### Response to Drug Industry Claims on Breast Cancer Drug Price Differences in the United States and Other Countries

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A new congressional report shows that women without prescription drug coverage must pay substantially more for frequently prescribed breast cancer drugs in the United States than in other countries. The report finds, for example, that the drug Nolvadex, which contains tamoxifen and is the top-selling breast cancer drug in the United States, costs over eight times as much in the United States as in Canada or France. This fact sheet analyzes claims that the industry may make to discredit the report.

Claim: A bill recently passed by Congress would solve this problem, allowing pharmacists and wholesalers to import drugs from other countries and sell them to U.S. consumers at substantially reduced prices.

<u>The Facts:</u> Although legislation to allow drug imports was recently passed by Congress as part of the Agriculture appropriations bill, the legislation is so full of loopholes that one industry lobbyist was quoted as saying, "I doubt that anyone will realize a penny of savings from this legislation." According to the White House Office of Management and Budget, "the bill will fail to achieve its goal of providing needed relief from the high costs of prescription drugs" because it has "numerous loopholes that will render this provision meaningless."

One major loophole in the bill requires imported drugs to be relabeled with FDA approved labels but does not require drug manufactures to provide U.S. importers with these labels. As a result, the drug manufacturers can block the importation of drugs by denying U.S. importers permission to use their trademark- and copyright-protected labels.

For example, the drug Nolvadex is sold in Canada with a label that contains information in both French and English. In the United States, the FDA approved label only contains information in English. Because of these and other differences, the Canadian label is not approved by the FDA for use in the United States. Thus, even if Nolvadex was purchased at a lower price in Canada, it could not be legally resold in the United States.

Another major loophole in the bill allows drug manufacturers to require that foreign wholesalers charge U.S. market prices for drugs that are reimported into the United States. In this case, even if imported

drugs could be legally sold in the United States, consumers would not realize any savings.

# Industry Claim: Women in countries with lower prices for breast cancer drugs have reduced access and fewer choices for breast cancer drugs.

<u>The Facts:</u> There is no relationship between the prices of breast cancer drugs and their availability in other countries. The congressional report analyzed the five most frequently used brand name, outpatient breast cancer drugs in the United States. Prices in Canada, the U.K., Italy, and France are much lower than prices in the United States, but with only one exception (the drug Fareston is not available in Canada) all of these drugs are available in the four countries.

# Industry Claim: Countries with low drug prices experience reduced research and development of new drugs.

<u>The Facts:</u> There is no direct relationship between drug prices and research and development of new drugs. Although prices for breast cancer drugs in the United States are higher than prices in other countries, three of the five breast cancer drugs in this study are manufactured by companies headquartered outside the United States. Arimidex and Nolvadex, the most popular breast cancer drug in the United States, are manufactured by AstraZeneca, which is headquartered in the U.K. Another popular breast cancer drug, Femara, is manufactured by Novartis, a Swiss company.

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."

Industry Claim: The price that residents of other countries pay for cheaper breast cancer drugs is a health care system that rations care and delays access to treatments, resulting in reduced quality of care.

<u>The Facts:</u> There is no evidence of major differences in the quality of care received by breast cancer patients in the United States and in other countries. U.S. women pay over twice as much as women in the United Kingdom for the five breast cancer drugs analyzed in the minority staff report. But in the ten-year period from 1987 to 1997, breast cancer fatality rates fell at a faster rate in the U.K. than they did in the United States.<sup>4</sup> Prices of breast cancer drugs in Canada are lower than in the United States, but fatality rates for breast cancer in Canada have declined at similar rates as those in the United States.<sup>5</sup>

### Industry Claim: Countries with low drug prices face delays in access to prescription drugs.

The Facts: 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 having the highest drug prices in the world, introductions of new drugs are delayed in the United States. According to an industry spokesman:

In the two most recent periods, 1990-1994, 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>6</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, breast cancer drug prices in the United States are much higher than in the U.K., but approval times in the U.K. are 13% faster than in the United States.<sup>7</sup>

# Industry Claim: Congress recently passed legislation to expand insurance coverage for uninsured breast cancer patients.

<u>The Facts:</u> While Congress recently passed legislation to expand coverage for a small group of breast cancer patients, the legislation would not provide coverage for most women with breast cancer.

This legislation is the Breast and Cervical Cancer Prevention and Treatment Act of 2000. It would give states the option of providing Medicaid coverage to low-income women screened and diagnosed with breast cancer through CDC's Breast and Cervical Cancer Early Detection Program. State program requirements vary, but they can provide breast cancer screening services to women between the ages of 40 and 65 who earn up to 250% of the poverty level.

The legislation has many limitations. The legislation does not require that states provide coverage for women in the screening program, does not cover most women, and does not cover any women over the age of 65. Currently, only 15% of women eligible under CDC's Early Detection Program are screened.

#### **Endnotes**

- 1. *Uncertainty Casts a Shadow on Support for a Measure That Allows Import of Drugs*, New York Times (Oct. 10, 2000).
- 2. Office of Management and Budget, *Statement of Administrative Policy: H.R. 4661 -- Agriculture, Rural Development, Food and Drug Administration and Related Agencies Appropriations Bill FY 2001* (Oct. 11, 2000).

- 3. Testimony of Gordon M. Binder, Chairman and CEO, Amgen, before the House Commerce Committee (May 25, 1999).
- 4. Lancet, UK and USA Breast Cancer Death Down 25% In Year 2000 At Ages 20-69 (May 2000).
- 5. Health Reports, Trends in Breast Cancer Incidence and Mortality, 8(2), 29-37 (1996).
- 6. Testimony of Fred Lyons, Pharmaceutical Research and Manufacturers Association, before the House Commerce Committee (May 1 and 2, 1996).
- 7. Drug Information Journal, *Drug Review in Canada: A Comparison with Australia, Sweden, the United Kingdom, and the United States*, 32, 1133-1141 (1998).