#### The Prescription Drug Fairness For Seniors Act: Industry Myths vs. Reality

Prepared by Minority Staff Committee on Government Reform U.S. House of Representatives

#### Industry Allegation: The legislation extends price controls to the pharmaceutical industry.

<u>The Facts</u>: The Prescription Drug Fairness for Seniors Act does not impose price controls on the pharmaceutical industry. Instead, the legislation ends <u>price discrimination</u>. Under the legislation, companies can sell their prescription drugs in other industrialized countries at any price they choose. The goal of the bill is to allow senior citizens access to prescription drugs at these same low prices.

If a drug company refuses to extend its average foreign price to the senior citizen market, the only consequence to the drug company is that the federal government will no longer buy drugs from the company. In this way, the bill uses the buying power of the federal government to end price discrimination and help seniors gain access to the low prices that drug companies' charge in other countries.

## Industry Allegation: The average foreign prices mandated by the bill are in effect price controls because other industrialized countries control drug prices.

<u>The Facts</u>: Foreign countries set maximum drug prices in a number of different ways. Some, like Canada, take an approach similar to the Prescription Drug Fairness for Seniors Act, requiring that prices for brand name drugs do not exceed the prices in other industrialized countries. Others, such as France, require that prices for new drugs be set no higher than prices for drugs that are already on the market, unless the new drug can be shown to be superior. In all cases, however, the drug manufacturers can choose whether to enter these international markets. If the manufacturer does not believe that the company can earn a reasonable rate of return on drug sales in a foreign country, they do not have to sell the drug in that country.

### Industry Allegation: The legislation will force the pharmaceutical industry to reduce research and development expenditures.

<u>The Facts</u>: Historically, there is no evidence to support the industry's claim that preventing pharmaceutical companies from overcharging for their products reduces research. In 1984, Congress passed the Hatch-Waxman Act, which increased the availability of generic drugs and provided more competition for brand name drugs. Before the legislation was enacted, the

pharmaceutical industry testified that "the bill under consideration today could result in a decline in scientific research and innovation."<sup>1</sup> According to the industry:

The bill's proposed restrictions . . . could have far ranging adverse effects on the development of new technology in this country, including serious implications for the future of university-based research and the emerging and vitally important field of biotechnology research. . . . Investment in private pharmaceutical research is likely to decline and will no longer provide the kind of products that have brought such an improvement in public health over the last 30 years.<sup>2</sup>

However, this legislation did not reduce innovation in the pharmaceutical industry. Indeed, according to industry data, over the next five years pharmaceutical companies more than doubled their investment in research and development, from \$4.1 billion to \$8.4 billion.<sup>3</sup>

In 1990, Congress passed legislation that created the Medicaid drug rebate, requiring drug companies to reduce their prices for drugs sold to the Medicaid program. At the time, the Pharmaceutical Manufacturers Association opposed legislation to reduce Medicaid drug prices because "[i]ncentives for pharmaceutical research will be reduced."<sup>4</sup> This legislation, however, did not reduce innovation in the pharmaceutical industry. After 1990, pharmaceutical companies tripled their spending on research and development, from \$8.4 billion in 1990 to \$26.4 billion in 2000.<sup>5</sup>

Moreover, the industry's assertion that research will be reduced assumes that drug industry revenues will decrease under the legislation – an assumption that is not shared by independent analysts in the securities industry. Reducing prescription drug prices will lead to an increase in the volume of sales, as seniors that were previously unable to afford prescription drugs would now be able to afford their medications. According to a Merrill Lynch analysis:

 $^{2}Id.$ 

<sup>3</sup>Pharmaceutical Research and Manufacturers of America (PhRMA), *Pharmaceutical Industry Profile 2000* (2000) (www.phrma.org/publications/publications/profile00/).

<sup>4</sup>Testimony of Gerald J. Mossinghoff, President, Pharmaceutical Manufacturers Association, before the House Subcommittee on Health and Environment (September 14, 1990) (attachment to testimony dated May 22, 1990).

<sup>5</sup>*Pharmaceutical Industry Profile 2000, supra* note 3.

<sup>&</sup>lt;sup>1</sup>Testimony of Jack Stafford, President, American Home Products, before the Senate Subcommittee on Courts, Civil Liberties, and the Administration of Justice (June 27, 1984).

Volume increases could overwhelm negative pricing impact. It is important to remember that a reduction in prescription drug prices, both with or without associated prescription benefit coverage, is likely to be associated with price elasticity and increased utilization (especially for Medicare recipients that currently have no drug coverage).<sup>6</sup>

#### Industry Allegation: If the legislation is enacted, the pharmaceutical industry simply will not be able to develop important new drugs.

<u>The Facts</u>: There is no evidence that drug companies in countries with low prices are unable to develop new drugs. Although the United States has the highest drug prices in the world, more than two thirds of new drugs are developed by companies headquartered outside the United States.<sup>7</sup> England tightly controls drug prices, yet according to the drug industry's own figures, significantly more new drugs are developed per capita in the United Kingdom than in the United States.<sup>8</sup>

The drug industry's own testimony indicates that despite the high drug prices in the United States and the low drug prices in other countries, many drug companies are moving research from the United States to other countries. In 1999, the CEO of Amgen testified before Congress that due to delays in FDA approval, "more and more companies [are] taking products to clinical trials offshore."<sup>9</sup>

### Industry Allegation: Foreign countries with low drug prices face delays in access to prescription drugs and restricted choices because of these low prices.

<u>The Facts:</u> There is no relationship between the prices at which drugs are sold in a given country and the speed at which they are approved and put on the market. In fact, the drug industry has recently complained that in spite of paying the highest drug prices in the world,

<sup>6</sup>Merrill Lynch, *Pharmaceuticals: A Medicare Drug Benefit: May not be so Bad* (June 23, 1999).

<sup>7</sup>Boston Consulting Group, *Ensuring Cost Effective Access to Innovative Pharmaceuticals: Do Market Interventions Work?*, 41 (Apr. 1998).

<sup>8</sup>According to the Pharmaceutical Research and Manufacturers of America, 14% of new medicines are developed in the United Kingdom. PhRMA, *U.S. Is the World Leader in Drug Innovation* (Dec. 1999). On a per capita basis, one drug was developed in the United Kingdom for every 2.8 million residents during the period from 1975 to 1994. In the United States, by comparison, one drug was developed for every 4.0 million residents during the same period.

<sup>9</sup>Testimony of Gordon M. Binder, Chairman and CEO, Amgen, before the House Commerce Committee (May 25, 1999).

U.S. consumers are faced with delayed introductions of new drugs. According to an industry spokesman:

In the two most recent periods . . . two-thirds of the products approved by our FDA were approved someplace else first, sometimes in as many as 70 countries. In 1995, the most recent period, again, two-thirds of the products that were approved here in this country were approved someplace else first.<sup>10</sup>

Recently, Tufts University researchers compared drug approval times for 30 new products in the United States and Europe – where drugs are substantially less expensive – and found that approval times for the drugs were "virtually identical." Other analyses have found similar results. For example, drug prices in the United Kingdom are 33% lower than drug prices in the United States, but approval times in the United Kingdom are 13% faster than in the United States, <sup>11</sup> Similarly, drug prices in Sweden are 32% lower than drug prices in the United States, <sup>12</sup>

Contrary to its current claims, the drug industry has previously testified that U.S. citizens sometimes have to go to Canada and other countries to get access to needed drugs. When Congress was debating FDA modernization, for example, industry representatives testified that U.S. citizens had to go to Canada to obtain drugs because the drug approval system is too slow in the United States.<sup>13</sup>

### Industry Allegation: The price that citizens of other countries pay for cheaper drugs is a health care system that rations care and delays access to treatments.

<u>The Facts:</u> This claim is simply a non sequitur. Whether or not the industry's claims about foreign health care systems are accurate, there is no evidence linking low drug prices in these countries to the problems in obtaining medical services (such as surgical procedures) alleged by the drug industry.

<sup>&</sup>lt;sup>10</sup>Testimony of Fred Lyons, Pharmaceutical Research and Manufacturers Association, before the House Commerce Committee (May 1 and 2, 1996).

<sup>&</sup>lt;sup>11</sup>Drug Information Journal, *Drug Review in Canada: A Comparison with Australia, Sweden, the United Kingdom, and the United States*, 32, 1133-1141 (1998).

 $<sup>^{12}</sup>$ *Id*.

<sup>&</sup>lt;sup>13</sup>Testimony of Fred Lyons, *supra* note 12.

#### Industry Allegation: The legislation does not guarantee lower prices because pharmacies, not drug companies, are responsible for the high retail markups paid by senior citizens.

<u>The Facts</u>: At the retail level, the pharmacy market is highly competitive: if consumers are unhappy with the prices charged at one retail outlet, they can buy their prescription drugs at a different outlet. This competitiveness guarantees that pharmacies will pass on to senior citizens the benefits of any lower prices for prescription drugs. According to a leading academic expert, Professor Stephen W. Schondelmeyer, the head of the University of Minnesota's Department of Pharmaceutical Care and Health Systems:

Once a patient is on a given prescription medication, the patient becomes a price competitive consumer. . . . Any discounts passed on to community pharmacies will be passed on to the consumer, or payor, of the prescription because of the competitive retail environment."<sup>14</sup>

The reports by the Special Investigations Division of the minority staff of the Committee on Government Reform demonstrate that the legislation will be effective: lowering prices that pharmacies pay for prescription drugs will lower retail prices for seniors. The reports compare the retail markup due to pharmacies with the total markup paid by retail customers. They find that drug companies, not retail pharmacies, are responsible for the significant differential between the prices paid by retail customers and the prices paid by the drug companies' most favored customers. The analyses find that while the average retail price differential is often over 100%, pharmacy markups account for only 22% of the price paid by retail customers. This indicates that it is drug company pricing policies, not pharmacies, that are responsible for the high prescription drug prices paid by seniors.

# Industry Allegation: The legislation does not address the problems with Medicare. It fails to provide seniors with what they really need: complete coverage for prescription medicines.

<u>The Facts</u>: The ideal solution for seniors would be to enact a Medicare drug benefit – a solution supported by many members of Congress. Questions have been raised about the price tag of this benefit, however. A comprehensive Medicare drug benefit has been estimated to cost a minimum of \$350 billion over the next ten years.<sup>15</sup> Although the Bush Administration has

<sup>&</sup>lt;sup>14</sup>Schondelmeyer, Stephen W., PRIME Institute, University of Minnesota, *Competition and Pricing Issues in the Pharmaceutical Market, University of Minnesota*, 12 (August 1994).

<sup>&</sup>lt;sup>15</sup>Democrats Double Bush's Proposal on Prescription Drugs, New York Times (Mar. 21, 2001).

submitted a prescription drug plan to Congress, this plan has been heavily criticized by members of Congress and is unlikely to become law.<sup>16</sup>

The Prescription Drug Fairness for Seniors Act is an intermediate step that reduces drug prices for seniors without costing the federal government anything. It will measurably improve the quality of life for senior citizens by lowering the price of brand name prescription drugs by approximately 40%. A senior citizen spending \$150 a month on prescription drugs could save over \$700 annually under the legislation.

It is ironic that the pharmaceutical industry criticizes the legislation for failing to provide a comprehensive Medicare drug benefit. Although the drug companies now say that they support the inclusion of prescription drug benefits in private-sector Medicare HMOs, they spent millions of dollars in the most recent elections to support legislators who would prevent a meaningful prescription drug benefit from being added to the Medicare program. A recent report indicated that "the returns [on this investment] have already begun.<sup>17</sup>

<sup>&</sup>lt;sup>16</sup>Bush Proposes Aid on Medicare Drugs, New York Times (Jan. 30, 2001).

<sup>&</sup>lt;sup>17</sup>Business Seeks Return on Investment in Bush Presidential Campaign, Wall Street Journal (Mar. 6, 2001).