Position Statement

Importation of Prescription Medications

The American College of Clinical Pharmacy believes that current systems for assuring the composition, quality, purity, safety, and packaging integrity of prescription medications that are imported into the United States are insufficient to justify their routine use in patient care.

Until such time as appropriate systems are developed and implemented, the existing legal prohibition against importation of prescription medications is in the best interests of patients' health, safety, and welfare.

There are significant and legitimate concerns regarding access to and cost of medications for many patients, including the elderly, the uninsured, and those living on fixed or poverty-level incomes. Such concerns should be addressed through policies and practices that increase access to and affordability of the U.S. medication supply. They should not be addressed by promoting the importation of medications that, while perhaps less expensive to purchase, may present both substantial risks and additional costs associated with adverse effects or therapeutic failures.

Policymakers, practitioners, the pharmaceutical industry, and other stakeholders should work collaboratively to establish reformed pricing policies that reduce the incentives, pressures, and temptations for the "commodity trading" atmosphere that currently exists in the pharmaceutical marketplace – and which drives much of the current interest in and support for importation.

The most expensive medication is the one that fails to achieve its intended therapeutic goal or causes significant adverse effects. Effective medication therapy management services provided by pharmacists can help assure enhanced economy, as well as safety and effectiveness, in the use of medications by patients.

Background:

For more than a decade, the increasing cost of prescription medications in the U.S. healthcare system has been a subject of major concern to health policy analysts, legislators, patients, insurers, and health professionals. As both the number of medications and their cost has grown, attention to the "price of drugs" issue has dominated a wide range of policy debates at the national level. From the era of generic drug legislation in the 1970's through the Medicare outpatient drug benefit bill enacted by Congress in late 2003, medication costs have often been the central element in discussions regarding expansion (or constraint) of medication benefits within government and private health plans or programs.

The issue has taken on a more urgent, and perhaps more sinister, turn within the past year or so as a result of several interrelated issues impacting the cost of medications:

- Explosive growth in the price of newer, "high-tech" medications, biotechnology products, and medication delivery systems;
- Increased reliance on prescription medications, especially in the expanding elderly population, as the primary treatment modality for most chronic diseases;
- Substantial price variations for pharmaceutical products for different purchasers and, in many cases, different nations;
- Use of the Internet for promotion, sale, and distribution (generally unregulated) of prescription medications, often (but not always) at prices substantially below those in the traditional U.S. health care system. Enhanced access to both product and pricing information via this mechanism has moved the debate on drug prices from the narrow realm of policymakers, providers, and insurers into the home of the average senior citizen or patient with a chronic disease who has computer access.

As a result of these events, the public and political pressure to "do something" about the price of prescription drugs has never been greater. Among the "somethings" that have attracted the most attention recently, importation of prescription medications from Canada and other nations has been embraced by a range of individuals and groups, from patient advocacy organizations to state governors, as one method to blunt the impact of rising medication costs. Some have suggested that efforts to "legitimize" importation through policy proposals that seek to reduce Medicaid drug costs (e.g., Illinois, Vermont) by encouraging purchasing of imported pharmaceuticals demonstrates the power of the issue to the public and its potential to significantly impact existing laws, regulations, and policy.

Recent efforts in Congress (e.g., H.R. 2427 – The Pharmaceutical Market Access Act of 2003) to promote and/or legalize importation have been met to this point with resistance by the Food and Drug Administration, many health professional associations, and the pharmaceutical industry – each for their own, generally understandable, reasons. The recently passed Medicare outpatient drug benefit legislation addresses the issue ineffectively, and is unlikely to provide any substantive guidance on the issue as the drug benefit is designed and implemented over the next two years.

ACCP's position reflects the belief of its leadership that expanded importation of prescription medications, under current systems of oversight, quality control, and product distribution security, presents a risk to patients, however difficult to quantify, that outweighs the economic savings that may be achieved. In effect, this approach to addressing the increasing cost of medications is a symptomatic one that fails to address the primary pathologies of the problem and runs the risk of making the "cure" more problematic than the "disease." It is vital, therefore, that the conditions and policies that contribute to the current allure of prescription drug importation be recognized and addressed by policymakers in truly substantive ways. ACCP welcomes the opportunity to begin to work with interested parties to address these issues.

The integrity of the nation's medication supply is an essential, even foundational, element of the larger objective of rational, safe, and effective medication use for patients – an objective to which the members of ACCP commit their professional efforts each day. The value of a clinical pharmacist's judgment and skills in managing the complex drug therapy of an individual patient is negated, if not irrelevant, in a system of care in which there is a significant possibility that one or more of the medications that the patient is consuming is NOT, in fact, what she and her health care providers believe it to be, whether in content, effectiveness, or pharmaceutical quality. We must work to assure that economic pressures and political responses do not override quality, clinical judgment, and, most important, patients' best interests.

Adopted by the ACCP Board of Regents
January 2004