Testimony of

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United Health Alliance
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Testimony
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Hearing on
(Re)importation of Prescription Drugs
July 14, 2004

Mr. Chairman, and Members of the Committee:

Thank you for inviting me to discuss (re)importation of prescription drugs.

Today's healthcare market presents many challenges. None is more controversial than that of technology in the form of a "pill". Pharmaceutical spending has almost doubled in less than a decade. More often than ever, our policymakers and physician providers are being queried as to why it is that Americans must pay many times more for their medications than their counterparts in other countries? As you know, over the past few years many of your constituents have been purchasing their medications from Canada. For these individuals, these medications are now affordable and even more importantly safe. From a pure medical standpoint, the most important part of a treatment plan that is intended to produce the best possible outcome for a patient, is the patients ability to comply with what 's prescribed by their provider/physician. Any medication, as part of a prescribed treatment plan, that is not affordable and therefore not accessible, is neither safe nor effective.

Quality and Compliance

Many of the recent conversations around (re)importation have focused on quality and safety issues. As providers of care, no one knows better than physicians and pharmacists how important quality is in the process of providing care. Quality can be defined in many ways, in this instance I

want to discuss the importance of compliance for an individual/patient. When a physician/ provider prescribes a medication as part of a treatment plan, they assume that the individual will have access. Many do so because they [the provider] have used samples provided to them at no costs to give to their patients. So, when they have a patient that responds well to a particular medication provided as a sample, they do naturally what comes next in the process...write a prescription for the medication. Unfortunately, medications supplied as samples, in general, are the very ones that are not affordable.

Clearly as a provider network, our major concern is the ability of patients to comply with a given treatment plan. When a patient cannot afford their medications it is costly for all of us. Are physicians concerned about quality? Absolutely. And there is a quality issue and exist on this side of the border. When a patient cannot take their medications, they most definitely will consume services elsewhere in our system, such as the emergency room or by being admitted to the hospital. That simply is not rational. This is not about people that won't comply with a treatment plan, this about individuals that can't afford to purchase prescription drugs in the country they live in. Also, let's keep in mind that we are talking about Canada not some third world country. Having said this, these individuals are willing to take the risk associated with accessing their medications across the border. Many of them have told us that there is certainly no more risk in doing this than they are at by not taking their medications as prescribed or not at all.

Let's talk about quality and safety. I would ask you to reflect on when the last time was that you witnessed an armored vehicle delivering medications from manufacturer to the community pharmacy in this country. This is an extreme example, but I would like to make a point about safety under the guise of quality. Much propaganda has surfaced over (re)importation of medications from other countries, particularly Canada. This attempt to frighten individuals that are already terrified of compromising their health by not being able to take their medications, creates a form of terrorism that is inexcusable. Some would have you believe that Canada's pharmaceutical supply is unsafe and of inferior quality. Ads placing pills side by side and questioning which one is the counterfeit drug and poisonous snakes around medication bottles, is a poor use of valuable resources and intended to produce fear (Exhibit A,B, C). It does nothing to help address the problems associated with access.

Facts/Observations:

? Parallel trade has existed safely in the EU for years. There is no evidence that parallel trade promotes counterfeiting when the appropriate controls and regulatory processes are established. (Exhibit D)

? (Re)importation from Canada exist. The U.S. consumer has taken upon themselves to demonstrate it works. Millions are currently utilizing as a means to comply with their treatment plans. (See Map displayed during testimony)

? The Canadian system is well regulated and safe (Exhibits E,F,G)

? Canada (as does) other countries) has the equivalent of the FDA with regard to oversight

? Customer satisfaction and compliance for those using (re)importation from Canada appears high

? Physicians engaged in the process. Compliance results in better outcomes and potentially lower costs to the overall system.

? Guidelines and standards can be [and have been] established for the oversight of mail-order. Accreditation process must be much broader than just the marketing via the internet (Exhibit H)

? U.S. Consumer created the mail-order industry in Canada. Legitimate mail-order in Canada welcomes standards and the regulatory process needed to provide safety controls for U.S. citizens protection from unscrupulous providers via mail-order. Particularly for "lifestyle, me-too" medications and controlled substances (Exhibit I)
? The community-based pharmacists must be re-integrated into the health management plan (mail-order has carved the community-based pharmacist out as a provider of quality oversight)
? Recent reports surface that make reasonable arguments for legislation to be passed (Exhibit J,K,l GAO,AARP and Sagar)
? Legislation is necessary to provide standards and oversight for what already exist

Background on United Health Alliance

United Health Alliance is a nonprofit physician-health system organization located in Southwestern Vermont. Our partners include a rural hospital, nursing home, home health agency and just over one hundred (120) community physicians. We serve residents of Vermont, New York and Massachusetts. Our mission is to promote a physician-driven organization whose principle services are to provide advocacy and leadership in the areas of care management, contracting, performance improvement and educational programs to maximize value for our physician-hospital membership and customers [patients]. Although we have committed to ten (10) guiding principles, none is more important to us than assisting the communities we serve at becoming the healthiest in the nation. Several years ago we found that although admirable, this objective was going to be very difficult to achieve given the circumstances that existed for some of our elderly and uninsured/underinsured. Very simply, they did not have access to affordable prescription drugs, therefore they were not able to comply with the treatment plans prescribed by their physicians. Although we had individuals that were seeking affordable medications via bus trips to Canada, we knew that this was not an option for the majority of the communities we serve by virtue of their medical condition and/or their limited resources. One of our physicians came to us and requested our assistance at investigating how we could help a patient of his with breast cancer from Massachusetts access her medications from Canada without having to get on a bus. Today that patient takes her medications because she can afford them. It cost her ninety (90) percent less in Canada. We compared the costs for 145 seniors for the first six months to see if what we had heard about the differences in pricing was in fact true. While these individuals would have had to pay just over $81,000 in the U.S., they paid approximately $22,000 for their medications in Canada (see Exhibit M). Our understanding is that there were no substitutions for the medications they were currently on. All medications accessed were for the treatment of chronic diseases such diabetes, heart disease and cancer. A price comparison of some of the more commonly prescribed medications for the treatment of these diseases has been provided along with this testimony. Although there is minor variation with some pricing in Canada, the savings are still significant and have been reported anywhere from thirty (30%) to (95%) percent (see Exhibit N)[Note: These prices have changed since supply has been cut to some pharmacies and wholesalers). Although the majority of the individuals that accessed their medication from Canada were the elderly on fixed incomes, with no prescription coverage, many individuals that have depleted their pharmacy benefits also are now accessing their medications from Canada. As we have conversations with employers located in the communities we serve about benefits and coverage for their employees we find many are concerned about how to continue the level of

coverage they currently provide, particularly with the growth in their expenditures for prescription drugs. The implications are frightening for all of us.

Compliance: Physicians assume that when they prescribe a medication (write a script) that the patient will take their medication as prescribed. They don't have any interest in where you get it filled. This is not to say that they would not be concerned if they thought there was a safety or cost issue. They are concerned about compliance with regard to a prescribed treatment plan.

FDA Site Visit: The FDA completed a site visit/audit of the UHA initiative on July 22, 2002. No notice to cease and desist was issued. Additional information can be provided to the Committee upon request.

Conclusion/Recommendations

Personal re-importation has for all intensive purposes, been implemented by the American consumer. It may or may not be a long-term solution, but it does provide an option until we can provide appropriate levels of coverage (access). Long-term viability will depend on the development of a program that can be implemented not just signed into law [as evidence by MEDSA 2000].
Barriers to access are unacceptable. (Re)importation of prescription drugs is working as a mechanism for access of affordable prescription drugs. Should the current process be improved upon ...absolutely! Should there be controls in place to monitor quality of those involved...absolutely!

Clearly, there is no simple answer with regard to the issues we are discussing. Barring any type of regulation of the pharmaceutical industry on this side of the border, personal (re)importation from Canada under controlled circumstances can provide an interim solution for those in need of access to affordable prescription drugs.

The passage of S2328 (The Pharmaceutical Market Access and Safety Act of 2004) with the incorporation of standards requirements for participation is essential to protect what has already been established by the U.S. consumer. I believe that all the intent of S2464 (Internet Pharmacy Consumer Protection Act) can be achieved by including language on standards requirements. The marriage of these two pieces of legislation is essential to the establishment of a "good health policy".

Epilogue
FDA Oversight

From the perspective of safety and oversight clearly the FDA [and other agencies] must be concerned as to how any initiative that would involve re-importation of prescription drugs would

be maintained under their current charge. Although challenging, it can be done. With regard to Canada it would not be that difficult to do. The following could/should be considered:

1. In order to maintain and provide an efficient means of oversight by the FDA, all participating pharmacies would be registered with the FDA. In order to do so, they would have to be accredited, much the same as the Joint Commission (JCAHO) accredits hospitals and other health institutions here in the United States. After meeting a set of quality standards the mail-order pharmacy would be awarded accreditation and allowed to register with the FDA. They would then be listed as approved as foreign participating mail-order. Once all requirements are met, the FDA or another entity, would issue non-counterfeitable seals/emblems for these pharmacies to use when shipping packages into the US (through Custom). No seal, no entry in to the U.S. (suggest the system currently used by the U>S. Treasury to protect U.S, currency)

Note: Flex Products is a world leader in the development of optically variable technology for counterfeit deterrence. Their Optically Variable Pigment (OVP) security technology is currently utilized by over 87 countries, including the US and the newly designed $10, $20, $50 and $100 bills.

2. With regard to monitoring of the quality of drugs being shipped, a proxy with the country (Canada) could be established. There is no reason that we can not accept the standards that are equal or higher established by another country. No country should be allowed to participate that does not have at the very least a set of standards equal to ours regulatory agency [FDA}. Additionally provider whether mail-order or wholesale should be able to meet standards of U.S.-based oversight organizations similar to JCAHO (The Joint Commission on Accreditation of Healthcare Organizations)

3. The role of US and Canadian physicians and pharmacists could/should be worked out through the development of a cross-border professional associations association (licensure/registration and protocol development).

4. Private/Public partnerships should be developed in order to reduce the costs at the Federal level [while maintaining the oversight and input of the FDA].

Major/Potential Barriers to Access from Canada:

1. Major pharmaceutical manufacturers recent actions to discontinue supplies to wholesalers and pharmacists in Canada for export. Although they accuse others of breaking the law, what they are doing although legal, is very unethical. Many individuals have complying with their treatment plans for almost three years and now they propose to take away their medications. All in the name of quality and safety...their answer... a prescription drug benefit under Medicare. With no costs controls put in place on the front end.

2. No one central clearinghouse to manage the process on this side of the border exists currently. His should be the FDA's responsibility.

3. Personal (re)importation is still considered illegal and therefore puts agencies such as the FDA in a very awkward position [actually impossible position until the law is changed and

implemented]. They are charged with enforcing what currently exists and it's almost impossible to do so. Their recent threats to prosecute those of us that aid and that we may "be found civilly and criminally liable" was expected at some point, but is such an incredible waste of time and resources. This will serve to accomplish only one thing and that to hurt the very individuals that we profess to serve. Those individuals that are currently complying with their treatment plans. All of this in the name of quality and safety. [a drug that is not accessible because it is not affordable is neither safe or effective]

Final Note:

In reality the economic model regarding sales for the pharmaceutical industry actually improves: 1) they now get inconsistent sales (unstable purchasing currently exist). Although the new sales would be a lower price, it would result in stability of purchasing and consistent compliance would result, which according to their own mission is their objective. 2) data reported by the Canadian pharmacies to the FDA could be very beneficial to research and development efforts and the development of a meaningful Medicare prescription drug benefit.

This concludes my prepared remarks. Thank you again for this opportunity and I would be happy to try to address your questions.

Respectfully submitted,

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