehouse in Freeport in the Bahamas. It is reported that it was established to buy prescription drugs from European wholesalers for sale to Americans. A Boston Globe reporter who visited the operation noted that the shipping methods being used “are designed to evade detection by the US authorities.” It was also reported that the drugs being shipped to Americans contained labels that were in French, Spanish and Italian.
  - Interestingly, although Ireland has been mentioned as one source of supply, one news report noted that the Irish Medical Board has indicated that it was not aware of any pharmacies that are participating in such a program and to do so without the proper licenses would be illegal; in fact the mail order of prescription products is illegal in Ireland. Some news reports indicated, however, that drugs may be lawfully shipped to other countries in Europe and then sourced to Americans who are making purchases over the Internet through Canada.

***More About the Potential Exploitation by Organized Criminals, Drug Traffickers and Terrorists***

As noted in the Interim Report, given the vulnerabilities that are present in the existing system, the potential exists for the nation's medicine supply to be exploited by organized criminals or drug traffickers or to be used as a vehicle for terrorist activity. Those shortcomings identified in the drug manufacture and distribution system must be realistically assessed, as does the fact that these systems are vulnerable to exploitation by terrorists as well as other criminal groups.

Terrorist groups, organized criminals and drug traffickers have already infiltrated the high-profit, low-risk counterfeit goods market to finance their operations. Recent articles in Business Week and Harper's Bazaar highlighted the links between counterfeit goods and terrorists and other crime groups. Unfortunately, the current prescription drug market poses few challenges for organizations that seek to develop counterfeit drugs or to divert legitimate product. There is considerable money to be made in the prescription drug business (in 2002, the U.S. spent more than \$162 billion on prescription drugs), the risk of getting caught is minimal, and even if caught, the penalties are low.

Further review has only enhanced the belief that the system is vulnerable to exploitation. Since the issuance of the Interim Report, the following information or activities have occurred or been discovered.

- In testimony before the United States House Committee on International Relations, Interpol Secretary Ronald K. Noble stated that the "the link between organized crime groups and counterfeit goods is well established" and that "intellectual property crime is becoming the preferred method of funding for a number of terrorist groups." Noble also said, "There are enough examples now of the funding of terrorist groups in this way for us to worry about the threat to public safety." He went on to say, "Law enforcement agencies have to recognize that Intellectual Property Crime is not a victimless crime. Because of the growing evidence that terrorist groups sometimes fund their activities using the proceeds, it must be seen as a very serious crime with important implications for public safety and security." Noble characterized the links between intellectual property crime and terrorist financing as either having "direct involvement" – the terrorist group is involved directly in the manufacture, distribution and/or sale of the counterfeit goods and use the proceeds to fund its activities - or "indirect involvement" – sympathizers are involved in the counterfeiting activities and channel funding to the terrorists groups to fund activities.

News reports stated that Interpol documents presented to the U.S. House of Representatives Committee on International Relations indicated that a wide range of groups – including Al-Qaeda - benefit from funds raised by sympathizers.

The examples included: Al-Qaeda (counterfeit shampoos, creams, colognes and perfumes); Hezbollah (Interpol was aware of three cases involving intellectual property crime and terrorist funding in South America); Chechen separatists (counterfeit CDs); ethnic Albanian extremists in Kosovo (consumer goods such as CDs, DVDs, clothes, shoes, and computer software); paramilitaries in Northern Ireland (counterfeit cigarette trafficking); and North African radical fundamentalist terrorists in Europe. Each of these groups has been found to profit from the production or sale of counterfeit goods. Reports indicate that counterfeit products include pirated CDs and DVDs, clothing, computer software, cigarettes and pharmaceuticals. Mr. Noble also concluded that intellectual property crime is a low risk – high return activity due to the low penalties if caught and the high return in relation to the initial investment.

- The acting head of the Food and Drug Administration, in August 2004, stated in an interview that he was very concerned about terrorists tampering with the prescription drug supply of the United States, referring specifically to illegally imported drugs. At that time, however, a spokesman from the Department of Homeland Security indicated that although it is aware that Al Qaeda and other terrorist groups have studied agro terrorism, DHS had not received any specific information regarding a threat to the nation's food or drug supply.
- In testimony before the U.S. Senate Committee on Banking, Housing and Urban Affairs during a hearing on Terrorist Financing, Michael J. Garcia, Assistant Secretary, U.S. Immigration and Customs Enforcement (ICE), Department of Homeland Security, stated, in the context of discussing actions being taken by ICE to address terrorist financing, that ICE targets “methods that terrorist and other criminal organizations could use to earn funds through investigations of intellectual property rights violations, counterfeit pharmaceuticals, human smuggling, commercial fraud, export violations, and cybercrime.”
- The Alliance Against Counterfeiting and Piracy, based out of the United Kingdom and comprised of members and organizations interested in combating intellectual property crime, issued a report entitled “Proving the Connection – Links Between Intellectual Property Theft and Organised Crime.” The report states that there is strong evidence that “...organised crime [is] controlling, exploiting and benefiting from intellectual property fraud.” It includes several examples to support the conclusion and cites to the UK's National Criminal Intelligence Service 2002 UK Threat Assessment which states “[m]any serious and organized criminals are involved, either in the manufacture of counterfeit products, or in their distribution, attracted by their high profits and low risk of detection, and no doubt conscious of the fact that the penalties for intellectual property crime offences are rarely more than minimal.” The report also cites the Organised Crime Task Force in Northern Ireland and its Threat Assessment 2002 which reported that given the scale of

intellectual property theft in Northern Ireland (the Police Service of Northern Ireland seized counterfeit goods worth 6.7 million pounds in 2002) and the nature of criminality in that country, “it is inconceivable that terrorist organisations are not directly complicit.” The Alliance report states that this Threat Assessment states that 34% of the organised crime groups in Northern Ireland were involved in product counterfeiting.

- The International Anti-counterfeiting Coalition, in a publication “Facts on Fakes” noted that the “[l]ow risk of prosecution and enormous profit potential have made criminal counterfeiting an attractive enterprise for organized crime groups.” In addition, it cited a number of examples of cases which draw connections between organized crime and terrorist groups and counterfeiting, indicating that such groups use the sale of counterfeit goods to raise and launder money. Some of those examples involve counterfeit cigarettes, CDs as well as other commercial goods. A few are discussed below:
  - One BBC article discusses an investigation conducted by an Italian financial newspaper which reported that connections were found between a large shipment of counterfeit goods and the terrorist group, Al Qaeda. The shipment contained approximately 8 tons of counterfeit shampoo, face creams, Vaseline, cologne and perfume. It was being transported from Dubai to Britain through Denmark and was seized in Copenhagen. The European Commission Customs Coordination Office confirmed that the man who had dispatched the goods had links to Bin Laden’s group. In addition, a UN monitoring group indicated that Al Qaeda does in fact keep part of its funds in banks in Dubai.
  - An October 2002 Associated Press article reported that “U.S. authorities have several investigations under way examining evidence suggesting that Hezbollah, Hamas and other terror networks might be selling counterfeit products to pay for their worldwide activities. Terrorists are benefiting from counterfeit merchandise schemes...” quoted a U.S. government advisory. That same report noted that counterfeit operations in South America, near the tri-border region (Paraguay, Brazil and Argentina), may have been used to raise money to support terrorist operations and groups. It was reported as part of the AP story that counterfeit CDs were being sold to raise money for Hezbollah.

In the fall of 2004, a book, [A Sick Business – Counterfeit Medicines and Organized Crime](#) written by Graham Satchwell, a former detective Superintendent from the United Kingdom, was released. It documents an investigation he conducted for the Stockholm Network into the links between counterfeit medicines and organized crime and terrorism. He identifies a number of cases

that show a clear link between counterfeit medicines and organized crime and terrorism. Mr. Satchwell also identifies a number of issues with the current prescription drug market in the United Kingdom and Europe. For example, the book discusses parallel trade in the United Kingdom and Europe and mentions some of the risks associated with the practice. Mr. Satchwell notes that parallel trading of prescription medicines as it currently exists and the repackaging that is often necessary allows for the introduction of counterfeit goods, creates the potential for errors in translation as the drugs are traded among various countries. Also, given the process, i.e., multiple handling, the “sell by” dates could expire before reaching the consumer. He concludes that the more pharmaceuticals that are parallel traded the greater the risk of the introduction of counterfeits and that there is not sufficient attention being paid to this issue in the United Kingdom or Europe.

Along the same line, the President’s budget provides for increases in funding related to bioterrorism and this month, Interpol hosted its first global conference on preventing bioterrorism. Furthermore, the Director of the Federal Bureau of Investigation, Robert S. Mueller III, stated in his testimony before the United States Senate Committee on Intelligence, when discussing the FBI’s current views regarding threats against the United States and how the organization is responding, that second among the three areas of greatest concern to the FBI is the “growing body of sensitive reporting that continues to show Al Qa’ida’s clear intention to obtain and ultimately use some form of chemical, biological, radiological, nuclear or high-energy explosives (CBRNE) material in its attacks against America.” And finally, a recent editorial in The New York Times regarding “Our Necessary Insecurity” noted, “the anthrax attacks of the fall of 2001 only began to suggest the devastating power of biological weapons. While officials are all too aware of the mortality rate that would follow an attack with weapons grade anthrax, smallpox or the plague, controls are still spotty. Lethal pathogens are too often stored in insecure laboratories.”

The President’s budget also proposes cuts to many of the FDA’s inspection programs, including a 5.8% cut in foreign drug plant inspections. It seems contradictory to open the borders in a way that will make the nation’s medicine supply less safe while at the same time devoting resources to protecting our borders from other threats.

While government officials continue to look for ways to secure American borders, on a daily basis tens of thousands of mail parcels and courier packages containing shipments of suspected prescription drugs ordered from the Internet go unchecked through the approximately 355 “ports of entry” into the United States. They are not inspected for a few reasons. For example, some of those operating Internet pharmacies have devised methods to conceal the contents of what is being shipped, and given the volume, those responsible for monitoring these imports simply do not have the resources to inspect even a fraction of the parcels in a meaningful way. Consequently, the drugs

being imported could be safe, but also they could be adulterated, unapproved, or counterfeit. Another fact to consider is the areas of the world that demonstrate an increase in the level of activity as it relates to counterfeit prescription drugs: China, Eastern Europe, South America, and certain parts of Asia, for example, Pakistan and India. In these areas intellectual property rights are compromised, counterfeiting is rife and terrorists and other crime groups often work together in furtherance of their respective goals. History has shown that terrorist groups often infiltrate an existing business network in order to finance their operations. It is not difficult to imagine that the Internet drug trade could be one such vehicle to either finance their operations or use as a method of attack.

Since we already know, for example, that the former Soviet Union devoted great effort to developing a ballistic delivery system for pathogens and that terrorists are capable of identifying weaknesses, like those that resulted in the September 11<sup>th</sup> attacks, it is not far-fetched to imagine terrorists deploying the easy flow of corrupted medicines. It is critical that existing issues with respect to the drug distribution system be addressed and that similar to the steps that are being taken to protect this nation's borders, steps should be undertaken to protect the nation's medicine supply.

### ***Reports Show Questionable Economic Benefit From Importation***

Although the economic implications relative to importation were not the primary focus of this review, it is difficult to discuss importation without addressing the cost of prescription medicines in some form or manner. Most would agree that the reason so many Americans, whether elected representatives or consumers, are turning to importation as the solution to the problem of the cost of prescription medicines in the United States is that due to price controls certain drugs are cheaper in Canada and other countries. On a case-by-case basis, that may be true. However, a number of studies indicate that the adoption of a system that resembles parallel trade and/or price controls, programs that, to simplify, are functionally equivalent to commercial importation, would not necessarily produce savings for patients similar to those being enjoyed by individuals importing prescription medicines independently. On the contrary, some studies found that patients would experience little to no savings. Instead, for example, the potential savings may go to the "middlemen," i.e., those involved in the distribution of the drugs, or to other third parties.

In addition, it has been reported that since it is likely that commercial importation would result in revenue losses for pharmaceutical companies, there would be a resulting negative impact on research and development in the long term. Fewer new and innovative medicines would be developed to treat existing and future ailments. And as stated in the HHS report, this would result in "reducing benefits to future drug consumers and adversely affecting public health." Finally, studies have found that commercial importation could also have a potentially negative impact on local economies. Reduced

investments in research and development could have an effect on how the pharmaceutical and biotechnology industries currently run their operations and could translate into lost jobs, and losses in personal income and tax revenues.

The following summarizes, in a very general way, the findings of some of these studies or reports. This discussion is not intended to be detailed or exhaustive since the pricing of prescription medicines in this country and around the world is a complicated issue, but it is intended to demonstrate a point: even though many of those who support a commercial importation program state that such a program will generate significant cost savings for consumers, the studies reviewed do not support this contention.

- Savings to consumers would be only one to two percent of their total drug spending, with most of the benefits going instead to third party purchasers like insurance companies and HMOs.<sup>2</sup>
- Patients receive little to no savings from parallel trade; parallel traders take in more of the profits as compared to others involved in the business; orders for prescription medicines from the manufacturers decline appreciably in destination countries; and source countries can experience product shortages.<sup>3</sup>
- Importation of prescription medicines from foreign sources could reduce incentives to invest in research and development (one study found a reduction in R&D spending by as much as 25% to 30%), thereby causing a reduction in the future supply of new drugs.<sup>4</sup>
- Price controls reduce revenues for drug companies, thereby discouraging investments in research and development, reducing the number of new medicines, and, in turn, impacting the health and longevity of Americans.<sup>5</sup>

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<sup>2</sup> “Report on Prescription Drug Importation.” Department of Health and Human Services. December 2004 and “Would Prescription Drug Importation Reduce US Drug Spending?” The Congressional Budget Office. April 29, 2004.

<sup>3</sup> Panos Kanavos, PhD., Joab Costa-i-Font, PhD., Sherry Merkur, PhD., and Marin Gemmill, MA. “The Economic Impact of Parallel Trade in European Member States: A Stakeholder Analysis.” The London School of Economics. January 2004.

<sup>4</sup> John A. Vernon, Ph.D. testimony before the US Senate Committee on Health, Education, Labor and Pensions hearing on “Importation of Prescription Drugs.” May 20, 2004 and “Pharmaceutical Price Controls in OECD Countries – Implications for US Consumers, Pricing, Research and Development, and Innovation.” The US Department of Commerce International Trade Administration. December 2004.

<sup>5</sup> John A. Vernon, Rexford E. Santerre, and Carmelo Giacotto “Are Price Controls Good for your Health?” The Manhattan Institute. December 2004 and Jacob Arfwedson. “Reimportation (Parallel Trade) in Pharmaceuticals” The Institute for Policy Innovation. July 15, 2004.

- Importation would result in a significant reduction (estimated to be a drop of \$14.8 billion in the first 12 years after implementation) in pharmaceutical and biotechnology research and development leading to a decrease in the number of new drugs approved on an annual basis (an estimated 70% reduction in the first 12 years). A specific look at the impact on the state of Massachusetts, where an estimated 10% of the nation's pharmaceutical and biotechnology research dollars are spent, finds a loss of more than 3,900 jobs and a drop in economic activity worth \$247 million by 2010. Similar findings were reported in a study that focused on the implications of such a program in Michigan.<sup>6</sup>
- Per capita spending on pharmaceuticals in Europe is 60% less than in the U.S. These savings, however, are not without consequence as the pharmaceutical research industry has shifted from Europe to the U.S. Similar research investments were made in the U.S. (\$9 billion) as in Europe (\$10 billion) in 1992. By 2002, however, the U.S. had outstripped Europe as the recipient of investment dollars (\$26 billion as opposed to \$21 billion in Europe). Drug launches followed a similar trend: Europe launched 81 new products between 1993 and 1997, while the U.S. launched 48. From 1998 to 2000, Europe launched 44, while the U.S. launched 85.<sup>7</sup>

Setting aside the safety issues for a moment, it remains unclear that a commercial importation program will yield the anticipated benefits; however, it may have a number of significant consequences. Those findings regarding the legalization of an importation or price control program include: that consumers may not necessarily realize a meaningful cost savings in the long run; that it will have a negative impact on the revenues of the pharmaceutical companies; that as a result, there will be reduced incentive to invest in research and development; that in turn, there will be fewer drugs on the market; and with fewer new and innovative drugs on the market, the health and longevity of Americans will be negatively affected. Further, reduced investments in research and development may result in lost jobs and income. Given that importation might curtail the research and development of future medicines over the long term, yielding significant societal and monetary costs, the short term savings that may be realized from importation, if any, should be carefully weighed against the long term costs.

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<sup>6</sup> David G. Tuerck, John Barrett, Douglas Giuffre, and Zaur Rzakhanov. "The Impact of Drug Reimportation and Price Controls: The US and Massachusetts." The Institute for Policy Innovation. September 9, 2004 and Dr. Dean G. Smith, "Prescription Drug Importation, Investment and Employment in Michigan." Department of Health Management & Policy. The University of Michigan. August 18, 2004.

<sup>7</sup> Jim Gilbert and Paul Rosenberg, Bain & Company, Inc. "Addressing the Innovation Divide." World Economic Forum. Davos, Switzerland. January 22, 2004

## **RECOMMENDATIONS**

Based upon the findings, a number of steps should be considered in order to ensure that every possible effort is made to adequately protect this nation's medicine supply. The questions and issues related to the safety of imported medicines are real and should not be dismissed. Accordingly, the following recommendations are offered:

- The safety of this nation's medicine supply cannot be assured without investing significant resources into an already overburdened system. Thus, the vulnerabilities that exist in the current system should be addressed. The FDA, Customs and Border Protection and other regulatory entities should be provided with the authority and the resources necessary to ensure that the "gold standard" is not compromised further. For example:
  - An effective pedigree requirement should be implemented – a system needs to be implemented that provides for the documentation and verification of each transaction involving the sale, transportation, exchange and/or distribution of prescription medicines from point of manufacture to point of sale. In the absence of the federal system, states may also wish to consider passing laws requiring such pedigrees. See, for example, Florida's law, which includes a paper pedigree system and/or the California law, which requires electronic pedigrees for dangerous drugs by 2007. Additionally, every effort should be made to develop and implement system-wide RFID or other electronic "track and trace" technologies, such as the program being used by Purdue Pharma L.P. and Wal-Mart.
  - The "secondary wholesale" market as well as repackaging operations should be reviewed and consideration should be given to strengthening federal requirements for wholesalers and distributors.
  - Consideration should be given to improved enforcement efforts and enhancing or increasing the penalties for counterfeiting or otherwise tampering with the nation's medicine supply.
  - Consideration should be given to developing and implementing uniform standards for the operation of Internet pharmacies – such as the program developed by the National Association of Boards of Pharmacy VIPPS (Verified Internet Pharmacy Practice Sites) Program.
- Given the critical role that medicines play in the overall health care of the people of this country, a threat and vulnerability assessment of the nation's medicine supply should be conducted by the Department of Homeland Security. In

February 2003 The National Strategy for The Protection of Critical Infrastructures and Key Assets was released by the President. The document identified a number of America's critical infrastructures and key assets and outlined guiding principles for protecting those entities from terrorist attack. Public Health was identified among the critical infrastructure sectors that had "major protection initiatives" identified. It did not appear from the discussion of the challenges and initiatives set forth in the report that particular consideration was given to the safety and security of the nation's medicine supply. This assessment should be conducted in concert with other relevant agencies and should be undertaken as quickly as possible.

- At the same time as efforts are underway to address the safety issues associated with the current system, doctors, healthcare professionals and consumers need to be better educated regarding the options that are available to access cheaper medicines, such as drug discount cards or other patient assistance programs. Examples include:
  - The Medicare Discount Card – This is authorized by the Medicare Prescription Drug Improvement and Modernization Act of 2003 and is designed to give immediate relief to Medicare-eligible seniors and disabled persons.
  - Discount Programs Operated by States, Municipalities and Pharmaceutical Companies – Approximately 49 states, Washington D.C. and many municipalities have programs that guide individuals to lower cost prescription drugs that do not involve importation. In addition, there are a number of industry sponsored websites that assist patients or health care providers with locating cheaper medicines. Examples include:
    - § HelpingPatients.org is an interactive website that helps to direct patients to patient assistance programs that would be most helpful to them. It is a comprehensive, one stop link to thousands of medicines offered through hundreds of patient assistance programs sponsored by pharmaceutical companies, governments, and local organizations.
    - § TogetherRX Access Plan – offers discounts of 25% to 40% on 275 products for people younger than 65 who do not have prescription insurance or Medicare and meet certain income limits.

- § Comparison Shopping Programs – Several states and organizations have programs that offer price comparisons on prescription drugs and that may assist patients locate the lowest cost prescription medicine in a geographically convenient location.
- § Greater consideration should be given to use of generic alternatives.
- There is a need to develop a system to assess whether, and the extent to which, people are being harmed as a result of importing drugs from foreign sources. Currently, there is no formal mechanism in place to adequately quantify the problem. Thus, an effort should be undertaken by the healthcare and medical profession to attempt to identify the scope of the problem. For example, consideration should be given to modifying emergency room, medical examiner and doctor protocols urging that the following questions be asked. Where are the prescription medicines being purchased and are they available for testing. Included within this assessment should be an effort, as difficult as it might be, to determine whether a disease has progressed because the product was ineffective. In addition, consideration should be given to modifying the FDA’s “MedWatch” system, which tracks adverse events involving FDA-approved products, in order to capture additional information related to this issue.
- Consumers must be made more aware of the risks associated with importing medicines from foreign sources. Not only is there a risk from the compromised quality of the product they may be receiving, but also there may be serious health implications if their doctors and/or pharmacists are not aware of all of the medicines they are taking. In addition, because current legislative proposals extend beyond Canada, for example, proposing importation from 25 or more countries, a study should be undertaken, similar to that which was conducted by the HHS Task Force regarding Canada, to assess the feasibility and the risks associated with such a program. Patient safety requires no less.
- Access to safe, effective and affordable medicines is a significant issue for many Americans, particularly the uninsured and the underinsured, and it should be addressed; but importation is not the answer. In order to reduce reliance on importation and create greater access at more affordable prices, there needs to be a candid discussion among the pharmaceutical companies, the health care industry, governments and trade organizations, consumer groups and other interested parties regarding the cost and accessibility of prescription medicines in the United States and abroad.

This report is not the first to include recommendations to address the issues raised regarding the vulnerabilities in the existing system, the issues associated with counterfeit goods worldwide or the risks associated with importing drugs from foreign sources. For example, the FDA's Counterfeit Drug Task Force issued a report last year entitled "Combating Counterfeit Drugs: A Report of the Food and Drug Administration" which contained several recommendations worthy of consideration; a Florida Grand Jury convened to study the safety of prescription drugs in Florida issued a report containing a number of recommendations related to improving the drug distribution system in that state as well as around the country; and although not specific to pharmaceuticals, the World Customs Organization and Interpol have been working on a series of proposals to combat counterfeiting worldwide. Each merits further consideration and attention.

## **CONCLUSION**

The review completed by Giuliani Partners identified a number of serious risks associated with the importation of non-FDA approved medicines from foreign sources. The evidence is overwhelming. The information and findings clearly demonstrate that this country should not establish a commercial importation system. It would compromise patient safety and expose the nation's medicine supply to exploitation by organized criminals and terrorists. All Americans deserve access to safe, effective and affordable prescription medicines. But it became very clear during this review that safety and effectiveness cannot be assured through an importation program.

Careful consideration should be given to the following:

- The weaknesses in the existing system are well documented. Not only this report but the HHS Task Force and others have identified a number of problems that must be addressed to maintain the "gold standard."
- Incidents involving counterfeit drugs are on the rise and the World Health Organization estimates that as much as 10% of the world's medicine supply is counterfeit. By expanding the sources for drugs, it will be harder to ensure authenticity and chain of custody. The risk to patient/consumers of receiving some of that counterfeit product increases proportionally.
- The Internet mail-order pharmacy business has exposed a number of safety concerns, from the quality and source of the product being ordered to the difficulties associated with oversight.
- The Canadian government has expressed concerns about the impact of the cross border drug trade on its supply and has stated that Canada cannot serve as America's drugstore. Further, more and more Canadian Internet pharmacies have publicly stated that they are filling orders with drugs from other countries.

Patients cannot assume that the drugs they receive are identical to what they would get in the United States.

- We must learn from experience regarding the actions of organized criminals, drug traffickers and terrorists. Such groups have already infiltrated the high-profit, low-risk counterfeit goods market to finance their operations. Given the shortcomings identified in the existing drug manufacture and distribution system, it could be vulnerable to exploitation by terrorists and other criminal groups.
- Saying that a commercial importation program is safe does not make it so. Many of the safety features being discussed in the context of pending importation legislation are not necessarily reliable:
  - There currently exists no national pedigree system, notwithstanding the fact that the law has been in place for more than 15 years. Meaningful ways to “track and trace” medicines electronically, while being used successfully in a few places in the system, are still a few years away from system wide implementation (estimates range from 18 months to several years).
  - Existing anti-counterfeiting technology is a delaying tactic at best, since advances in technologies enable counterfeiters to produce better copies of products and packaging in a more timely fashion.
  - It is estimated that the FDA resources required to implement a safe system will cost billions. Even if the resources were available, it is questioned whether the FDA would have the necessary authority to perform the required inspections in other countries. We cannot and should not rely on other countries to perform these tasks for us. As was stated in the HHS Task Force Report and by Canada as well, foreign governments are primarily concerned with the safety and effectiveness of the drugs sold to their own citizens, not necessarily those that are being exported to other countries.
- Furthermore, studies find that the primary reason for importing medicines from foreign sources - saving consumers money on the cost of their prescription medicines – may not necessarily be achieved in the long run.

Based upon what has been learned during this review, importation from foreign sources is likely to result in increased risk, including increased opportunity for the introduction of counterfeit and other sub-standard medicines into the nation’s medicine supply. It is evident that the risks are too great and that there are simply too many unanswered questions and outstanding issues to contemplate such a program.

Fix the existing system. Ensure that it is not vulnerable to exploitation by terrorists and other criminal elements. Utilize existing discount programs to provide patients with the medicines they need. And relevant parties should engage in a candid discussion about the cost of prescription medicines in the U.S. and abroad. Importation of non-FDA approved prescription drugs from foreign sources is not the answer.

**Giuliani Partners LLC  
Examination and Assessment of  
Prescription Drug Importation From Foreign Sources  
To the United States**

**Interim Findings  
May 11, 2004**

**INTRODUCTION**

The availability of safe, effective and reasonably priced medications for all Americans is at the center of an important, ongoing debate regarding our health care system. As the costs of medicines have increased, so has the focus of pricing on this debate. Individuals and even local and State governments have sought alternative means to obtain necessary medicines at lower costs, and these initiatives have further narrowed the debate to the value of importing Canadian or foreign medicines into the United States.

However, the safety and efficacy of these same imported medicines has received less attention and focus and is often overshadowed or even ignored by the pricing issue. From the outset, there is little dispute that the high price of many prescription medicines becomes an impediment to access. And while the price of today's medicines exist in part to provide for the development of tomorrow's cure, patient access should be expanded by exploring methods for lowering costs for those in need.

Giuliani Partners LLC has been retained by the Pharmaceutical Research and Manufacturers of America (PhRMA) to evaluate the risks, if any, associated with the importation of Canadian and foreign medicines.

In recognition of the public health implications associated with importation, and at the request of Congress, the United States Department of Health & Human Services has convened a Task Force on Drug Importation to examine these very concerns. Acknowledging the importance of this issue to the public, the Task Force is working with great alacrity to provide its recommendations to HHS. Giuliani Partners LLC will be providing the Task Force with a more detailed report encompassing our preliminary findings and conclusions as part of our effort to inform this critical debate and to assist the Task Force in its work. For now, we have made a series of interim findings that are worth discussing today to widen the lens through which the issue of the importation of drugs is viewed, and consequently address the equally important issues of safety and risk in the Task Force's assessment.

It is important to note from the outset that there appears to be a fundamental misunderstanding about the source of the less expensive drugs at the center of this discussion. Initially, this debate was framed around “re-importation” – in other words, the importation (from Canada) of medicines manufactured under U.S. Food and Drug Administration (FDA) oversight and now available at a lower cost via Canada. Under such a system, a patient could reasonably assume that the medicine was safely and properly manufactured under FDA oversight without corruption in the supply chain. However, that is not necessarily what is occurring. Instead, U.S. patients are receiving medicines from foreign countries (albeit ordered through Canada or sources purporting to be Canadian based) that were manufactured or re-packaged without any oversight by the FDA or Health Canada (the Canadian FDA counterpart).

Indeed, several U.S. States that provide links to websites for their citizens to order “Canadian” drugs have graphic disclaimers disavowing any warranty about the product and relinquishing the state government from any legal liability with regard to the product or care from the on-line pharmacy. In some instances, the Canadian pharmacy website requires the patient to sign a waiver that denies the patient any legal recourse in the U.S. for harm caused by these imported drugs. The current U.S. regulatory process, while not perfect, protects patients seeking medicines from U.S. pharmacies. This raises an important question that must be reviewed when assessing the relative risks associated with obtaining imported medicines against the potential rewards of lower prices.

#### Product Quality: What Is In Our Medicine?

When a patient seeks to fill a particular prescription for a particular medicine, there is an assumption that the medicine is in the exact form, quality, potency and dosage as directed by the patient’s physician. Anything less constitutes a risk to that patient’s health and well-being.

Based upon our review to date, we have found that some patients who believe they are purchasing re-imported Canadian medicines are in fact receiving non-FDA approved drugs from foreign countries that are not at all what they claim to be. There is significant evidence that patients have received drugs through the Internet that are past their expiration date, are sub-potent (or, in some cases, more potent than indicated), contain the wrong dose, are contaminated or clearly counterfeited, are not properly stored or shipped (i.e. medicines that require constant refrigeration or others that must be protected from freezing) among other problems. We have found that medicines ordered over the Internet that purport to be manufactured under FDA oversight or delivered through Canadian pharmacies are in fact manufactured in countries such as Pakistan, China, Iran, Singapore and many others. The fundamental question of product quality and integrity must be at the center of this important discussion.

Set forth below is an outline of the review we have undertaken. Significant questions are raised regarding the level of safety for patients and indeed for our nation from the relaxation of importation controls. It is vital that the Task Force and others carefully and thoughtfully consider all of these legitimate concerns so that our health care system can be as safe, effective and accessible as possible.

## **SYSTEMIC ISSUES**

The American system for manufacturing, distributing and selling prescription medicines is significantly regulated and often referred to as the “gold standard.” Notwithstanding this fact, however, there are identifiable weaknesses in this process that can compromise the quality and integrity of our medicine supply.

### **The Distribution Chain**

On its face it appears that the distribution chain for prescription medicines in the United States is fairly straightforward – manufacturers sell their products to wholesalers, who in turn sell the products to retail pharmacies or stores, who in turn dispense medicines to patients with prescriptions. It is not until the system is studied in greater detail that one begins to appreciate both the complexities and the vulnerability of the distribution chain and the potential for exploitation or abuse.

Some contributing factors are as follows:

- Wholesalers or distributors are primarily regulated by the states with no uniform standards across state borders. States have a comparatively small number of investigators to monitor the licensed wholesalers; thus, given the sheer number of wholesalers, oversight is minimal.
- There are thousands of “secondary” pharmaceutical wholesalers in addition to McKesson, AmerisourceBergen and Cardinal Health (the “big three”) involved in the distribution of prescription medicines. As reported in The Washington Post, there are more than 6,500 small wholesalers nationwide.
- There is no uniform mechanism, i.e., a chain of custody or “pedigree,” to track the medicine from point of manufacture to point of sale; the FDA has not implemented the pedigree requirement that was mandated by law in 1988.
- Repackaging is a vulnerable point in the process and can provide an opportunity for counterfeit or non-FDA approved products to compromise the system.

### Report of the Florida Grand Jury

Two years ago the State of Florida convened a statewide Grand Jury to examine the safety of prescription drugs in Florida and to analyze the sale and resale of prescription drugs in the wholesale market. The report, released in February 2003, found an overwhelming need for tighter regulation and oversight of the pharmaceutical distribution industry. Many of those interviewed by Giuliani Partners indicated that the problems identified in the Florida Grand Jury Report are pervasive throughout the United States. A summary of the Grand Jury's findings follows.

- Oversight of the system is lax.
  - Minimal background checks are required for licensing wholesalers and warehouse operators were found to be uneducated amateurs, some with criminal records.
  - Corrupt wholesalers are neither investigated nor prosecuted.
  - Despite existing requirements, drugs are being distributed with either incomplete or, in many cases, non-existent pedigree papers to document the products' supply chain history.
  - Inspection of wholesaler operations by the appropriate authorities and oversight by responsible agencies is spotty at best.
- Funding for oversight agencies is inadequate.
  - The Florida Bureau of Statewide Pharmacy Services employs only nine field inspectors to inspect 422 wholesalers statewide.
- Product quality is compromised.
  - Widespread problems with the quality and integrity of the secondary wholesale drug supply were found to include:
    - § expired drugs re-labeled with falsely extended dates
    - § previously dispensed medicines
    - § illegally imported drugs
    - § sub-potent drugs
    - § drugs that contained an entirely different substance from the one listed on the container's label
- Health risks are significant.
  - The mainstream market is compromised by corrupt, secondary wholesalers. Diverted drugs are often combined with counterfeit medicines or re-labeled or repackaged. Then, these compromised drugs enter the mainstream market through corrupt secondary wholesalers and are dispensed by legitimate pharmacies, hospitals or clinics. By way of example, a father in Michigan who thought he was injecting his son with a

growth hormone later found that the vials actually contained insulin. These drugs were traced to a legitimate pharmacy in Orlando, Florida.

- Incentives for counterfeiting and diversion are considerable.
  - The huge profits derived from these activities rival those of illicit narcotics traffickers, while the penalties are minor by comparison.

### Challenges to Oversight and Enforcement

There are challenges associated with the oversight and enforcement of our current laws with regard to ensuring that medicines being purchased or sold in this country are FDA-approved, safe and effective.

- The current volume of parcels of drugs coming into this country through the mail (it is estimated to be more than 10 million packages annually) and the increasing volume of Internet purchases make meaningful inspection by the FDA almost impossible.
- The FDA has less than 100 investigators to deal with drug importation issues nationwide, and its investigative authority is limited relative to its ever-increasing law enforcement responsibilities. For example, the FDA has no administrative subpoena authority in order to facilitate the conduct of its investigations; thus it must either partner with another investigative agency or request subpoenas from the local United States Attorney's office.
- Investigating and prosecuting counterfeit drug cases or illegal Internet sales cases are not, with few exceptions, a priority for the federal or state law enforcement agencies.
- The penalties are comparatively low for engaging in this kind of activity – the current penalties for FDA violations are approximately 3 years.
- The technologies being advanced as mechanisms to ensure an imported drug shipment is safe and effective are not foolproof, and, in some instances, not yet available.
  - Electronic Track and Trace – most agree that these technologies, e.g., using bar coding or radio frequency identification (RFID) chips that could track drug products in real time throughout the system and then provide an electronic pedigree, are still very costly when available.
  - Counterfeit resistant technologies that include covert and overt packaging and labeling techniques, such as holograms, watermarks, color shifting inks or fluorescent inks, as well as chemical agents, are widely used by the

- industry already. However, they can be easily duplicated and, therefore, must be changed on a periodic basis.
- “Unit of Use” packaging, which is a container closure system designed to hold a specific quantity of drug product for a specific use and dispensed to a patient without any modification except for appropriate labeling, does eliminate the need for some repackaging; however, there are packaging and cost issues for the manufacturers, and some drugs do not lend themselves to such packaging.
  - Authentication testing, while not a technology *per se*, is also an option when determining the integrity of a pharmaceutical product. It is a complicated, time consuming and costly process, however, and can be performed only by the original manufacturer. There are no available tests that can be conducted “in the field” to ascertain whether a product is real or fake.

These factors, among others, make it a high profit, low risk business for the counterfeiters or those involved in circumventing the laws in supplying medicines outside the traditional distribution chain, and, therefore, it may be appealing to organized crime and terrorist organizations.

### **PRODUCT QUALITY**

Weaknesses in the existing system already threaten the quality and integrity of the nation’s drug supply. Despite best efforts, the evidence we have seen thus far supports the notion that the drug supply is indeed vulnerable. Some examples are as follows:

#### **Random Examinations Conducted by the FDA and U.S. Customs and Border Protection**

The FDA and U.S Customs and Border Protection conducted a number of random inspections or “blitzes” at several mail ports in the fall and early winter of 2003.

- In the first inspection, 1,153 drug products were examined and 1,019 or 88% were not approved by the FDA; the drugs came from countries such as India, Thailand, and the Philippines.
- In the second exam, 1,982 parcels were examined and 1,728 or 87% were not approved; 16% of those shipments were from Mexico.
- Many of the drugs examined during these visits were non-FDA approved for many reasons, including:
  - improper labeling, e.g., there were no instructions for proper use;
  - the presence of controlled substances;

- potentially recalled drugs, e.g., drugs that had been withdrawn from the market for safety reasons;
- animal drugs not approved for human use;
- drugs requiring risk management and/or restricted distribution (e.g., initial screening or periodic monitoring); drugs with clinically significant drug interactions; or drugs requiring careful dosing; and
- required special storage conditions for certain drugs were violated.

### Portal Visits

In order to gain an appreciation for the scope of the problem, United States mail facilities were visited to observe the volume and nature of the packages allegedly containing prescription drugs entering the United States. A number of the observations follow.

#### *John F. Kennedy Airport Mail Facility*

At the invitation of United States Senator Norm Coleman, former New York City Mayor Rudolph W. Giuliani and former New York City Police Commissioner, Bernard B. Kerik, accompanied the Senator on a visit in March, 2004 to the US Mail facility located at JFK Airport. Customs officials advised that approximately 40,000 packages of suspected drug shipments are received each day from the postal service for review and inspection. Based upon information, the FDA focuses on “countries of interest” and visually inspects 500 to 700 parcels per day. Thus, the majority of packages are sent on to the addressee uninspected. The following was learned:

- Drugs purported to be Xanax, Valium (Diazepam), Lorazepam, Vicodin (all controlled substances) and Lupron were observed; there were numerous packages from the Netherlands, Brazil, Pakistan, as well as other countries.
- Many of the drugs contained in the parcels were non-FDA approved because they were inappropriately packaged, expired, mislabeled or otherwise noncompliant.
- The sheer volume of shipments overwhelms Customs and FDA; FDA has only 6 staff members assigned to JFK.
- Although much of what is inspected is non-FDA approved, few parcels are actually detained. The processing requirements to detain a shipment are cumbersome and time consuming. The rules require the FDA to send a notice to the addressee of the package. If the person does not respond or the response is insufficient, the package must then be returned to the sender (manufacturer). This process varies significantly from the way controlled substances or narcotics are handled. Such drugs can be destroyed without further processing.

*Miami International Mail Branch Facility Visit in March 2003*

Giuliani Partners was provided with a Congressional staff report regarding a similar review of the Miami facility in March 2003. The findings of the bipartisan Congressional report were consistent with the findings of this review:

- Congressional staff witnessed “thousands of shipments of foreign drugs” being processed; the packages were from countries such as Honduras, Costa Rica as well as Great Britain; and the packages purportedly contained “valium” (diazepam), Reteina (Ritalin), Zolipidem, and Ciprofloxacin.
- The volume of drugs coming through the mail facilities is too great to allow for any meaningful inspection.
- Parcels are only visually inspected; there is no testing as to the quality or integrity of the product.
- FDA and Customs detain very limited numbers of questionable drugs coming into the facility because of the cumbersome nature of the detention process.

The Increase in Counterfeit Drugs

- Most of those interviewed by Giuliani Partners agreed that:
  - The number of incidents involving counterfeit medicines is increasing;
  - The increased use of Internet sale and purchase is exacerbating the problem;
  - The counterfeiting techniques are becoming more sophisticated and harder to detect;
  - There are vulnerabilities in the current distribution system that contribute to the problem; and
  - Opening the borders for wholesale importation will worsen the problem.
- The former Commissioner of the FDA, Dr. Mark McClellan, testified before the U.S. Senate Committee on Commerce, Science and Transportation on March 11, 2004 that the FDA has seen its number of counterfeit drug investigations increase four-fold since the late 1990’s. “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.”

- On its website, the World Health Organization (WHO) states that while the true extent of the problem of counterfeit drugs is difficult to know or measure, they have estimated that at least 8% – 10% of the world’s total drug supply is counterfeit.
- An August 30, 2002 Washington Post story cites the Shenzhen Evening News in reporting that an estimated 192,000 people died in China in 2001 because of counterfeit drugs. Another news story reported that as much as 50% of China’s drug supply is counterfeit (Investor’s Business Daily dated October 20, 2003).

#### Reported Incidents of Adverse Effects

Without question, the most frequently asked question by proponents of importation is “who is really being harmed by the purchase of medicines from outside of the United States?” There appears to be no easy answer to the question. Because receipt of imported medicines is unregulated, there are no systems in place to effectively monitor whether injuries result from the taking of compromised medicines. When complications arise from taking imported medicines and a patient does consult with his or her doctor or reports to an emergency room, no one is asking the question ‘where do you purchase your prescription medicines?’ Patients are also reluctant to report adverse reactions that may be attributable to medicines illegally purchased from outside the country.

Given these circumstances, coupled with the systemic challenges discussed earlier, it is difficult to ascertain the actual source of an imported drug. The following are some examples of actual incidents where people taking medicines with undocumented origins were adversely affected as a direct result of taking the prescription drugs. These cases represent the dangers of obtaining drugs from sources outside of the United States’ closed system.

- In La Mesa, California, Ryan T. Haight, 18, died in his bedroom of an overdose after taking narcotics obtained on the Internet. After his death, his parents found a bottle of the painkiller Vicodin in his room with a label from an out-of-state pharmacy. An investigation by federal drug agents showed that the teenager had been ordering addictive drugs online and paying with a debit card his parents gave him to buy baseball cards on eBay. (Washington Post, October 19, 2003)
- In Sacramento, California, James Lewis, 47, a former triathlete, shopped the world for painkillers that flowed unimpeded from pharmacies in South Africa, Thailand and Spain. His wife discovered him dead of an overdose on the living room couch. (Washington Post, October 19, 2003)

- A 15-year-old paraplegic boy went into convulsions and died after taking a non-FDA approved drug called Lincocin which had been smuggled in from Mexico. (Los Angeles Times, March 10, 2001)
- Juris Abolins, 43, used painkillers off and on for years to treat pain from kidney stones. His roommate found him slumped on his bedroom floor dead. An autopsy revealed the presence of controlled substances in his blood stream. Relatives found a Federal Express slip for drugs purchased from a website in Tijuana, Mexico. (Washington Post, October 19, 2003)

### **THE INTERNET**

Over the past several years, hundreds of websites have appeared on the Internet selling prescription medicines. While some sites provide legitimate prescription services, many sites are illegitimate and pose significant risks to all patients who use them.

#### **Private Investigation Regarding Internet Purchases**

A security and investigative firm based out of New York City, Beau Dietl & Associates, conducted an investigation regarding the importation of foreign medicines and reported its findings in December 2003. The results were disturbing:

- More than 1400 websites were identified as selling prescription drugs.
- 352 of those sites did not require a prescription when ordering.
- 142 of 170 orders were placed without a prescription and at the time of the report, 79 orders were filled without a prescription.
- Many of the medicines received were not only shipped in improper packaging but came from foreign countries such as Pakistan.
- An order for Ciprofloxacin was placed, received and tested. It was determined to be only 65% potent.
- The investigation found that website operators were often difficult to identify and trace; and some of those identified were found to have questionable backgrounds:
  - One website owner/operator was a convicted felon;
  - Other website owners could not be traced because the registration information was false;
  - Many sites failed to comply with legal requirements – doctors wrote prescriptions without ever meeting the patient; and one Internet doctor was a convicted sex offender.

- Websites were easily established with no minimum qualifications, standards, or oversight.
- Once the websites were established, emails were received from various suppliers offering to provide medications from “several countries,” or “bulk meds from Pakistan” for resale in the U.S. market.

The results of this investigation offer a troubling snapshot of the nature of the Internet pharmaceutical business.

#### The CASA White Paper

The National Center on Addiction and Substance Abuse at Columbia University, under the direction of Joseph Califano, former Secretary of the Department of Health, Education and Welfare, the predecessor of the U.S. Department of Health and Human Services, released a study in February 2004 regarding the sale of controlled, dangerous and addictive prescription drugs in America. It looked particularly at Internet sales and teamed with the same New York City investigative firm to conduct the review. CASA characterized its findings as “alarming.”

During a one-week period of observation, the firm identified a total of 495 web sites offering Schedules II through V controlled substance prescription drugs. Examples of the controlled substances available online included painkillers, stimulants, and nervous system depressants.

- Of the 157 sites selling controlled substance prescription drugs on the Internet
  - 90% (141) did not require a prescription
  - 4% (7) required that a faxed prescription
  - 2% (3) required that a mailed prescription
  - 4% (6) made no mention of prescriptions
- Of the sites, 47% disclosed that the drugs would be coming from outside the United States; 28% stated the drugs would be shipped from a US pharmacy; and 25% gave no indication where the drugs would be coming from.
- The analysis determined that there were no mechanisms in place to block children from purchasing these drugs.

#### Canada – The Implications of Importation

It is generally agreed that prescription medicines purchased by Canadians in a Canadian drug store are safe and effective. Like the United States, Canada has a system

of regulatory controls over its medicine supply. However, the same cannot be said for the drugs that are being imported to Canada and then exported. In fact, the Canadian government is not inspecting those medicines that are being imported to Canada and then exported to the United States. The Canadian government has clearly stated that it would not be responsible for the safety and quality of prescription drugs exported from Canada into the United States or any other country. Furthermore, the Canadian Food and Drug Act does not apply to any packaged food, drug, cosmetic or device not manufactured for consumption in Canada and not sold for consumption in Canada.

With respect to the question of drug supply capacity, it is undisputed that Canada does not have supply sufficient to provide for its residents and Americans as well. (In 2002, 3.1 billion prescriptions were filled in the U.S. compared to 335 million prescriptions filled in Canada.)

According to information provided by Industry Canada, a department of the Canadian Federal Government, from September 2002 to September 2003, there was a significant increase in drugs imported into Canada from the following countries:

- Singapore up 30%
- Ecuador up 198%
- China up 43%
- Iran up 2,753%
- Argentina up 221%
- South Africa up 84%
- Thailand up 52%

Prudential Financial, Inc. released similar findings, stating that Canadian Internet pharmacies were increasingly obtaining their product from other countries such as Bulgaria (exports to Canada up 300%), Singapore (up 101%), Argentina (up 171%), South Africa (up 114%), Pakistan (up 196%), as well as others. Further, some Canadian pharmacies, such as Canadameds.com, have publicly indicated that because of the increasing demand from the United States, they are turning to Great Britain for prescription drugs.

### **THE POTENTIAL FOR EXPLOITATION BY NARCOTICS TRAFFICKERS, ORGANIZED CRIMINALS AND TERRORISTS**

The terrorist attacks of September 11, 2001 demonstrated how vulnerable this country is to those who have total disregard for human life or who mean us harm. Since that time, the United States has invested billions of dollars to protect our borders. Despite all that has been done, we have not focused on the vulnerability of the nation's medicine supply as a potential target. The present controlled system of importation and

inspection is open to exploitation and abuse. Any further removal of controls, much less the total opening of the borders to foreign drugs, would create a situation that terrorists, drug dealers and organized criminals might well use to their advantage. It seems counter-intuitive to contemplate opening our borders with regard to our medicine supply when in all other aspects of border security and protection, we as a country are looking for ways to tighten security.

A July 22, 1998 story in Insurance Day, while reporting on pill piracy and the World Health Organization's efforts to confront pharmaceutical fraud, stated that "Interpol believes that this aspect of the drug trade is closely connected with the narcotics cartels and that the profits generated by it are in part used to finance international terrorism." The article further stated that Interpol had been following the global counterfeit drug racket for some time and based its belief on evidence uncovered by police in North America and Western Europe.

Further, in her book, Funding Evil, How Terrorism is Financed – and How to Stop It, Rachel Ehrenfeld makes numerous references to the fact that terrorists use counterfeiting activities as a means to fund their terrorist acts. While counterfeit prescription drugs are not specifically referenced, the use of illegal drugs to fund such activities is well documented.

GlobalOptions Inc. identified the potential terrorist threats to America's medical supply in its work, An Analysis of Terrorist Threats to America's Medicine Supply. In sum, it identified three potential threats. First, the "mere infiltration of terrorists in the counterfeit drug market poses a threat to the public." Terrorists could easily produce and sell harmful prescription drugs. Second, terrorist groups could use the profits raised through the sale of counterfeit or diverted drugs to fund their activities. And third, terrorists could use poisoned drugs as a method of attack or, worse, as a weapon of mass destruction.

This study cited numerous examples of links between counterfeiting activities of various types and terrorist groups, where such groups were using the proceeds from these sales to fund their terrorist activities. In particular, the authors pointed to the following:

- The activities of the Irish Republican Army in the early 1990's in Florida that included the manufacture of a counterfeit drug product used to treat livestock. Proceeds from this operation were used to purchase guns;
- An international drug ring raised millions of dollars for Hezbollah. The report states that the terrorist group's operatives legitimately purchased large quantities of pseudoephedrine in Canada, smuggled it into the United States, and produced "speed."

## **THE CONCLUSION**

After conducting a preliminary, independent review of the issues associated with the wholesale importation of prescription medicines, it is evident that the existing pharmaceutical system is open to significant exploitation of counterfeit, diluted or adulterated drugs coming into the United States. The limitations of our system should be addressed before it is opened to wholesale importation.

The Health and Human Services Task Force on Drug Importation is currently considering all of these issues. The Task Force should be allowed to complete its mission as Congress directed before any major statutory changes are contemplated. Given the seriousness of this issue and its implications for the health and safety of Americans, a thorough and well-informed analysis is necessary.

Our interim findings can be summarized as follows:

- Although the current pharmaceutical manufacturing and distribution system is comprehensive and regulated, counterfeit or otherwise adulterated products still penetrate the market.
- There are serious questions as to the quality and safety of the medicine products coming into the United States from foreign sources.
- There are no minimum standards and little or no regulation regarding the operations of Internet pharmacies.
- There are identifiable weaknesses in the current pharmaceutical distribution chain (e.g., the “secondary” wholesale distribution market and the lack of a drug pedigree)
- The agencies responsible for enforcing the existing laws and regulations are already overwhelmed with the current volume of non-FDA approved prescription medicines coming into the United States.
- The potential exists for the use of the nation’s medicine supply as a vehicle for terrorist activity.
- There are serious implications for Canadians with the current demand on their drug supply.

As noted previously, this review and these findings are preliminary. However, the issues discussed herein strongly suggest that no action be forced on the FDA or other government oversight agencies until the HHS Task Force has completed its analysis. In

the meantime, the public should be made aware of the risks associated with importing medicines from outside the United States. As the importation debate continues, it is vital that all aspects of this important public health issue be carefully assessed. We should not minimize the potential risks surrounding importation.