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Prescription Drug Importation: First, Do No Harm

(This is the second in a series of RPC papers focusing on the Medicare Modernization Act and its ability to reduce rising prescription drug costs.)

- Executive Summary -

- As out-of-pocket prescription drug costs rise for Americans, questions have been raised as to why U.S. consumers pay more for prescription drugs than do their foreign neighbors.
- Many foreign countries impose strict price controls on pharmaceuticals, making the cost of such drugs less expensive for their citizens. Yet, foreign price controls lead to higher drug costs in the United States as the fixed costs of research and development (R&D) for expensive new breakthrough therapies are shifted to American consumers.
- Some policymakers have proposed reopening the Medicare Modernization Act to permit the importation of pharmaceuticals from overseas as an alternative means to reduce drug prices for Americans.
- The Medicare Modernization Act rejected of the use of government price controls.
- Drug importation is an indirect form of a government-imposed price control. The Medicare law's rejection of this approach was predicated on the understanding that consumers will suffer if manufacturers fail to pursue innovative R&D.
- Extensive research indicates that drug importation will lead to grave market distortion and possibly risk consumer health.
- Congress should carefully consider experts' warnings and allow the new Medicare law – only four months on the books – the opportunity to work. The Medicare Modernization Act contains several important cost-reduction provisions. The first of these is the availability of new prescription drug discount cards as of May 3. Other provisions in the law that will address drug costs include better trade strategies, quicker approval of generic drugs, and more competitive price negotiations.

Introduction

The Medicare Modernization Act (P.L. 108-173) has been on the books only a few months, with many of its provisions yet to be fully implemented, but some – skeptical that it will reduce the price of prescription drugs in a timely manner – already are proposing to reopen the law. The alternative most often suggested is drug importation from foreign countries.

The Medicare law includes an array of policy changes designed to reduce the price of prescription drugs – not just for Medicare beneficiaries but, in some cases, for all individuals. These measures include faster market approval of less-expensive generic drugs, incentives to negotiate the lowest possible prices for beneficiaries, and a greater emphasis on pharmaceutical trade negotiations with foreign countries. When implemented, these and other initiatives should result in lower cost drugs for all Americans.

Specific to Medicare beneficiaries, the law’s policy changes include substantial subsidies for low-income seniors and disabled beneficiaries, as well as the means to increase competition among private health plans, which ultimately will result in a richer and greater selection of benefit packages.

Shortly after the law’s enactment and before any provision could be implemented, one Democratic opponent of the bill introduced a measure allowing the importation of pharmaceuticals from foreign countries, stating that this was the best means to obtaining lower drug prices.¹ This paper will review the rationale behind the Medicare law’s price-reduction measures, and examine the implications of an alternative approach – drug importation.²

A Look at What is Driving the Debate

According to the Centers for Medicare and Medicaid Services (CMS), “prescription drug spending is projected to be the fastest-growing sector” of the health care industry.³ Given the growing reliance on pharmaceutical therapies – as compared to traditional forms of treatment such

¹“Senator Edward M. Kennedy Introduces the Health Security and Affordability Act,” Statement, January 22, 2004. See also footnote 8 for a listing of other bills that have been introduced.

²For additional discussion of the new Medicare law, refer to Senate Republican Policy Committee paper, “Pharmaceutical Price Controls Abroad: An Unfair Trade Policy,” November 6, 2003.

³Centers for Medicare and Medicaid Services, “2003 Expected to Mark First Slowdown in Health Care Cost Growth in Six Years,” Press Release, February 11, 2004. The CMS health care spending projection data found that while prescription drug spending is expected to decline over the next three years due to slower growth in drug prices, expiration of patent protection for several top-selling drugs, and increased use of multi-tiered copays, drug spending is still the fastest-growing sector of the health care industry.

as hospitalization – many insurers have increased drug copayments and deductibles as one way to grapple with the rising demand for prescription drugs. However, the increase in out-of-pocket drug expenses – accompanied by the prevalence of drug-pricing information available via the Internet – has led to a new level of cost-consciousness. In turn, many have questioned why U.S. consumers generally pay more for prescription drugs than do their foreign neighbors.

A quick look overseas helps explain why drug prices are less expensive there. Most foreign countries, as part of their national health care systems, dictate prices through government controls. This is necessary to keep their health care costs within government budgets. The lower prices abroad, in turn, have led to higher prices in the United States as the fixed costs of research and development (R&D) for costly new breakthrough drug therapies are shifted to American consumers.⁴

The intent of the new Medicare law was to alleviate this burden by using competition and incentives to reduce, as much as possible, the costs to American consumers, while requiring U.S. trade negotiators to be more aggressive in getting foreign governments to pay their fair share. The rejection of U.S. government price controls in the new law was predicated on the understanding that someone has to pay for the true cost of R&D, or it will not occur – to the detriment of consumers everywhere. Government price negotiations were expressly rejected by the Medicare conferees due to their fear that establishing such controls would be detrimental to innovation. (The provision contained in the Medicare law that prevents price controls is commonly referred to as the noninterference clause.) If the federal government interfered in sensitive price negotiations, effectively a ceiling would be set for pharmaceuticals and prices would be prohibited from fluctuating with the market’s changing demands.⁵

State Efforts to Reduce Drug Prices

Currently, the importation of prescription drugs from overseas by individuals, wholesalers, and pharmacists is prohibited unless such drugs are certified to be safe and cost-effective.⁶ Despite the prohibition, the price differentials between the United States and elsewhere have led to a proliferation of online foreign pharmacies as consumers search for ways to reduce their personal prescription drug costs. State and local government entities, also intrigued by potential prescription drug cost savings, have begun to look abroad as a means for reducing their health care

⁴Mark B. McClellan, M.D., Ph.D., then Food and Drug Administration Commissioner, speech before the First International Colloquium on Generic Medicine, Cancun, Mexico, September 25, 2003.

⁵For additional details, please refer to RPC paper, “A Look at the Role of the Medicare Non-Interference Clause: Competition vs. Price Controls,” March 9, 2004.

⁶Congressional Research Service, “Prescription Drug Importation and Internet Sales: A Legal Overview,” March 5, 2004, p. 8. The Medicine Equity and Drug Safety (MEDS) Act of 2000 allowed the importation of drugs from specified foreign countries by pharmacists, wholesalers, and pharmacists but only if the HHS Secretary can certify the safety and cost-effectiveness. The Medicare Modernization Act only permitted the importation of drugs from Canada.

expenditures on behalf of all residents or for specific populations, such as prison inmates or Medicaid recipients. According to the National Conference of State Legislatures, at least 14 state legislatures so far this year have considered drug importation proposals in some form. Examples of states' efforts include the establishment of web sites that link state residents to Canadian pharmacies, or in some cases, the providing of coverage for prescription drugs purchased from these pharmacies as part of a state or local government employees' health plan, or even the purchase of Canadian pharmaceuticals in bulk for certain populations.⁷

Nationwide Proposals

The drug importation debate is not contained within individual states' borders. At least 15 bills have been introduced in the 108th Congress to implement a nationwide drug importation policy, including broad-based commercial importation unimpaired by the federal safety and cost-effectiveness certification requirement as stipulated by current law.⁸ The impact of a nationwide policy is discussed below.

The Implications of Drug Importation: the Integrity of the Drug Supply

While the foreign price tag for certain drugs can be attractive, policymakers and consumers must fully examine the implications associated with drug importation because the price tag alone can be deceiving.

HHS Task Force on Drug Importation to Report its Findings Later This Year

The new Medicare law mandated that a comprehensive evaluation be conducted to ensure the integrity of our nation's drug supply. One of the immediate responses to this mandate was the creation of the Task Force on Drug Importation.⁹ This task force, chaired by U.S. Surgeon

⁷"States Pushing Drug Importation Plans," *National Journal*, February 23, 2004.

⁸See: "The Pharmaceutical Market Access and Drug Safety Act," introduced by Senator Byron Dorgan on April 21, 2004. Similar measures include "The Reliable Entry for Medicines at Everyday Discounts through Importations with Effective Safeguards Act," introduced by Senator Grassley; and "The Pharmaceutical Market Access Act of 2003," introduced by Congressman Gutknecht. At least 12 other drug importation measures have been introduced during the 108th Congress, based information provided by the Congressional Research Service.

⁹U.S. Department of Health and Human Services, "HHS Names Members to Task Force on Drug Importation," Press Release, March 16, 2004. The task force has held three listening sessions (March 19, April 5, and April 14).

General Richard H. Carmona, M.D, currently is studying and identifying existing safety and cost-effectiveness concerns associated with drug importation. It must report its findings to Congress by December 10.¹⁰

Prior to the passage of the Medicare reform law, the Food and Drug Administration (FDA) had discovered ample evidence of prescription drug products that had been shipped via Canada to U.S. consumers but that were packaged or stored incorrectly, as well as knowingly counterfeit drugs that made their way across the U.S. border (details of which are documented below). Such findings provided one reason why the Medicare conferees unanimously agreed that a comprehensive evaluation was necessary. Many would argue that these findings also represent an important reason why it is critical that Congress wait for the Task Force to report its findings before acting on drug importation legislation.

Previous Government Findings on the Potential Dangers of Imported Drug Shipments

During 2003, the FDA and the U.S. Customs and Border Protection (CBP) conducted a series of spot checks of international mail shipments, and discovered not only unapproved drugs coming across the U.S. border, but also potentially dangerous imported drugs. According to then FDA Commissioner Mark B. McClellan, of the approximately 1,100 initial spot checks conducted, agents found several unapproved drugs, such as alti-azathioprine – an immunosuppressant drug that can cause severe bone marrow depression. The unapproved drugs were shipped from Canada, India, Thailand, and the Philippines.

Also documented by FDA were findings from a second round of approximately 2,200 spot checks, which included several FDA-recalled drugs, such as dipyron – a drug that can cause fatal blood disease. Other discoveries included controlled substances, such as Codeine, Valium, and anabolic steroids, as well as drugs that require special packaging but were shipped in “loose sandwich bags, tissue paper, or envelopes.”¹¹ Most of these drugs arrived from Canada, Mexico, Japan, the Netherlands, Taiwan, Thailand, and the United Kingdom.

The FDA and CBP examinations were conducted in less than a dozen cities. The results suggest that U.S. consumers could be subjected to even greater danger, possibly related to homeland security, if drug importation is considered legal and available on a much broader basis. For instance, HHS Secretary Tommy Thompson stated last fall, “We need to be cautious about further opening up our borders to medicines coming into the country, especially given the world

¹⁰While the Medicare law created a deadline for the report of December 2004, HHS Secretary Thompson has recently stated his hopes that the task force may issue its report as early as this summer.

¹¹Statement of Dr. Mark B. McClellan, then Commissioner of the Food and Drug Administration, before the Senate Committee on Commerce, Science, and Transportation, March 11, 2004. All examples mentioned above are included in Dr. McClellan’s testimony. Spot examinations were conducted in Miami, New York (JFK), San Francisco, Carson, Buffalo, Dallas, Chicago, Seattle, Memphis, and Cincinnati international mail facilities.

we live in today.”¹² A year earlier, Elizabeth G. Durant, executive director of trade programs for the Customs Service, issued a similar warning:

“A disturbing trend is the increase in bulk shipments through the mail indicating that these products could be making their way to pharmacy shelves. . . . From an overall perspective, a spiraling volume of goods at our borders has put immense pressure on our ability to enforce the nation’s laws and protect the borders against the threat of terrorism. Although we have taken some positive steps, successfully identifying and handling imported pharmaceuticals presents a daunting task for Customs.”¹³

Resources Insufficient to Conduct Safety Inspections

In addition to potential health threats, recent questions have been raised as to whether the federal government has the necessary resources to conduct sufficient safety inspections of drug shipments. Last year, the FDA provided insight into this question during testimony about the growing volume of counterfeit pharmaceuticals. John M. Taylor, associate commissioner for regulatory affairs at FDA, stated:

“With the available resources and competing priorities facing the agency, experience shows that we are unable to visually examine the large volume of parcels containing prescription drugs that arrive each day. The agency responded to the challenge by employing a risk-based enforcement strategy to target our existing enforcement resources effectively in the face of multiple priorities, including homeland security, food safety, and other important tasks. However, this system is already overwhelmed by the number of incoming mail packages that must be evaluated, and this state of affairs presents a significant ongoing challenge for the agency.”¹⁴

The Canadian Safety Myth

Most drug importation proposals make reference to Canada as initial exporter, with the possibility of allowing shipments from other countries at a later date.¹⁵ Canadian pharmaceuticals often are perceived as safe and effective, coming just over the northern border as opposed to drugs being packaged in some far-away place that is unfamiliar to Americans. Clearly, some states have

¹²“Ask the White House,” an online interactive forum with HHS Secretary Thompson, September 25, 2003.

¹³U.S. Senate Special Committee on Aging Hearing, titled “Buyer Beware: Public Health Concerns of Counterfeit Medicine,” July 9, 2002.

¹⁴U.S. Senate Commerce, Science and Transportation Committee Hearing on the Cost of Prescription Drugs and Drug Importation, November 20, 2003.

¹⁵See, for example, “The Pharmaceutical Market Access and Drug Safety Act,” introduced by Senator Byron Dorgan, and other legislative proposals listed under footnote 8.

demonstrated their preference for Canada with the creation of web sites that direct consumers to Canadian pharmacies, as discussed earlier. The new Medicare law also expresses this preference by identifying Canada as the only country whereby pharmacists, wholesalers, and individuals can import prescriptions upon certification of safety and cost savings.¹⁶ Even a quick word search on the Internet finds over 200,000 citations for online Canadian pharmacies.¹⁷

However, despite the seeming consensus that Canadian drugs are safe and are packaged similarly to U.S. standards, there is growing concern that Canada could simply become a means for trans-shipment of such products that do not originate in actual Canadian pharmacies as assumed. The FDA repeatedly has issued warnings about unknown sources when purchasing pharmaceuticals online, emphasizing that “American consumers cannot be certain that the [imported] drugs they receive are actually dispensed by the person from whom they are ordered.”¹⁸ The agency has evidence of some online web sites, which contain phrases like “the most trusted pharmacy in Canada,” that actually are registered elsewhere, in places such as Barbados and Israel.¹⁹

With the increased reliance on prescription drug therapy, U.S. consumers should have confidence that the treatments furnished to them are safe and effective. However, given current evidence, this confidence can quickly erode if the United States opens its borders to accept medicines shipped from around the world. Homeland security, mislabeling, and tampering of imported drugs are real concerns. Therefore, policymakers must recognize that imprudent legislative solutions to reduce the price of prescription drugs could, in fact, endanger the integrity of the nation’s drug supply. Even if additional resources are provided to the FDA, it seems unlikely, based on the above testimony, that the agency could quickly provide oversight that would be sufficiently vigilant.

Implications of Drug Importation: Protecting Drug Innovation

In addition to safety concerns from proposed legislation, consumers should be concerned about the effect of importation on drug innovation. Without robust R&D, new drugs will remain undiscovered or unavailable. And, importation of cheaper drugs will reduce capital available for such R&D.

¹⁶Medicare Prescription Drug, Improvement, and Modernization Act of 2003 Conference Report (108-391, section 1121). Printed November 21, 2003.

¹⁷Web search for “Canadian pharmacy websites” led to 231,000 listings. Conducted on April 21, 2004, using www.google.com.

¹⁸U.S. Food and Drug Administration Statement by William K. Hubbard, Associate Commissioner for Policy and Planning, before the House of Representatives Government Reform Subcommittee on Human Rights and Wellness, June 12, 2003.

¹⁹U.S. House of Representatives Energy and Commerce Subcommittee on Oversight and Investigations Hearing, June 24, 2003.

Importation Could Result in Adverse Economic Consequences

Last fall more than 180 economists, including Nobel economist Milton Friedman, issued an open letter to Congress regarding drug importation and its adverse economic consequences.²⁰ Their primary concern was that it would result in the indirect imposition of foreign price controls in the United States. They contend that if drugs are imported from foreign countries, then the foreign price essentially sets the U.S. price. According to Stuart E. Eizenstat, former Clinton deputy Treasury secretary (and also a former undersecretary of Commerce), such a policy could cause significant market fluctuations, especially when importing large quantities for public consumption because, “in effect, it allows the ‘dumping’ of [foreign] goods into the U.S. market, which U.S. trade laws expressly guard.”²¹

Paradoxically, economists and academics at a recent drug importation conference warned that importation would fail to achieve the significant savings predicted by proponents. In addition, concerns were raised during the conference that the supply of drug products to U.S. consumers would be restricted because pharmaceutical companies would be unwilling to ship large volumes to Canada, knowing that many of the products were to be imported back into the United States.²²

Threats to a Robust Research and Development Environment

Of equal concern to market disruptions is the possibility of suppressed medical innovation – not just related to patented (also known as brand-name) pharmaceuticals but to generic drugs as well. According to the Generic Pharmaceutical Association, “FDA-approved generic drugs account for more than 51 percent of all prescriptions filled in the United States.” These drugs provide substantial savings to Americans especially since they “represent less than eight cents of every dollar consumers spend on prescription drugs.”²³ If a nationwide importation policy were adopted, the incentive to produce less expensive – but equal-quality – generic drugs would be lost.

In addition to the pharmaceutical market, biotech products also could be adversely affected. For instance, the role of biologics has quickly transformed the medical landscape as science looks for less invasive treatments by using certain proteins in order to treat rare, and often fatal, cancers and other diseases. The biotech industry has exploded to \$30 billion in sales per year – an

²⁰“Milton Friedman and Many Others on the Consequences of Price Controls,” Tech Central Station, November 20, 2003.

²¹Letter by Stuart E. Eizenstat to Speaker Hastert, July 11, 2003.

²²Press coverage of the Reimportation of Pharmaceuticals: Economic and Policy Implications Conference sponsored by the University of Michigan College of Pharmacy and AstraZeneca Pharmaceuticals, Inc., on April 20, 2004.

²³Generic Pharmaceutical Association, “More Generic Pharmaceutical Utilization, Not Unregulated Drug Importation, Answers America’s Drug Cost Crisis,” testimony before the HHS Task Force on Drug Importation by the, April 5, 2004.

example of its growing presence in the nation's health care delivery system.²⁴ However, these compounds are the most expensive to research and develop. Given the promise of such breakthrough medicines, it would be shortsighted and a grave disservice to U.S. consumers if policymakers were to implement a nationwide drug importation policy, specifically a price-control policy that hampers future investment.

Finally, another segment impacted by price control policies is medical technology. Innovative medical technologies offer critical forms of treatment in today's health care environment. However, strict government pricing mechanisms can cause significant delay or, in some cases, deny patients access to state-of-the-art medicine. For example, in France, medical technologies in private hospitals are reimbursed at government-determined rates and also subjected to government-determined volume limits. Similar artificial price limits are being enforced in Japan, Korea, and Taiwan through a process referred to as reference pricing.²⁵ This process establishes a government-imposed price that is artificially based on prices in other countries. The danger of this approach, however, is that governments may fail to capture the true cost of care in their own country.

Congress cannot afford to overlook these examples. Study after study documents the ill effects of government price controls on market innovation. Research shows that in countries in which governments control the price of pharmaceuticals, manufacturers often delay the launch of a new drug product rather than accept a low price.²⁶ Moreover, manufacturers will be reluctant to invest the necessary resources to explore unknown but promising medical advances since they would be unable to recoup their costs associated with the expense of R&D. European countries have witnessed the exodus of their own R&D pharmaceutical functions to markets with less government intrusion, such as the United States – an important potential side effect recently raised by the *Wall Street Journal* that must be taken into account if a nationwide importation policy is pursued.²⁷

²⁴Testimony Before the HHS Task Force on Drug Importation by Bruce L. Downey, Chairman and Chief Executive Officer of Barr Pharmaceuticals, Inc., April 5, 2004.

²⁵Both examples are contained in written testimony submitted by the Advanced Medical Technology Association (AdvaMed) for the Subcommittee on International Trade and Subcommittee on Health Joint Hearing, titled "International Trade and Pharmaceuticals," April 27, 2004.

²⁶Patricia M. Danzon, Y. Richard Wang, and Liang Wang, "The Impact of Price Regulation on the Launch Delay of New Drugs – Evidence from Twenty-Five Major Markets in the 1990s." National Bureau of Economic Research, July 2003.

²⁷*Wall Street Journal*, Review and Outlook, "Drug Wars," April 26, 2004.

The New Medicare Law Should Be Allowed the Time to Show Results

Given the negative implications of a widely expanded drug importation program, as detailed above, policymakers should exercise patience and give the new Medicare law a chance to work before dismissing its reform efforts. That law is only four months old, and most of its provisions that could reduce prices have yet to be implemented. The first of such provisions in the new law is set to be implemented on May 3, 2004.

On that date, seniors and disabled Medicare beneficiaries will have their first opportunity to receive drug discounts when they begin applying for Medicare-approved cards for use at participating pharmacies.²⁸ The benefit: Seniors will be able to obtain cheaper drugs in their own community rather than risk their health in obtaining potentially dangerous products shipped from overseas. The private sector has responded to the demand by offering seniors an array of cards designed to meet seniors' specific health care needs. It is expected that seniors will save up to 25 percent from current prices. The savings will be even greater for low-income beneficiaries because they will be eligible for an annual \$600 credit.

Conclusion

Ample testimony from government officials and economic advisors suggests Congress should weigh the potential benefits of the new Medicare law against the consequences of a drug-importation policy. The HHS Task Force on Drug Importation is in the process of learning more from consumers and experts alike. It would be wise for Congress to receive that task force report before opening the new law. U.S. trade negotiators also are just beginning to develop and pursue trade strategies that reduce drug costs. Finally, the Medicare program is on the verge of providing beneficiaries with a historic, voluntary prescription drug benefit that will provide significant cost-savings.

Congress need not act in haste. It would be prudent to give these initiatives a chance to produce results before possibly disrupting the market and risking consumer health.

²⁸U.S. Department of Health and Human Services, "HHS Gives Seal of Approval to Medicare Drug Discount Cards," Press Release, March 25, 2004. Discounts will be available June 1.