



**TESTIMONY BEFORE THE
SUBCOMMITTEE ON INTERSTATE COMMERCE,
TRADE, AND TOURISM
OF THE
U.S. SENATE COMMITTEE ON COMMERCE, SCIENCE,
AND TRANSPORTATION
ON
POLICY IMPLICATIONS OF PHARMACEUTICAL IMPORTATION
FOR U.S. CONSUMERS**

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AARP is pleased that the Committee is moving forward with the issue of prescription drug importation. Congress has been considering legislation to provide for importation of lower-priced prescription drugs for well over a decade, and we strongly urge you and your colleagues to take action this year to enact S. 242, the Pharmaceutical Market Access and Drug Safety Act. We believe this legislation includes measures to ensure the safety of imported prescription drugs, while at the same time allowing Americans to gain access to lower-priced prescription drugs.

Prescription Drug Prices Continue to Rise at Unsustainable Rates

Prescription drug costs continue to rise. Recent reports estimate that total spending on health care is expected to double by 2016, and much of this is due to rising prescription drug costs.¹

A recent AARP study revealed that, on average, pharmaceutical manufacturer prices for the 193 brand name drugs most widely used by older Americans rose at nearly twice the rate of general inflation in 2006.² Reversing the trend between 2004 and 2005, when the average rate of increase in manufacturer drug prices fell, the 2006 average growth rate of 6.2 percent represents an up-tick from the 2005 average increase of 6.0 percent. For the 153 brand-name drugs that were in the market since 2000, this translates into a cumulative average price increase of 53.6 percent, over two-and-one-half times the general inflation rate of 20.1 percent over the same period.³

The new Medicare prescription drug benefit is helping tens of millions of Medicare beneficiaries better afford their prescription drugs. However, even with

¹ John A. Poisal, et al., Health Spending Projections Through 2016: Modest Changes Obscure Part D's Impact, *Health Affairs*, 21 Feb. 2007.

² David J. Gross, Leigh Gross Purvis, and Stephen W. Schondelmeyer, *Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Older Americans, 2006 Year-End Update*, AARP Public Policy Institute Data Digest #DD154 (Washington, DC: AARP), March 2007.

³ Id.

this new program, Medicare beneficiaries are still feeling the effects of rising prescription drugs costs in the form of the higher premiums, deductibles, co-payments and – for some beneficiaries – lack of coverage in the donut hole.

Medicare beneficiaries are not the only group impacted by rising prescription drug prices. Escalating prescription drug prices continue to hamper employers' ability to provide health insurance coverage for their workers and families. In addition employers are increasingly eliminating or curtailing their retiree prescription drug coverage.

Pressures also continue to squeeze public programs at both the state and federal level. Rising drug prices also plague Medicaid, and put pressure on states' ability to maintain current coverage levels. These prices also hamper states' ability to expand eligibility to meet the increasing need as fewer employers provide access to affordable health care coverage.

Finally, rising prescription drug prices particularly hurt the almost 47 million Americans who lack health insurance. These individuals pay among the highest prices in the world for their prescription drug needs. Some don't fill prescriptions because they cannot afford to do so.

Public Support for Importation Grows

For the millions of Americans without drug coverage and those with limited coverage, importation is seen as an option to obtain access to affordable medications. A recent AARP poll found that AARP members overwhelmingly support Congress allowing for the importation of drugs from Canada and Europe.⁴ While AARP does not believe prescription drug importation is the sole

⁴ AARP Knowledge Management, Medicare Price Negotiation of Prescription Drugs – A National Poll February 12, 2007, page 8, available at: http://assets.aarp.org/rgcenter/health/rx_negotiation.pdf

solution to soaring drug prices in the United States, we do believe it is one way to begin to secure lower priced drugs.

Our members and their families question why brand name drug prices in Canada and other industrialized countries can be lower – sometimes by as much as 50 percent lower – than prices in the U.S. It is a national embarrassment that people from all over the world come to the United States to access our advanced medical systems while many of our own citizens need to look outside our borders in order to afford their prescription drugs.

The simple fact is that importation is already happening. In 2003, Americans purchased approximately 12 million prescription drug products (valued at almost \$700 million) from Canada alone.⁵ As prescription drug prices continue to rise, more and more individuals are choosing to import prescription drugs. We have a responsibility to ensure that Americans who choose to import prescription drugs do so safely. Congress can no longer afford to do nothing but hope that the millions of Americans who purchase prescription drugs from abroad do so without dire consequences.

Congress Should Act Quickly to Pass the Dorgan-Snowe Legislation

We believe that Congress should enact legislation that provides appropriate safeguards while at the same time ensuring a workable system for prescription drug importation. Currently, many prescription drugs sold for market in the U.S. are already manufactured abroad and brought into the U.S. safely and legally by prescription drug manufactures. If these manufacturers can import drugs safely and legally, then a process can be created to allow American consumers to safely import drugs.

⁵ HHS Task Force on Drug Importation, Report on Prescription Drug Importation, December 2004, at 11-12.

S. 242 balances the challenge of designing a prescription drug importation program to ensure the integrity of pharmaceuticals while at the same time providing consumers access to lower price prescription drugs. We strongly urge you and your colleagues to enact S. 242 this year.

Dorgan-Snowe Ensures the Safety of Imported Drugs

Access to lower-priced prescription drugs isn't enough. These prescription medications must be safe and efficacious. Recent news reports highlight an increasing problem with the use of counterfeit drugs. Implementing a system of safety procedures could begin to alleviate this serious problem.

AARP supports the approach taken in S. 242 to create a system that provides for importation of safe, effective pharmaceuticals. The legislation first legalizes personal importation from Canadian pharmacies and wholesalers. Regulation of the Canadian pharmacy system closely resembles its U.S. counterpart, and drugs purchased from Canada can be as safe as drugs purchased in the United States.

Under the legislation, importers and exporters must agree to allow their place of business to be inspected by the Food and Drug Administration ("FDA") not less than twelve times per year. The legislation also tasks the FDA with the responsibility of ensuring that the prescription drugs imported from abroad are comparable to drugs available in the U.S. market. If the difference between the foreign drug and its U.S. counterpart is minimal, the FDA can allow the drug to be imported into the U.S. However, if the difference is significant, a supplemental application may be required. If the supplemental application would not be approved, the FDA will prevent the importation of the prescription drug.

To ensure that the FDA isn't besieged with inspection and certification requirements, the legislation allows the FDA to phase-in its review of registered

importers and exporters, provided that priority is given to entities that can process a high volume of sales. Likewise, the legislation also permits the FDA to phase-in its review of foreign versions of FDA-approved drugs to determine whether they are the same as their U.S. counterparts. AARP believes that phasing in these provisions will further bolster the safety of the importation plan by providing FDA the opportunity to conduct thorough inspections and review.

Pedigree Requirements

One way of effectively ensuring the safety of pharmaceuticals is the institution of pedigree requirements – the ability to trace a drug from the point of origin to the point of dispensing. In order to accomplish this task in an expanded international arena, the Dorgan-Snowe legislation mandates that importers and exporters may only purchase prescription drugs from a manufacturer or entity that can establish a drug's pedigree. These requirements include identification of the drug's prior sale or transaction and contractual authority to inspect records to determine whether an entity engaged in the system is in compliance with applicable safety and other standards. AARP believes that standards such as these are crucial to protecting the quality and efficacy of imported pharmaceuticals.

In order to ensure safety, pharmaceuticals imported from another country should be equipped with anti-tampering materials and anti-counterfeiting measures. As the technology in this area progresses, imported pharmaceuticals should be equipped with state of the art devices, such as bar codes, and specialized ink, or other appropriate technology. The Dorgan-Snowe bill requires the use of anti-tampering and/or track-and-trace technologies to prevent counterfeiting of imported drugs.

Finally, S. 242 provides that pharmaceuticals imported by wholesalers and pharmacies be labeled in such a way as to indicate to the consumer that the drug

has been imported under the new system. Consumers will thus expect to realize some savings from these pharmaceuticals.

Anti-Gaming Provisions

We recognize that some manufacturers are already curtailing their drug supply to Canada and other countries, which could lead to supply shortages or fear of retribution by entities that engage in importation. An importation proposal that does not seek to prevent entities from pressuring those who engage in importation will amount to nothing more than an importation system in name only. Our members do not want hollow promises of importation – they want legislation passed that will allow them the opportunity to fill their prescription safely and at a lower price.

Therefore, AARP believes that anti-gaming provisions are a vital component of any importation legislation. The Dorgan-Snowe legislation seeks to prevent entities – particularly pharmaceutical manufactures – from eliminating or curtailing drug supply to those who engage in importation of prescription drugs to the U.S. so that the system can work as Congress intends.

Protection from Rogue Internet Pharmacies

Many consumers who choose to purchase prescription drugs from abroad do so through Internet pharmacies. Unfortunately, many consumers fall victim to rogue Internet pharmacies due in part to the inability to distinguish between reputable and fly-by-night operations.

The Dorgan-Snowe legislation instructs the FDA to maintain a website listing approved pharmacies. Having the FDA web site as the point of contact for a list of approved pharmacies provides consumers with an official, secure source of information on safe drugs. However, not all consumers have access to the

Internet; therefore, the legislation provides that the FDA must also maintain a toll-free number where consumers can get information on approved foreign sources.

Conclusion

The Dorgan-Snowe legislation provides for a safe and effective system for allowing importation of prescription drugs. Our members, and all Americans, need Congress to enact this bi-partisan, legislation this year. We are pleased to see this Committee and Members from both Houses of Congress and both sides of the aisle moving forward on this issue. AARP pledges to work with you to make safe importation a reality.