Submission Of

THE HONORABLE RUDOLPH W. GIULIANI

Chairman & CEO
Giuliani Partners LLC

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BUYERS BEWARE: THE DANGERS OF PURCHASING PHARMACEUTICALS OVER THE INTERNET

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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.

<u>Challenges to Oversight and Enforcement</u>

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), Lorazapam, 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), Zolipedem, 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.

<u>The Increase in Counterfeit Drugs</u>

- 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 McClellen, 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 Hezballah. 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.