

Testimony of
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July 14, 2004

Mr. Chairman and members of the Committee, my name is Joanne Disch. I am a member of AARP's Board of Directors. On behalf of the organization and our over 35 million members, thank you for convening this hearing and for including AARP in your discussions about the need for safe importation of prescription drugs.

In November 2003, Congress enacted some sweeping changes to Medicare - including long-overdue prescription drug coverage. We believe that the new law lays the foundation for affordable Medicare prescription drug coverage upon which we will build over time. AARP will continue to work with Congress to strengthen and improve the drug benefit and the Medicare program.

The Need for Importation Legislation

The Medicare prescription drug benefit was an important first step. But now more needs to be done to control the rising costs of prescription drugs so that Americans of all ages can afford needed medications. Modern medicine increasingly relies on prescription drug therapies; yet the benefit of these therapies still eludes those Americans who cannot afford to pay escalating drug prices.

Prescription drug importation is not the sole solution to soaring drug prices in the United States. However, AARP believes that a system providing for the safe and legal importation of prescription drugs can serve to put downward pressure on drug prices and will permit consumers to realize some savings on the cost of their prescription drugs.

CMS estimates that, in 2003, per capita spending on prescription drugs rose approximately 12 percent, with a similar rate of growth expected for this year. Much of the increase in drug spending is due to higher utilization and the shift from older, lower cost drugs to newer, higher cost drugs. However, rapidly increasing drug prices are a critical component.

A recent AARP study revealed that, on average, pharmaceutical manufacturer prices for the brand-name drugs most widely used by older Americans increased at more than double the rate of general inflation from 2000 through 2003. The average annual increase in manufacturer prices charged to wholesalers for these drugs increased from 4.1 percent in 2000 to 6.9 percent in 2003. For the 155 brand-name drugs that were in the market for the entire four year period, this translates into a cumulative average price increase of over 25 percent. Last month, AARP released another study examining prescription drug prices for the 12 month period ending in

March 2004. This study revealed that the prices charged by pharmaceutical manufacturers to wholesalers for these brand-name drugs increased faster than the previous years - by an average of 7.2 percent, a figure particularly troubling given that the average annual rate of general inflation actually fell during this same time period.

High drug prices, combined with the surging growth of the older population, are also taking a toll on state budgets and private sector health insurance costs. Medicaid spending on prescription drugs increased at an average annual rate of nearly 20 percent between 1998 and 2001. Until lower priced drugs are available, pressures will continue to squeeze public programs at both the state and federal level. Pressure will continue on the private sector as well, possibly leading to elimination of, or reductions in, employer-provided drug benefits. Further, over 43 million Americans currently have no health insurance coverage. Without access to negotiated prices, these Americans pay among the highest prices for prescription drugs in the world or, worse yet, don't fill prescriptions because they cannot afford to pay for them.

AARP surveys demonstrate that our members consider drug prices exorbitant and the single most significant barrier to obtaining needed medications. Responses to an AARP Bulletin questionnaire last fall showed that our members split pills, skipped doses, asked doctors for free samples, and sold possessions because the costs of needed medications were too expensive. One woman poignantly noted that she begged for the unfinished prescriptions of friends who had died, hoping their left-over drugs would meet her needs.

Americans of all ages need affordable prescription drugs now. Safe importation of prescription drugs from Canada is one way to begin to secure lower priced drugs. Our members question why drug prices in Canada can be lower, sometimes far 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. But with the same drugs selling, in some cases, at 30 percent and even 50 percent less in Canada and overseas, it is hardly surprising that so many make that choice.

It is no longer a question of whether we should or should not allow the importation of drugs from abroad. The simple fact is that importation is already happening. Many Americans travel to Canada for less costly prescription drugs, or purchase their drugs through the Internet without any systematic U.S. oversight process in place to assure safety. Importation of drugs is likely to continue whether or not Congress acts. The trend is growing, and we have a responsibility to ensure that Americans can access lower cost drugs without putting their health at risk. We believe that Congress should enact legislation that provides appropriate safeguards and, at the same time, ensure a workable system.

AARP therefore supports S. 2328, the Dorgan-Snowe importation legislation, which would legalize importation of prescription drugs through a system designed to ensure safety and lower drug costs. We strongly urge you and your colleagues to take action that will lead to enactment of S. 2328. We believe the Dorgan-Snowe legislation meets the challenge of designing a prescription drug importation program that will ensure the integrity of pharmaceuticals and provide consumers access to lower cost prescription drugs.

A safe system of importation is paramount. The drafters of S. 2328 have worked with AARP and others to revise their legislation to include additional safety measures and consumer protections to ensure the integrity of pharmaceuticals entering into the United States from abroad.

Safety Issues

The health and safety of individuals is critical in any importation system and AARP supports the approach taken in S. 2328 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. We believe that drugs purchased from Canada can be as safe as drugs purchased in the United States.

FDA Certification

Congress has charged the Food and Drug Administration ("FDA") with ensuring the safety and effectiveness of U.S. pharmaceuticals. S. 2328 provides that only drugs that have been approved by the FDA may be imported. Drugs manufactured for distribution in other countries may differ slightly from drugs destined for the U.S. Some differences may be minimal and have little or no effect on the efficacy of the drug. Other differences may actually change the efficacy of the drug. In cases where pharmaceuticals significantly differ from its U.S. counterpart, S. 2328 requires that a supplemental application be filed and the FDA approves the application before the pharmaceutical may be imported.

In addition, the safety and authenticity of imported pharmaceuticals must be assured at each point along the stream of commerce, including regular inspection of the flow of prescription drugs to the ultimate point of dispensing. The Dorgan-Snowe legislation mandates that importers and exporters agree to allow inspection of their facilities by the FDA not less than once every three weeks.

Consumers purchasing prescription drugs should be provided with a list of FDA-approved entities that engage in importation. This is particularly important for consumers who purchase prescription drugs through Internet pharmacies. Many consumers fall victim to rogue Internet pharmacies due in part to the inability to distinguish between reputable and fly-by-night Internet pharmacies.

The Dorgan-Snowe legislation instructs the FDA to maintain, on its website, a list of 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.

Pedigree Requirements

One way of effectively ensuring the safety of pharmaceuticals is the institution of pedigree requirements - being able 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, we believe legislation must provide a way to trace pharmaceuticals back to the point of manufacture and enforce pedigree requirements. Each entity that handles prescription drugs should be required to maintain records as to the drug's pedigree. Furthermore, there should be no impediments to an entity's ability to receive records regarding a drug's pedigree.

The Dorgan-Snowe legislation includes mandatory pedigree requirements. Importers and exporters may only purchase pharmaceuticals from a manufacturer or entity that can establish a drug's pedigree, or chain of custody. 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.

Anti-tampering/Anti-counterfeiting Requirements

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 anti-counterfeiting technology on imported drugs.

Labeling

It is important that consumers have the necessary information included with the prescription drugs they purchase. Because pharmaceuticals may be manufactured in countries where English may not be the official language, the Dorgan-Snowe legislation provides that pharmaceutical labels and patient package inserts destined for the United States be written in English as well. In cases where a pharmaceutical's inactive ingredients differ from the active ingredients approved by the FDA, the drug's package must bear an advisory label indicating that fact for individuals with potential allergies.

Finally, S. 2328 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.

Funding

AARP believes that in order to ensure the integrity of an importation system the FDA will need appropriate authority and resources to effectively monitor and enforce these standards. The Dorgan-Snowe legislation provides for appropriate FDA funding through registration fees assessed to importers and exporters who wish to engage in the importation system as well as inspection fees capped at no more than 1 percent of the price of prescription drugs importers/exported. If the FDA requires additional financial resources in order to accomplish their goal of protecting the safety and efficacy of the U.S. prescription drug supply, then AARP would support this additional funding.

Anti-gaming

We recognize that some manufacturers are already curtailing their drug supply to Canada, which could lead to supply shortages. We share the concern of many who fear that legislation, absent some mechanism to prevent manufacturers from undermining the newly created importation system, will amount to nothing more than a false assurance in an individual's ability to engage in an importation system. Our members do not want hollow promises of importation legislation - they want legislation passed that will allow them the opportunity to fill their prescription safely and at a lower cost.

AARP believes that a vital component of any importation legislation is anti-gaming provisions. The Dorgan-Snowe legislation seeks to prevent entities - particularly pharmaceutical manufacturers - from eliminating or reducing drug supply to those who engage in importation of prescription drugs to the United States thereby ensuring that an importation system will work as effectively as Congress intended.

Related Issues

Beyond the creation of an importation system, there are additional issues that we urge Congress to consider. There remains a strong need to examine the safety of pharmaceuticals within the United States' drug supply in order to prevent counterfeit, diluted, or ineffective drugs. As Congress examines foreign pharmaceutical supply systems, there is also an opportunity to revisit the integrity of the U.S. pharmaceutical system - from point of manufacture to the ultimate consumer. The FDA should be required to submit reports to Congress, annually or as otherwise appropriate, to monitor the impact of regulated importation on the price, quality, and access to pharmaceuticals both in the U.S. and worldwide.

Conclusion

Our members want Congress to enact bipartisan legislation this year to allow for legal, safe importation of lower cost prescription drugs. AARP is pleased to see this Committee and Members of Congress from both sides of the aisle moving forward on the issue of importation legislation. We understand the challenges Congress faces in designing a program that will not only ensure the integrity of pharmaceuticals, but also does not create an overly burdensome process that would prevent consumers from gaining access to lower cost prescription drugs. We believe the Dorgan-Snowe legislation meets that threshold, and we urge its enactment this year.

AARP appreciates the opportunity to testify and looks forward to working with the Committee to help our members afford the medications critical to their health and well-being.