



**Pricing of Breast Cancer Drugs in Maine:
Breast Cancer Victims Face Discriminatory Prices**

Prepared for U.S. Representative Tom Allen

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U.S. House of Representatives**

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EXECUTIVE SUMMARY

Many women in Maine who have breast cancer must pay high prices for lifesaving prescription drugs. This report, which was prepared at the request of U.S. Representative Tom Allen, who represents Maine’s 1st Congressional District, investigates the cause of these high prices. It is the first report to analyze how price discrimination by drug manufacturers affects the cost of prescription drugs purchased by women with breast cancer in Maine.

Breast cancer is the most common form of cancer among women in the United States. This year, approximately 180,000 women will be diagnosed with breast cancer, and over 40,000 will die. Many of these women lack coverage for prescription drugs and face severe financial problems affording the medications that they need to survive. In Maine, an estimated 900 women will be diagnosed with breast cancer this year, and 200 will die from the disease.

This report investigates the pricing of five prescription drugs that are commonly prescribed to treat breast cancer. It compares the prices that women in Maine without prescription drug coverage must pay for these drugs with the prices that drug manufacturers charge favored customers, such as HMOs and the federal government. The report finds that:

- C Price discrimination by drug manufacturers forces Maine women to pay inflated prices for breast cancer drugs.** Women in Maine with breast cancer who pay for their own drugs must pay an average of 102% to 106% more for the breast cancer drugs than the drug manufacturers’ favored customers (Table 1). The drug with the highest price differential is Megace, manufactured by Bristol Myers-Squibb. Women in Maine must pay 340% more than favored customers for a one-month supply of Megace. Women who buy tamoxifen, the most frequently prescribed breast cancer medication, must pay 53% to 72% more than favored customers.

Table 1: Maine Women Are Forced to Pay Higher Prices for Breast Cancer Drugs than Favored Customers

Drug	Manufacturer	Price for Favored Customers	Price for Maine Breast Cancer Patients	Price Differential for Maine Breast Cancer Patients	
				Percent	Dollar
Megace (20 mg)	Bristol-Myers Squibb	\$39.60	\$174.28	340%	\$134.68
Tamoxifen (10 mg)	AstraZeneca/Barr	\$58.00	\$99.48/\$88.53	72%/53%	\$41.48 /\$30.53
Arimidex (1 mg)	AstraZeneca	\$117.47	\$179.04	52%	\$61.57
Fareston (60 mg)	Schering-Plough	\$59.12	\$86.25	46%	\$27.13
Femara (2.5 mg)	Novartis	\$155.15	\$185.46	20%	\$30.31
Average Price Differential				106%/102%	

- C **Price discrimination by drug manufacturers costs women in Maine thousands of dollars.** In dollar terms, the impact of price discrimination by drug manufacturers can be enormous. Not only are breast cancer drugs expensive, they must often be used daily for long periods of time. The report finds that for a year of treatment, a woman in Maine without drug coverage will pay almost \$1,600 more than a favored customer for the drug Megace and over \$700 more than a favored customer for Arimidex. Tamoxifen, the most frequently prescribed breast cancer drug, has a typical course of treatment that lasts five years. Women in Maine who purchase their own drugs must pay \$1,800 to \$2,500 more for tamoxifen than favored customers over this period.
- C **Drug manufacturers, not pharmacists, are primarily responsible for the high prices paid by women in Maine.** Drug manufacturers have argued that the differences between the low prices paid by favored customers and the high prices paid by consumers without drug coverage can be attributed in large part to pharmacy markups. The report investigates this contention and finds that it is drug manufacturer pricing strategies -- not pharmacy or wholesale markups -- that primarily cause the price differentials observed in this report. For the breast cancer drugs analyzed in this report, the average wholesale and pharmacy markup is only 13%. It is price discrimination at the manufacturer level that is the principal cause of the high drug prices paid by women in Maine with breast cancer.

I. BREAST CANCER INCIDENCE AND TREATMENT

Breast cancer is the most common form of cancer for women in the United States. In 2000, approximately 180,000 women in the United States will be diagnosed with breast cancer, and over 40,000 will die.¹ Over the course of a lifetime, one in eight women in the United States will be diagnosed with breast cancer.² In Maine, approximately 900 women will be diagnosed with breast cancer this year, and 200 will die.³

Initial therapy for breast cancer usually requires surgical removal of the tumor.⁴ Additional prescription drug therapy (known as adjuvant therapy) is often recommended to prevent the growth and spread of cancer cells throughout the body. There are two types of drug therapy for breast cancer: chemotherapy and hormonal therapy. Chemotherapy drugs kill cancer cells directly. Hormonal drugs function by curtailing the production of or blocking the effects of estrogen, a natural hormone that can accelerate the growth of breast tumors.

The breast cancer drugs used in adjuvant therapy are expensive, especially the drugs used in hormonal therapies. Breast cancer patients spend over \$1 billion annually on prescription drugs used to treat the disease.⁵ The costs are particularly high when patients are prescribed drugs in combination and directed to take the drugs over extended periods of time. Typical hormonal therapies are taken daily for up to five years.⁶

Many women with breast cancer do not have prescription drug coverage to pay their drug expenses. Overall, almost 60% of breast cancer patients are age 65 or over.⁷ These women usually receive health insurance through Medicare, which does not pay for most prescription

¹Cancer Journal for Clinicians, *Cancer Statistics, 2000* (Jan./Feb. 2000). This ranking excludes basal and squamous cell skin cancers and in situ carcinomas except urinary bladder. (Online at http://www.ca-journal.org/articles...07-033/graphics/50_007-022_t01.gif).

²Katrina Armstrong, M.D., Andrea Eisen, M.D., and Barbara Weber, M.D., *Assessing the Risk of Breast Cancer*, *New England Journal of Medicine* (Feb. 24, 2000).

³*Cancer Statistics, 2000*, *supra* note 1.

⁴National Cancer Institute, *Cancer Facts: Therapy: Questions and Answers About Adjuvant Therapy for Breast Cancer* (1999) (online at <http://cancernet.nci.nhi.gov>).

⁵Committee on Government Reform, Minority Staff, *Analysis of Sales of Prescription Drugs Used in Hormonal Treatment of Breast Cancer* (Oct. 1999).

⁶National Comprehensive Cancer Network and American Cancer Society, *Breast Cancer Treatment Guidelines for Patients* (1999) (online at www.nccn.org).

⁷National Cancer Institute, *Estimated U.S. Cancer Prevalence Counts* (1999).

drugs. While some women on Medicare have supplemental drug coverage, their coverage is often inadequate.⁸ Over 30% of women in the Medicare program -- approximately six million women -- have no prescription drug coverage of any kind.⁹

Women younger than 65 also often lack prescription drug coverage. The number of Americans without health insurance reached 44.3 million in 1998, a record high.¹⁰ Nationwide, 15% of women younger than 65 -- over five million women -- have no health insurance coverage at all.¹¹ Some analysts have estimated that there are over 20,000 women younger than 65 in the United States who have breast cancer and are in need of financial assistance to pay for treatment.¹²

For women with breast cancer who must pay for their own prescription drugs, the costs can be staggering. Because of the high costs of treatment, many women with breast cancer are forced to delay diagnosis and treatment, or forego appropriate care.¹³

II. OBJECTIVE OF THE REPORT

⁸Although Medicare beneficiaries can purchase supplemental "Medigap" insurance privately, the prescription drug coverage provided by these policies is often prohibitively expensive and inadequate. For example, one Medigap policy requires beneficiaries to meet a \$250 deductible, and then covers only 50% of the cost of prescription drugs, up to a maximum benefit of \$1,250. Health Affairs, *Prescription Drug Coverage, Utilization, and Spending Among Medicare Beneficiaries* (Jan./Feb. 1999). The best supplemental prescription drug coverage is available to those who have private sector, employer-based coverage. But only 24% of Medicare beneficiaries have this type of prescription drug coverage. National Economic Council, Domestic Policy Council, *Disturbing Truths and Dangerous Trends: The Facts About Medicare Beneficiaries and Prescription Drug Coverage* (July 22, 1999).

⁹Health Affairs, *Medicare Beneficiaries and Drug Coverage*, 252 (Mar./Apr. 2000).

¹⁰U.S. Census Bureau, *Current Population Reports: Health Insurance Coverage* (Oct. 1999).

¹¹*Id.*

¹²Testimony of Susan Braun, President and CEO, Susan G. Komen Breast Cancer Foundation, before the House Subcommittee on Health and the Environment (July 21, 1999).

¹³*See* Testimony of Dr. Stanley Klausner, Director of Breast Services, Brookhaven Memorial Hospital, and Fran Visco, President, National Breast Cancer Coalition, before the House Subcommittee on Health and the Environment (July 21, 1999).

Rep. Allen asked the minority staff of the Government Reform Committee to investigate the high drug prices faced by women in Maine with breast cancer who lack prescription drug coverage. In particular, he requested that the staff examine whether drug manufacturers have adopted pricing strategies that force women with breast cancer who lack drug coverage to pay higher prices for breast cancer drugs than other purchasers.

Several studies have found that drug manufacturers engage in price discrimination, charging low prices for drugs used by favored customers, such as HMOs or the federal government, and higher prices for drugs used by individual consumers who must pay for their own drugs. For example, in 1998 the Congressional Budget Office conducted a detailed examination of prescription drug pricing and concluded that:

Different buyers pay different prices for brand-name prescription drugs. . . . In today's market for outpatient drugs, purchasers that have no insurance coverage for drugs . . . pay the highest prices for brand name drugs.¹⁴

The first studies to investigate the impact of price discrimination on Maine seniors were requested by Rep. Allen. These studies show that drug manufacturers charge uninsured seniors in Maine more for prescription drugs than they charge favored customers such as the federal government and HMOs, consumers in Canada and Mexico, and even veterinarians who use the drugs to treat dogs, cats, and cattle.¹⁵

This report, the fourth study on price discrimination requested by Rep. Allen, is the first report to investigate whether the drug manufacturers who make breast cancer drugs engage in price discrimination in Maine. It is also the first report to attempt to quantify the extent of price discrimination in Maine for breast cancer drugs.

III. METHODOLOGY

¹⁴Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, xi (July 1998).

¹⁵See Minority Staff Report of the House Committee on Government Reform and Oversight, *Prescription Drug Pricing in the 1st Congressional District in Maine: Drug Companies Profit at the Expense of Older Americans* (Oct. 1998); Minority Staff Report of the House Committee on Government Reform and Oversight, *Prescription Drug Pricing in the 1st Congressional District in Maine: An International Price Comparison* (Oct. 1998); Minority Staff Report of the House Committee on Government Reform, *Prescription Drug Price Discrimination in Maine: Drug Manufacturer Prices Are Higher for Humans than for Animals* (Nov. 1999).

A. Selection of Drugs

This report focuses on five leading drugs that are approved by the Food and Drug Administration (FDA) as out-patient hormonal treatments for breast cancer.¹⁶ These drugs are:

- C Tamoxifen, a hormone therapy manufactured by AstraZeneca (under the brand name Nolvadex) and by Barr Laboratories.¹⁷ Tamoxifen is the most frequently prescribed breast cancer medicine in the United States, and is used to treat early and advanced breast cancer in pre- and post-menopausal women. The drug is also the only drug approved by FDA as a treatment to reduce the risk of breast cancer in women at high risk of developing the disease. Total sales of Nolvadex in 1998 were \$523.7 million.¹⁸
- C Femara, a hormone therapy manufactured by Novartis. Femara is a second-line therapy usually used to treat advanced breast cancer when treatment with tamoxifen has failed. Total sales of Femara in 1998 were over \$150 million.¹⁹
- Arimidex, a hormone therapy manufactured by AstraZeneca. Arimidex is another second-line therapy usually used to treat advanced breast cancer when treatment with tamoxifen has failed. Total sales of Arimidex in 1998 were \$121 million.²⁰
- C Megace, a hormone therapy manufactured by Bristol-Myers Squibb. Megace is generally a third-line therapy used in the treatment of advanced breast cancer when treatment with tamoxifen and Arimidex has failed. Total sales of Megace in 1998 were \$121.9 million.²¹

¹⁶This study does not include oral chemotherapy drugs that are used to treat breast cancer. These drugs are generally taken for a short period of time (six months or less). Moreover, because they are chemotherapy drugs, they fall into the narrow class of drugs that are covered by Medicare. Other breast cancer drugs, such as Taxol, are not included in this analysis because they are generally dispensed in a hospital setting, not via out-patient prescription.

¹⁷Barr Laboratories manufactures a “licensed” generic version of tamoxifen. This version is available as a result of a patent claim settlement with AstraZeneca that gave Barr the exclusive rights to distribute this generic version.

¹⁸Zeneca, *Annual Report and Accounts and Form 20-F 1998* (1999) (available online at <http://annualrep.zeneca.com/7.htm>).

¹⁹Forbes, *A New Career for Dr. Vasella* (Feb. 9, 1998).

²⁰*Annual Report and Accounts and Form 20-F 1998*, *supra* note 19.

²¹Bristol-Myers Squibb, *Products over \$100 Million in 1998* (1999) (available online at <http://www.shareholder.com/bmy/financials.cfm>). Megace is also available in a generic version. Consumers who purchase drugs in their generic versions sometimes pay less than those who

C Fareston, sold in the United States by Schering-Plough. Fareston is a first- or second-line treatment for advanced breast cancer. Total sales in 1998 were approximately \$17.4 million.²²

B. Determination of Prices for Women in Maine

In order to determine the prices that breast cancer patients without prescription drug coverage are paying for breast cancer drugs in Maine, the staff of Rep. Allen's congressional office conducted a survey of nine drug stores in his district. Rep. Allen represents the 1st Congressional District of Maine, which includes Portland and the surrounding communities.

C. Determination of Prices for Favored Customers

Drug pricing is complicated and drug companies closely guard their pricing strategies. In order to determine the prices that drug manufacturers charge their most favored customers, the minority staff used the prices on the Federal Supply Schedule (FSS).²³ FSS prices are the prices at which many federal agencies can purchase drugs. They are negotiated by the federal government and the drug manufacturers.

According to the U.S. General Accounting Office (GAO), an investigative arm of Congress, "[u]nder GSA procurement regulations, VA [Department of Veterans Affairs] contract officers are required to seek an FSS price that represents the same discount off a drug's list price that the manufacturer offers its most-favored nonfederal customer under comparable terms and conditions."²⁴ As a result, according to GAO, "federal supply schedule prices represent the best publicly available information on the prices that pharmaceutical companies charge their most favored customers."²⁵

purchase the brand-name version, although the Congressional Budget Office has found that the availability of a generic drug often does not decrease the cost of the brand-name product. See *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, *supra* note 14.

²²Orion Group, *Orion Group Annual Report 1998* (1999) (available online at <http://www.orion.fi/ewww/index.html>).

²³There is no FSS price available for the generic version of the drug tamoxifen, manufactured by Barr Laboratories. For the price comparison for this drug, the minority staff compared the retail price of the generic version of the drug with the FSS price for the brand name version, Nolvadex. Because favored customers most likely negotiate better prices for the generic than the brand name version of the drug, this is likely to be a conservative assumption, underestimating the true price difference.

²⁴U.S. General Accounting Office, *Drug Prices: Effects of Opening Federal Supply Schedule for Pharmaceuticals Are Uncertain*, 6 (June 1997).

²⁵Letter from William J. Scanlon, Director, GAO Health Financing and Public Health

D. Determination of Drug Markups

In order to assess whether the differences between the prices paid by women in Maine and the prices paid by favored customers could be attributed to post-manufacturer markups, this report examined the markups charged by drug wholesalers and pharmacists. To determine these markups, the Wholesale Acquisition Cost (WAC) was obtained for the five drugs analyzed in this report. These WAC prices are the average prices at which drug manufacturers sell the drugs to wholesalers, who then resell them to pharmacists for retail distribution. The WAC prices were compared to the average retail prices for the drugs in Maine. The difference between the WAC prices and the retail prices for the drugs represents the post-manufacturer markup of wholesalers and pharmacists.

E. Selection of Drug Dosage

Prices were obtained for a monthly supply of each of the drugs. Fareston, Arimidex, and Femara are generally taken once daily, and 30 tablets represent a monthly dose of these drugs. Nolvadex is generally taken twice daily, and 60 tablets represent a monthly dose for most women with breast cancer. Eight Megace tablets are taken daily, and 240 tablets represent a monthly dose of this drug.

IV. FINDINGS

A. Breast Cancer Drugs Are More Expensive for Women in Maine than for Favored Customers

The breast cancer drugs investigated in this study are substantially more expensive for women in Maine than for favored customers such as HMOs and the federal government. For the five hormonal therapies for breast cancer, Maine women without prescription drug coverage must pay an average of 102% to 106% more than the drug manufacturers' favored customers for a one month supply (Table 1). This means that, on average, the prices paid by Maine women are more than twice the prices paid by favored customers.

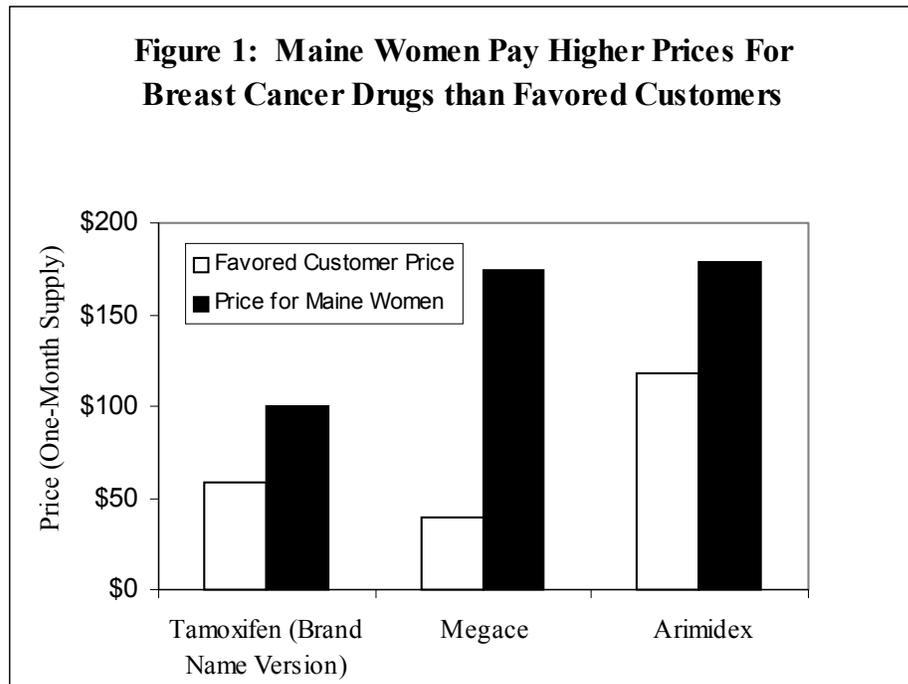
All five drugs are more expensive for women with breast cancer in Maine who lack drug coverage than they are for drug manufacturers' favored customers. The drug with the highest percentage price differential is Megace, the hormone treatment manufactured by Bristol Myers-Squibb. Favored customers pay only \$39.60 for a one month supply of Megace, while women in Maine who lack prescription drug coverage must pay \$174.28 -- over four times as much.

Two different price differentials are presented in this report for tamoxifen because tamoxifen is dispensed both under the brand name Nolvadex and as a licensed generic drug. The brand name version, Nolvadex, costs women in Maine with breast cancer 72% more than the

Section (Apr. 21, 1999).

manufacturer's favored customers. The licensed generic costs 53% more.

Overall, three of the five drugs have price differentials of more than 50% (Figure 1). Femara, manufactured by Novartis, has the lowest price differential, 20%.



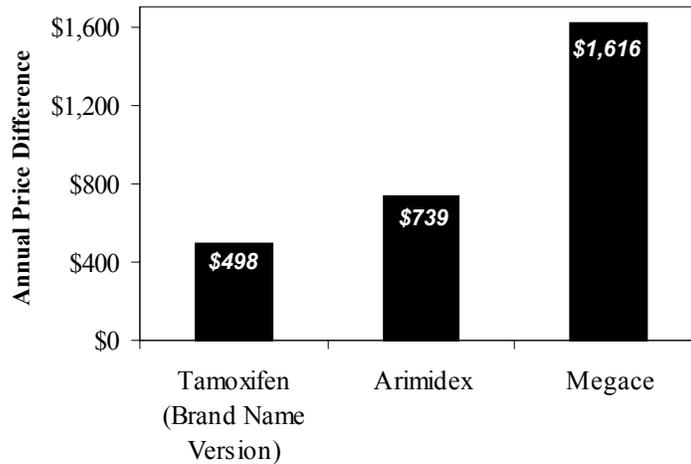
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\$5,900 on the drug -- \$1,830 to almost \$2,500 more than a favored customer.

Some women who initially begin taking tamoxifen have a recurrence of the disease, and switch to second-line therapies such as Arimidex. For these women, the price differences can be even larger. Arimidex is sold by AstraZeneca and is used to treat advanced stage breast cancer. A woman with breast cancer in Maine without prescription drug coverage pays over \$60 more than a favored customer for a monthly prescription of Arimidex. For one year of treatment, a breast cancer patient in Maine would pay over \$2,100 for Arimidex, compared to \$1,410 for a favored customer. This is a price difference of over \$700. Megace has the highest price difference in dollars. A breast cancer patient in Maine who pays for her own drugs would pay \$1,616 more than a favored customer for a one year supply of Megace (Figure 2).

C. Price Discrimination by Drug Manufacturers Is the Primary Cause of the Price Differentials

Figure 2: Maine Women Pay Hundreds of Dollars More Per Year for Breast Cancer Drugs than Drug Manufacturers' Favored Customers



Drug manufacturers have argued that it is misleading to compare prices paid by individual consumers with what they describe as “wholesale level” prices paid by favored customers such as HMOs and the federal government. According to the manufacturers, the differential between these two prices is often largely explained by the markups charged by pharmacies.

This report assessed this contention by comparing the Wholesale Acquisition Cost for the five drugs, which is the average price that drug manufacturers charge drug wholesalers, with the average retail price for the drugs in Maine. This comparison showed that the combined wholesale

and pharmacy markup for these breast cancer drugs is an average of only 13%. This markup can explain less than one third of the difference between the prices paid by breast cancer patients in Maine and the prices paid by favored customers.

The drug manufacturers have also suggested that lower prices paid by favored customers are simply due to volume discounts given to those who purchase large amounts of pharmaceuticals. The findings in this analysis indicate that this does not account for the observed price differentials. Drug wholesalers, which purchase drugs for resale to pharmacies, purchase drugs in large volumes. But the wholesale acquisition cost (WAC) at which drug wholesalers are able to buy the five breast cancer drugs examined in this report are 80% higher than the prices for favored customers.

These findings indicate that the high prices for breast cancer drugs in Maine are attributable primarily to manufacturer-level price discrimination. The drug manufacturers charge low prices for these drugs when they are sold to favored customers, such as HMOs and the federal government, but substantially higher prices when the drugs are intended for use by women with breast cancer who lack prescription drug coverage. The consequence of this price discrimination is that the women with breast cancer who can least afford high drug costs, such as women on Medicare and uninsured younger women, are forced to pay the most for the drugs that they need to survive.