

NHPF Forum Session
Meeting Announcement

**NATIONAL
HEALTH
POLICY
FORUM**

**The Economics of
Prescription Drug Importation**

A DISCUSSION FEATURING:

Colin S. Baker
Associate Analyst
Health and Human Resources
Division
Congressional Budget Office

Margaret Nowak
Analyst
Health Cost Estimate Unit
Congressional Budget Office

Randall Lutter, PhD
Chief Economist
Food and Drug Administration

Stephen W. Schondelmeyer, PhD
*Professor of Pharmaceutical
Economics*
University of Minnesota College
of Pharmacy

**Wednesday,
June 9, 2004**

11:45 am — *Lunch*

12:15–2:00 pm — *Discussion*

**National Guard Memorial
Building**

One Massachusetts Avenue, NW
Walsh-Reckord Hall of States —
First Floor

To register:

Please call Tiombé Diggs at
202/872-1392 as soon as
possible. Space is limited.

**For additional
information on this topic:**

See the report by the Congressional Budget Office, *“Would Prescription Drug Importation Reduce U.S. Spending?”* (April 29, 2004); available at <http://www.cbo.gov/showdoc.cfm?index=5406&sequence=0>.

THE GEORGE
WASHINGTON
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The Economics of Prescription Drug Importation

The recent growth in prescription drug spending in the United States, totaling 10.5 percent of health expenditures in 2002, has sent individuals and state and federal policymakers in search of more affordable prescription drugs. Many proposals have focused on bringing prescription drugs from other countries into the United States, thereby importing not only the drugs but the savings associated with their lower prices. Prices for brand name drugs¹ in Canada, for example, can be as much as 50% below prices in the United States. Though individuals have pursued opportunities to import prescription drugs through the mail and by traveling to Canada and Mexico, many policymakers have been hesitant to broaden this practice through commercial importation. Significant debate has arisen about whether such initiatives will, in fact, lead to an adequate supply of safe and affordable drugs for American consumers.

The U.S. Food and Drug Administration (FDA) and others have expressed concern about the safety of drugs being imported from other countries. They cite FDA's lack of authority and resources to protect consumers from drugs that may be potentially dangerous, including those that are counterfeit, improperly labeled, expired, or not accompanied by appropriate directions for use. Though the importance of safety in the importation debate is recognized, this meeting will focus exclusively on the economics of prescription drug importation, similar to the Congressional Budget Office (CBO) report on which it is based.

SESSION OVERVIEW

This meeting will explore the potential economic impact of prescription drug importation, including its potential effect on drug prices, supply, spending, and research and development. Building upon a recent Congressional Budget Office (CBO) report, "Would Prescription Drug Importation Reduce U.S. Spending?" the meeting will examine recent developments in the ongoing debate over drug importation, including passage of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003.

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Under current law, it is generally illegal to import prescription drugs from other countries. Recent legislative activity at the federal level, however, has sought to change this. A bill (H.R. 2427) that would permit the importation of prescription drugs from 25 countries was approved earlier this year by the U.S. House of Representatives, but it subsequently stalled in the Senate. Several other proposals have been introduced or are under consideration. The Medicare Prescription Drug, Improvement, and Modernization Act (MMA), which was enacted in late 2003, contains provisions that would allow the importation of prescription drugs from Canada, but only if certain conditions are met. One of these conditions requires the Secretary of Health and Human Services to certify that such importation will “(A) pose no additional risk to the public’s health and safety; and (B) result in a significant reduction in the cost of covered products to the American consumer.” This certification has not yet been provided by the secretary.² The secretary is also required to complete a study on drug importation that will examine a broad range of issues from safety to intellectual property rights. A task force has been named to explore these issues and make recommendations to the secretary.

Many state and local officials, responding to the demands of their constituents, have chosen not to wait for federal action and are pursuing programs to import lower cost drugs for city and state employees, retirees, Medicaid recipients, and for use in state prisons and hospitals. Despite warnings by FDA against such practices, interest in drug importation continues to grow. Nearly half of all states are exploring opportunities—either individually or collectively—to import prescription drugs from Canada.

As the pursuit of cheaper imported prescription drugs continues from the individual level to the federal level, the question remains: Would wide-scale importation of prescription drugs into the United States result in significant savings for purchasers?

CBO’s analysis begins with the premise that the prescription drug market is unique for a number of reasons. The research and development (R & D) necessary for the creation of a new drug is costly and time-consuming, though the true cost is the subject of significant debate. In order to protect their investment in R & D, drug manufacturers are awarded patents that give them the exclusive right to sell their product for a number of years after it is approved. The exclusive rights granted during the life of a patent lead to imperfect competition within the prescription drug market. Some policymakers have expressed concern that U.S. purchasers disproportionately finance the R & D associated with the development of new drugs. In addition to these considerations, the level of regulation required also distinguishes the prescription drug market. In many countries including the United States, new drugs must meet safety and efficacy

standards; the United States also requires that drugs be approved for distribution in certain forms, dosages, and strength levels, and be produced in certain FDA-approved facilities.

The CBO report describes prescription drug importation as a form of *parallel trade*, or “the legal movement of products across borders without the explicit consent of the manufacturer, usually in response to price disparities.” Parallel trade for some goods may offer savings, but those characteristics that make the prescription drug market unique are also likely to limit the savings that could be achieved through this type of trade. As a result, parallel trade within the prescription drug market could possibly lead to higher prices abroad rather than lower prices in the United States. Furthermore, an adequate volume of importable drugs would need to be available in order for parallel trade to result in significant savings. The greater the volume, the greater the likelihood of success. In response to increased importation, both foreign governments and drug manufacturers could act to restrict the volume of drugs available to the United States, thus limiting the success of any commercial reimportation effort to produce meaningful savings, according to CBO.

KEY QUESTIONS

The Forum session will review the CBO’s findings and explore the economic impact of widespread importation of prescription drugs into the United States. Issues to be discussed include the following:

- What would be the short- and long-term impact of drug prices in the United States if drug importation were allowed? On prices in foreign countries?
- Would there be sufficient sustainable drug volume from other countries to meet the needs of the United States?
- Could the volume of drugs available to the United States be limited by drug manufacturers and by export restrictions of foreign governments?
- What impact would wide-scale importation of lower-priced prescription drugs into the United States have on research and development by drug manufacturers?
- What impact would drug importation have on the discounted prices enjoyed by some sectors in the United States (e.g., beneficiaries of Veterans Affairs and Medicaid programs, large purchasers)?
- The need for new packaging and labeling and the increased liability to intermediaries are likely to increase some costs for imported drugs. How significant will these added costs be?

SPEAKERS

Colin S. Baker, an associate analyst in the Health and Human Resources division of the Congressional Budget Office and lead author of the CBO report, will provide an overview of the report, including a description of the prescription drug market, an explanation of drug importation as a form of “parallel trade,” and an overview of the anticipated economic impact on U.S. drug spending if importation were permitted. Baker’s main area of focus at CBO is the prescription drug market. In addition to his work on drug importation, he has completed an analysis of prescription drug rebates received by the Medicaid program.

Margaret Nowak, an analyst in the Health Cost Estimate Unit of the Congressional Budget Office, will provide an overview of the cost estimates that provided the basis for the CBO, including the expected savings from H.R. 2427, the importation bill that passed the House of Representatives earlier this year. Nowak’s main areas of focus at CBO are Medicare and prescription drug issues.

Randall Lutter, chief economist at the Food and Drug Administration, will provide a regulatory perspective on the economics of prescription drug importation. In his current role at the FDA, Lutter directs economic analyses of regulations and other policy initiatives. Before joining FDA, he was resident scholar at the American Enterprise Institute and fellow at the AEI–Brookings Joint Center for Regulatory Studies. He has also served at the Office of Management and Budget and at the President’s Council of Economic Advisers.

Stephen W. Schondelmeyer is professor of pharmaceutical economics in the College of Pharmacy at the University of Minnesota and director of the Prime Institute, which focuses on economic and policy analysis related to the role of pharmaceuticals in society. Schondelmeyer will react to the CBO report and provide his own assessment of the impact that importation is likely to have on drug spending in the United States. Schondelmeyer’s areas of expertise include pharmacy practice management, prescription drug reimbursement, drug benefit plan management, pricing patterns of the pharmaceutical industry, and pharmacoconomics and outcomes management. He has published many papers and his research has been widely quoted in the scientific, policy and public press.

ENDNOTES

1. Generic drugs are typically cheaper in the United States than in Canada.
2. The former Secretary of Health and Human Services, Donna Shalala, similarly did not certify the safety of prescription drug imports.