

## FACT SHEET

## Enactment of Republican Drug Import Legislation in 2000 Failed to Reduce Drug Prices for Uninsured Seniors

In October 2000, just prior to the last elections, the Republican-controlled House and Senate passed the Medicine Equity and Drug Safety Act. The legislation purported to reduce prescription drug price discrimination by allowing drug wholesalers to import lower-priced drugs from foreign countries. According to one of the bill's proponents, the legislation "will make it easier for our senior citizens to have access to . . . less costly drugs."

Passage of this bill was controversial. Republican members of Congress claimed that the bill would result in significant savings for seniors. One proponent claimed: "It's going to drive down the price of pharmaceuticals in the United States by increasing competition. . . . [T]his is going to help not just seniors . . . it is going to help everybody." Speaker of the House Dennis Hastert argued that "this arrangement could drop prescription drug costs by 30 to 50 percent, a welcome discount for many seniors who take medicines daily." <sup>3</sup>

The legislation was also supported by President Bush. As a candidate in the 2000 presidential debates, he said: "to make . . . prescription drugs more affordable for seniors . . . the new bill that was passed in Congress made sense."<sup>4</sup>

Democrats in the House, however, regarded the legislation as gimmick. Originally, Democrats in Congress were the main sponsors of prescription drug import legislation.<sup>5</sup> But by the time the legislation was finalized, Democrats contended that it contained so many loopholes that it would be ineffective. For example, Rep. Henry A. Waxman (D-CA), the ranking member of the Government Reform Committee, argued: "The bill is riddled with loopholes . . . [and] a sham.

<sup>&</sup>lt;sup>1</sup>Statement of Rep. Joe Skeen, Congressional Record H9681 (Oct. 11, 2000).

<sup>&</sup>lt;sup>2</sup>Statement of Rep. Jack Kingston, Congressional Record H9676 (Oct. 11, 2000).

<sup>&</sup>lt;sup>3</sup>Associated Press, GOP wins on pharmaceuticals reimportation (Oct. 11, 2000).

<sup>&</sup>lt;sup>4</sup>Exchanges Between the Candidates in the Third Presidential Debate, New York Times (Oct. 18, 2000).

<sup>&</sup>lt;sup>5</sup>See, e.g., H.R. 1885, 106th Congress (1999).

Instead of actually solving the problem, it gives America's seniors a placebo and hopes they won't notice until after the election." Minority Leader Dick Gephardt noted that "there is now widespread agreement that this measure will do next to nothing for the American people."

The final drug import provision was signed into law by President Clinton because it was attached to a larger agricultural appropriations bill, but he did not approve of the drug import provisions. According to the Administration's statement of policy, "this bill will fail to achieve its goal of providing needed relief from the high cost of prescription drugs. . . . [I]t is . . . wrong to provide false hope that this provision will work to address the problem."

As critics of the legislation predicted, the Medicine Equity Act has not been effective. A provision of the law required the Department of Health and Human Services (HHS) to halt implementation of the law if the HHS Secretary found that the legislation would not reduce drug prices or would be unsafe for consumers. In December 2001, HHS Secretary Donna Shalala found that "flaws and loopholes contained in the reimportation provision make it impossible for me to demonstrate that it is safe and cost-effective." In July 2001, HHS Secretary Tommy Thompson also analyzed the provision and declined to implement it, claiming that neither the potential savings for seniors nor the safety of imported drugs could be guaranteed. Secretary Thompson stated, "I do not believe we should sacrifice public safety for uncertain and speculative cost savings." <sup>10</sup>

International drug price comparisons conducted for members of Congress by the Special Investigations Division confirm that passage of the law has not had an impact on the pricing practices of drug manufacturers. The price comparisons demonstrate that uninsured seniors in

<sup>&</sup>lt;sup>6</sup>Statement of Rep. Henry A. Waxman, Congressional Record, H9673 (Oct. 11, 2000). According to Rep. Waxman and other members, the bill suffered from two major flaws. First, it contained a deliberate "catch 22" for would-be importers of lower-priced foreign drugs because it required the importers to label the drugs with the FDA-approved label, which would require the importer to obtain permission from the manufacturer. Second, the bill did not prevent manufacturers from requiring that foreign distributors charge U.S. importers more than foreign purchasers, thereby perpetuating price discrimination.

<sup>&</sup>lt;sup>7</sup>Statement of Rep. Dick Gephardt, Congressional Record, H9677 (Oct. 11, 2000).

<sup>&</sup>lt;sup>8</sup>Statement of Administration Policy, H.R. 4461 -- Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill FY 2001.

<sup>&</sup>lt;sup>9</sup>Letter from HHS Secretary Donna Shalala to President Bill Clinton (Dec. 26, 2000). Secretary Shalala cited three significant problems that would prevent the legislation from reducing drug prices: it allowed manufacturers to deny importers the use of required drug labels; it allowed manufacturers to enter into restrictive agreements with foreign wholesalers that would prevent them from selling the drugs for reimportation into the United States at lower prices; and its five year sunset provision would have a "chilling effect on private sector investment in the required testing and distribution systems."

<sup>&</sup>lt;sup>10</sup>HHS Press Release, Secretary Thompson Determines That Safety Problems Make Drug Reimportation Unfeasible (July 10, 2001).

congressional districts throughout the country continue to pay over twice as much for prescription drugs as purchasers in other countries. Moreover, U.S. prices for the five most popular drugs used by seniors have actually increased since passage of the Medicine Equity Act in October 2000. Based on published average wholesale prices, the price of Lipitor has increased by 23%, the price of Prevacid has increased by 19%, and the price of Prilosec has increased by 16% since enactment of the law. Overall, the average price of the five drugs has increased by 16%. <sup>11</sup>

<sup>&</sup>lt;sup>11</sup>Medical Economics Company, 2000 Drug Topics Red Book (2000); Facts and Comparison, Price Alert: The Official Guide to AWP Pricing (Mar. 15, 2002).