

**Statement of the American Pharmacists Association (APhA)  
to the Department of Health & Human Services'  
Drug Importation Task Force  
May 14, 2004**

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Dr. Carmona, members of the Task Force, thank you for inviting the American Pharmacists Association (APhA) to appear before you this afternoon. APhA welcomes the opportunity to present the views of the nation's pharmacists on the issue of prescription drug importation. I am Susan C. Winckler, a pharmacist and an attorney, and Vice President, Policy & Communications and Staff Counsel for APhA. APhA's 50,000 members include pharmacist practitioners, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in advancing the profession.

The Task Force has been charged with a significant responsibility – to determine if prescription drug importation can be conducted safely and its potential impact on public health, medical costs, and the development of new medications. To make this determination, the Task Force has been asked to consider a number of important questions ranging from the scope and volume of imported drugs, the adequacy of safety protections, and potential liability issues, to the need for modifications in manufacturing and distribution technologies, the drug distribution system, and state and Federal laws.

It is clearly an arduous task – these are not easy questions to answer. It is difficult to assess the current scope and volume of prescription drug importation into the United States. Because importation is illegal and the products enter the country outside of our normal distribution system, there is no method to accurately track the quantity, or the effects of, all the medications that illegally enter the U.S. That said, it is clear that at least “interest” in importation is increasing, and others may present statistics on the actual prevalence of importation activity.

We understand why the interest in importation has escalated in recent years – many have rallied around importation as the “solution” to providing consumers access to lower cost prescription drugs. As pharmacists, we are concerned that some patients – especially seniors – face challenges in accessing valuable, but sometimes unaffordable, medications. Any pharmacist who has ever worked in a community pharmacy can vividly recall the dismay of having to tell a patient – especially a senior on a fixed income – the cost of their medication, knowing that the cost may be more than the patient can afford. The Association and our pharmacist members strongly support efforts to enhance patient access to prescription medications. However, we have significant concerns with proposals to “solve” the problem by expanding importation. Our concerns generally fit in two areas: the integrity of the drug product itself and the impact of importation on patient care.

### **The Integrity of the Medication**

The current U.S. drug distribution system was not designed to facilitate prescription drug importation. The system was designed to keep unapproved and potentially unsafe medications from entering the U.S. drug supply. Current U.S. laws and regulations were put in place after several critical incidents resulted in patient harm. When patients were harmed by contaminated or ineffective medications, Congress took action to protect patients. Those actions included requiring evidence of safety and effectiveness, controlling the production and distribution of products, prohibiting the importation of unapproved medications, and other efforts to limit the presence of counterfeit and contaminated medications. Intentionally circumventing the U.S. regulatory system creates an opportunity for mislabeled, mishandled, subpotent, or counterfeit drugs to make their way into the hands of patients.

### ***Opening the Door to the Closed Distribution System***

The Task Force has been asked to consider how limiting importation to specific countries will affect the ability to ensure drug safety. While some countries, such as Canada, may have a system to regulate medications comparable to our system, it is important to recognize that a program to import prescription drugs from Canada – no matter how carefully designed – will open the closed U.S. regulatory system to countries beyond Canada. “Opening the door” to Canada opens the door – period. Even if attempts are made to limit access to one country, or even to specific pharmacies, opening the system will create incentives for unscrupulous operators to penetrate the system. Consider, for example, how U.S. regulatory authorities will know that one package of prescription drugs crossing the U.S. border is “legitimate” (a prescription filled through an “approved” importation program) versus another package of prescription drugs entering the U.S. from an unapproved country or pharmacy. The perils of personal importation via the internet are many. If our closed system is opened, we must have strong measures—and enforcement behind those measures—to help decrease the likelihood of unscrupulous operators preying on consumers through their medicine cabinet.

With our current system, few consumers perceive a threat from counterfeit medications—and that perception matches reality. But even with the comprehensive U.S. system, counterfeit drugs have penetrated our system. According to the Food and Drug Administration (FDA), the number of counterfeit drug investigations has increased four-fold since the late 1990s.<sup>1</sup> For example, last year 11,000 boxes of counterfeit Epogen<sup>®</sup> and Procrit<sup>®</sup> were found on pharmacy shelves and in patients’ homes. Three months later, the FDA discovered five lots of counterfeit Lipitor.<sup>®</sup> These examples support the need for review and refinement of our existing safety net, not the expansion of efforts to circumvent or relax that system. Poorly constructed importation relaxes that system, and damages our safety net. Just three months ago, the FDA warned of counterfeit Ortho Evra<sup>®</sup> contraceptive patches that contain no active ingredient and were being sold online by a company based in India. By opening the door to importation, we increase the risk the introduction of counterfeit medications into our drug supply.

Pharmaceuticals are affected by multiple factors that may not be readily apparent to consumers. The majority of American consumers are probably not aware that differences can exist between

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<sup>1</sup> William Hubbard. Statement before the Senate Committee on Finance Subcommittee on Health Care and Subcommittee on International Trade. April 27, 2004.

versions of a medication with the same active ingredients. Medications obtained outside of the U.S. may contain different formulations – with differences in the amount of active ingredient or differences in the type of inactive ingredients— both of which can affect the product’s stability and how the product works. Because of these differences, any safe importation system must limit importation to *products* approved by the Food and Drug Administration, not merely products that contain the same, or similar, active ingredients. Medications are different—and minor differences matter.

Storage and shipping conditions can also affect drug stability and potency. Consumers who obtain their medications outside the U.S. have no way to know how their medications were handled. Was the medication maintained at the correct temperature? Was the medication stored in the correct type of container? Was the medication properly protected during shipment? These questions must be addressed to assure that the FDA-approved product reaches the consumer as intended.

### **Impact on Patient Care**

Importation not only weakens the U.S. system of medication regulation, it also directly impacts patient care. While much of the importation debate is driven by disparities in drug pricing, those disparities are evident only on the front end—when we only know the cost of the drug, not the value. The most expensive medication is the one that doesn’t work: in the situation where the drug doesn’t lower blood pressure appropriately, the consumer paid good money, but got no benefit. In addition to paying cash, they paid for it with their health as their condition went unmanaged. The value of a medication should be assessed after the consumer has used it, after consultation with their pharmacist and doctor to make the best use of it. But this collaboration is challenged in many importation scenarios.

Because of the stigma involved in importing medications, many patients do not tell their physician or pharmacist about medications they are securing outside of the U.S. This is understandable, but dangerous. Unless the patient provides this information, pharmacists and physicians have no way of knowing what a patient is taking. Pharmacists’ ability to identify drug-to-drug interactions is extremely hindered, if not completely prevented, without knowing about a patient’s entire medication regimen or the content and strength of a particular drug.

If a patient obtains medications from multiple sources – in this case through importation and a local pharmacy – neither the domestic nor international pharmacist has the patient’s complete medication profile. The pharmacist is unable to determine whether the new prescription will conflict with any other medications the patient takes, whether the new prescription has ingredients that duplicate a current prescription, or whether its mere presence suggests other medical problems for the patient that should be followed-up with the patient’s physician. This virtual blindness compromises the ability of physicians to care for their patients and the ability of pharmacists to partner with patients to improve medication use and advance patient care.

Problems also occur when a patient suffers unexpected complications or does not respond as expected to a medication. Consider a patient working with their local physician to treat their high blood pressure. The patient imports a faulty medication that has no, or little, active ingredient. It is unlikely the patient will physically feel anything different; unlikely he would actually notice any difference in the product. Later the patient visits the physician and a blood-

pressure reading shows that the medication is not working. Because of our trust in the medication supply, it is highly unlikely that the physician will consider that there was a problem with the medication. Rather, the physician will likely assume that the medication did not work and will consequently either increase the dose or choose another medication. This sets the stage for using a stronger, but potentially unnecessary, medication and increasing overall health care costs.

Any proposals to legalize importation must address concerns with coordination of care. Allowing the importation of unapproved products will exacerbate this concern; and supporting personal importation will continue to create challenges for individual health care professionals and their patients. All of these scenarios cloud the promise of improved health from medications.

### **The Need to Address Issues of Concern**

When you consider all of the risks associated with the importation of prescription drugs, just a few of which I describe, it appears foolhardy to consider haphazardly opening our borders to imported pharmaceuticals. Allowing importation carries the risk that mislabeled, mishandled, subpotent, or counterfeit drugs will reach the hands of our friends, our family, our neighbors. It also disrupts the connections and improvements we are trying to make in the health care system.

But this discussion is not just academic – we know that unapproved and potentially unsafe drugs enter our country today. Despite laws generally prohibiting importation by anyone other than the manufacturer, illegally imported prescription drug products arrive in mailboxes every day. For example, recent examinations of mail shipments at four mail facilities by the FDA and the U.S. Customs and Border Protection Bureau found that of 1,982 packages examined, 1,728 contained unapproved imported pharmaceuticals.<sup>2</sup> The products included so-called “foreign versions” of FDA-approved drugs that may vary from U.S. standards in potency and purity, improperly labeled drugs, controlled substances, recalled drugs, drugs requiring special storage conditions, and drugs requiring close physician monitoring. The FDA also found that many of the drugs were manufactured outside of the U.S. in countries such as Canada, Mexico, Costa Rica, India, Pakistan, New Zealand, Taiwan, Thailand, and others.

Do importing consumers know about these challenges? Likely not. Do their doctors and pharmacists? They probably know of the challenges at some level, but they are not likely considering them in the context of their patient population. This situation is unacceptable. If we continue to allow importation without safeguards to assure the safety and quality of the medications, we risk further weakening the U.S. system of medication regulation, a system that has stood as the strongest in the world. More importantly, consumers are risking their health.

The question the Task Force should examine is not ‘do we allow importation?’ The question should be ‘what do we do to assure the safety and the integrity of the U.S. drug supply?’ I see two options. One, we begin strictly enforcing current law that prohibits importation. Provide the FDA, the Drug Enforcement Administration, Customs Bureau, and other regulatory agencies the funds and resources necessary to enforce the law; and continue efforts to find other means of

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<sup>2</sup> Food and Drug Administration. Press Release: Recent FDA/U.S. Customs Import Blitz Exams Continue to Reveal Potentially Dangerous Illegally Imported Drugs. January 27, 2004.

increasing access to affordable medications. But this option isn't likely. As more than one commentator has announced, there are no 'bodies in the streets'—no documentation of a consumer being killed by importing drugs. While enforcement of our laws may once have been an option, it doesn't seem likely today. At a minimum, however, policymakers should avoid any further endorsement of this unregulated and unknown practice. Rather than endorsing this practice, we must continue to educate consumers on the risks. The status quo must change.

If the current law does not work, we are faced with the second option: developing a new system to assure the safety of our medication supply. A new system, regardless of whether or not it allows importation, must resolve several issues of concern to ensure that patients continue to receive safe and effective medications—and that they know how to use those medications. A new system must address the role of the FDA and the State Boards of Pharmacy in maintaining a safe drug supply, respect the patient-pharmacist-physician relationship, require valid prescriptions, assure consumer recourse for harm, prevent efforts to circumvent US health care professionals, include measures to limit counterfeit and contaminated drugs, and address the differences between FDA-approved medications and foreign products. Even this long litany of issues is not an exhaustive list of what must be tackled when evaluating a system to protect the U.S. drug supply and American consumers.

Prescription drugs, unlike so many other products, are not just another commodity – we ingest them to affect our bodies. They are one of the most valuable weapons we have in our health care arsenal today and we must treat them as such. As pharmacists, we rely on the quality of the U.S. prescription drug supply to provide our patients with safe and effective treatments. As the FDA does when it evaluates a new prescription drug, we must look at both the risks and the benefits and determine if the benefits outweigh the risks. Importation may provide the benefit of lower cost prescription drugs, but as currently practiced it appears that the benefits do not outweigh the potential risks. We caution the Task Force against recommending importation as an alternative method of drug distribution without appropriate safeguards—both in statute or regulation and in enforcement. At a minimum, any legalization of importation should be limited to drug products approved by the Food and Drug Administration and assure coordination of care with the consumer's doctor and pharmacist.

In conclusion, thank you for the opportunity to provide comments on this important issue. APhA appreciates the Task Force's commitment to fairly and comprehensively examine the wide range of issues surrounding the prescription drug importation debate. We offer our assistance to the Task Force as you continue your valuable work. Thank you.