United States Senate
Committee on the Judiciary
"Examining the Implications of Drug Importation"
Questions for the Honorable Rudolph W. Giuliani

1. **You recently discussed a paper you wrote with findings on prescription drug importation from foreign sources. In your report, you state that the weaknesses in our existing system could potentially open the door for individuals interested in supplying drugs through illegal means, specifically, organized crime and terrorist organizations. Why do you believe these types of activities would be appealing to terrorist organizations and a threat to our homeland security? Your report had some sobering analysis about counterfeit drugs and terrorism.**

   The review conducted by Giuliani Partners revealed a number of weaknesses in the current system of prescription drug distribution. Given these weaknesses, it is conceivable that narcotics traffickers, organized criminals and possibly terrorists may view it as an easier way of getting counterfeit or otherwise compromised medicines into the United States. In light of what is already known about such criminals and how they operate, for example, they will look for opportunities that offer low risk of getting caught or being subjected to stiff penalties but also offer a high profit. Because of the weaknesses in the system, marketing counterfeit drugs could be an attractive opportunity. Since the majority of medicines coming into the United States via the mails are rarely inspected, the system could easily be exploited as a way of harming particular individuals, and creating confusion with, or polluting, the drug supply in the United States. Like the Tylenol incident in Chicago, panic and fear in addition to injury are the results.

   Experts who have studied this issue theorize that organized criminals, drug dealers or terrorists could produce and sell harmful or counterfeit drugs as a method of attack, or such groups could use the profits raised through the sale of such drugs to fund their activities. If the borders are porous then they may be vulnerable to exploitation. Unfortunately, based upon observations that have been made to date, such exploitation could easily occur. It seems counter-intuitive to open the borders with regard to this country's medicine supply when in all other aspects of border security and protection, this country is looking for ways to tighten security.

   Given the weaknesses that have been identified in the current system, it can be penetrated by compromised medicines. If you open it up even further through commercial importation, then it becomes even more vulnerable to compromise and, thus, even more of a temptation to criminals.

2. **How knowledgeable, in your opinion, do you think law enforcement agencies are about counterfeit prescription drugs, illegal internet sales, etc. as compared to illicit narcotics? Is it your opinion that we need to do a better job educating our law enforcement agencies about the potential dangers of these drugs?**

Understandably, law enforcement agencies are not extremely knowledgeable about this issue for a number of reasons and a better job does need to be done in order educate them about the dangers such drugs pose.

The importation of prescription drugs from foreign sources is a relatively new practice. It has only been in the last few years that more and more people are going on-line and filling their prescriptions via the Internet. Further, counterfeit or otherwise compromised medicines are not easily identifiable. Neither chemical tests nor technological devices exist to detect them. This is unlike drug cases involving heroin, cocaine and other illegal drugs where field tests exist to provide, in a relatively short period of time, a fairly good indication of whether a substance is actually heroin or cocaine, and can also provide a rough indication of the potency of the drug.

Under the current system the pharmaceutical company that manufactures the medicine is primarily responsible for performing the confirmatory testing on the products that are suspected of being counterfeit. The pharmaceutical companies report that such testing is often times very costly and time consuming.

Given the current volume of packages containing alleged prescription drugs coming into the United States, an estimated 40,000 packages per day at the JFK Airport mail facility alone, it is very difficult for law enforcement to inspect such packages in a of meaningful way. Thus, it is not the fault of law enforcement; the means do not currently exist to allow them to adequately perform this function.

With regard to better educating law enforcement about the potential dangers of these drugs, as more is learned about this business and advances in technology are made, it will become easier to train law enforcement about what to look for and how to combat it. Such a process would be similar to what happened when techniques were developed to combat the trafficking of narcotics.

3. **In the paper, you mention the distribution chain being fairly straightforward but there are chances for exploitation or abuse within the distribution chain – namely, there are no uniform standards for wholesalers or distributors; there are thousands of secondary pharmaceutical wholesalers; there is no uniform mechanism to track the medicine from the point of being manufactured to the point of sale; and repackaging these products is a point of vulnerability. Could you talk about how we can make improvements in this distribution chain for pharmaceuticals?**

Although it is impossible to create a perfect system, it is certainly possible to create a much better system to address some of the weaknesses that currently exist in the drug distribution system. For example, electronic pedigrees, such as those using radio frequency or RFID technology, that will better trace the flow of medicines from point of manufacture to point of sale are being developed to replace paper pedigrees; uniform or minimum standards for

wholesalers and distributors could be considered, such as those developed by the National Association of Boards of Pharmacy; the recommendations of the FDA's Counterfeit Drug Task Force could be considered for implementation (it suggests, for example, counterfeit resistant technologies, tightening requirements for repackagers and increasing criminal penalties for counterfeiting activities); the recommendations from the Florida grand jury report, which were similar to those made in the FDA report, could also be considered; and giving the FDA and other responsible agencies the necessary authority and resources to adequately address the current situation would all be steps to consider in order to improve and tighten up the distribution chain.

4. **What is the biggest concern you have about drug importation being legalized?**

The biggest concern about legalizing drug importation is that given what has been observed regarding the existing system, if it is opened further to authorize personal importation or, worse, commercial importation, then it will be subject to even greater exploitation and abuse. In view of the limits on staffing and resources, there are not nearly enough inspections being performed on the medications that come into the United States through the mails. An efficient system for determining pedigree, or for determining whether the medication is what it purports to be, have not been devised. And it is undisputed that the number of incidents involving counterfeit drugs is already increasing. In light of these facts, coupled with the other challenges to oversight and enforcement, the existing system must be improved before any sort of expansion or legalization is contemplated.

5. **We have heard a lot from opponents of importation about the safety concerns they have regarding importation – why, in your opinion, have we not seen more adverse events if there really is a safety concern? I am going to ask you the same questions I asked our FDA witnesses – who is really being harmed by imported drugs?**

Unfortunately, we may not know the answer to the question about who is being harmed. Currently, the importation of medicines from outside the United States is not legal, notwithstanding the FDA's personal use exemption, and, as a result, it is an unregulated practice. Since there are no systems currently in place to monitor this practice, there is no way to determine whether injuries result from taking compromised medicines. Some of those interviewed explained that the medicines being imported from foreign sources are often used for chronic illnesses, such as heart conditions, and if injury or death occurs, it is frequently assumed that it was a result of the condition and not the medicine. It is not usually a part of a physician's or emergency room's protocol to question where a patient may be filling his or her prescription. Thus, it is difficult to assess actual harm.

6. **Why do you believe that opening the borders for wholesale importation will increase the number of counterfeit drugs?**

   It is undisputed that even with our existing "closed" system of importation and distribution that the number of cases involving counterfeit drugs has increased. Further, it is known that this is a high profit, low risk business – the profit margins are large and risks of getting caught or severely penalized are relatively low – and, thus there is incentive for even greater exploitation. It remains unclear how a system of regulation and oversight could be implemented that will ensure safety when the prescription medicines may be coming from several different countries. The existing system is already overwhelmed. Given what we already know, if more drugs are imported from outside the country, the percentage of packages that can be inspected will, inevitably, be reduced dramatically. As a result, with fewer inspections there is even more of an opportunity for someone or some group to try to get counterfeit product into the country.

7. **I was interested to read in your report that the Canadian government is not inspecting drugs that have been imported to Canada and then exported to the United States. In fact, the Canadian government has stated that it will not be held responsible for the safety and quality of drugs exported from Canada to other countries, including the United States. I find this quite disturbing since most believe that drugs imported from Canada to the United States are safe. Would you care to comment on this?**

   Many of those ordering medicines over the Internet from a Canadian website believe that they are ordering and receiving the same FDA-approved product that they would obtain in their local domestic pharmacy. This may not necessarily be the case. If it is a Canadian Internet pharmacy that has been inspected or approved by a provincial board of pharmacy, then the patient may be receiving a Health Canada approved medicine, which would be roughly equivalent to a FDA approved medicine. However, there are many Internet pharmacies that purport to be Canadian but, in fact, operate out of other countries and/or are not necessarily dispensing legitimate medicines. Thus, while the Canadian system is, by and large, as safe as the American system, not all Internet pharmacies are regulated by the Canadian healthcare system. Accordingly, when ordering on line, a person cannot necessarily be sure that the order is being placed with a legitimate pharmacy that is dispensing a safe product. And given that such pharmacies fall outside of the Canadian regulatory system, they are not being inspected in the same fashion as the legitimate pharmacies. Indeed, as noted in the question, the Canadian government did state in a letter to The Washington Post that "[t]he Government of Canada has never stated that it would be responsible for the safety and quality of prescription drugs exported from Canada into the United States, or any other country for that matter."

   Another point to be made with regard to the quality of the medicines being obtained through the Internet is that many of the Canadian Internet pharmacies examined require written waivers in order to receive the medicines ordered.

The intended purpose of such waivers is to preclude a patient from holding a pharmacy responsible in the event there is something wrong with the medication received. If a person orders one medication, but gets another or receives a medication that is not of the right potency, the patient may not necessarily be able to hold the pharmacy accountable in the same manner he/she could if the pharmacy in question were an American pharmacy.

In addition, a few of the state or city sponsored websites that have direct links to Canadian internet pharmacies have disclaimer language which reads "certain inherent risks in ordering any product through the mail..." and "importation of drugs from Canada is not legal..." Such disclaimers also state that the purpose of the website is only to provide information and that the state would not be liable for any damage that occurs through the use of the site. The result is that Americans who order their medicines over the Internet may have no recourse to pursue the Canadian Internet pharmacy in the event of a problem. As a result, there is a lack of accountability in such a system.

8. **Question 5 repeated – see answer above.**

9. **As part of your investigation, you have traveled to mail facilities to review the flow of prescription drugs into the facilities. What surprised you or concerned you, if anything, at these visits?**

There were a few of things that were not only surprising but also raised a great deal of concern. The volume and types of medicines that were coming through the mail was of great concern. There were thousands upon thousands of parcels of medicines being shipped from a variety of countries. There were drugs purporting to be Xanax, Valium and Vicodin, which are all controlled substances. There was Lupron, an injectable drug used to treat cancer that requires the very careful supervision of a doctor when administered. In addition, many of the parcels contained medicines that were non-FDA approved – for example, some were expired, some were improperly labeled or packaged and some were obviously of a size and color different from the original.

Another area of concern is the lack of resources for those agencies that are responsible for inspection and enforcement at these facilities. Given the volume of packages reportedly containing prescription medicines – an estimated 40,000 packages a day coming into the JFK mail facility alone - it would seem that more inspectors as well as additional resources are necessary to adequately perform the inspections. Further, the technology that is available at the facilities is either outdated or not available; for example, modern tracking equipment is not readily available and the computer programs being used did not appear to as useful as they could be. Also, the cumbersome bureaucratic process that the FDA must comply with in order to detain, return and/or destroy the drugs that are obviously non-FDA approved was quite surprising. This process could be streamlined so that more time could be spent on inspections.

10. What is your opinion about incentives for counterfeiting and diversion of prescription medicines compared to illicit narcotics?

Under the current penalty scheme, it is far riskier for a person to engage in the illegal sale of narcotics than the illegal sale of diverted or counterfeit prescription medicines. Given the following factors - the weaknesses in the current system that were discussed previously, the fact that the punishment for getting caught engaging in such activity is comparatively light, and the large profits that can be made – there appears to be a greater incentive for people to break the law and engage in counterfeiting or diversion activity. Thus, the penalties for diverting prescription drugs or counterfeiting should be and re-examined and, in all likelihood, increased. An average penalty of three years for such an offense does not appear sufficient compared to the nature of the crime. Currently, it is a high profit – low risk business. When most of the penalties were passed, such activity was not a major problem in the United States. The major focus was primarily illegal drugs.

11. Why do you suppose that investigating and prosecuting illegal Internet sales or counterfeit drug cases are a lower priority for federal and state law enforcement agencies?

Historically, the major focus has been on investigating and prosecuting cases involving heroin, cocaine, marijuana, and other illegal drugs, particularly because of the violence and other associated crime that follows the drug trade. It takes time, even for law enforcement, to learn that, while heroin and cocaine are still a problem, there is this new problem, which is becoming much worse – that is the diversion, counterfeiting and misuse of prescription medications, particularly those that are controlled substances. Although law enforcement and prosecutorial resources are stretched rather thinly, they should begin to dedicate additional resources to investigating these types of crimes and abuses. It is not hard to imagine that given the money involved in this industry, the same people who are engaged in manufacturing, distributing and selling illegal drugs, could also become involved in the manufacture and sale of counterfeit prescription medicines.