Breast Cancer Drugs Are More Expensive on Long Island than in Foreign Countries

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Prepared for Rep. Carolyn McCarthy

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Special Investigations Division
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U.S. House of Representatives

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EXECUTIVE SUMMARY

Many women on Long Island who have breast cancer must pay high prices for lifesaving prescription drugs. This report, which was prepared at the request of Rep. Carolyn McCarthy, investigates how these prices compare with the prices paid for the same drugs by women in other countries.

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. The high cost of breast cancer drugs has a special impact on Long Island women because women on Long Island suffer from breast cancer at rates that are among the highest in the nation.

This report analyzes the pricing of five brand-name prescription drugs that are commonly prescribed to treat breast cancer. It compares prices for these breast cancer drugs on Long Island with prices for these same drugs in Canada, the United Kingdom, France, and Italy. It is the first report to compare prices of breast cancer drugs on Long Island with the prices of the same drugs in foreign countries.

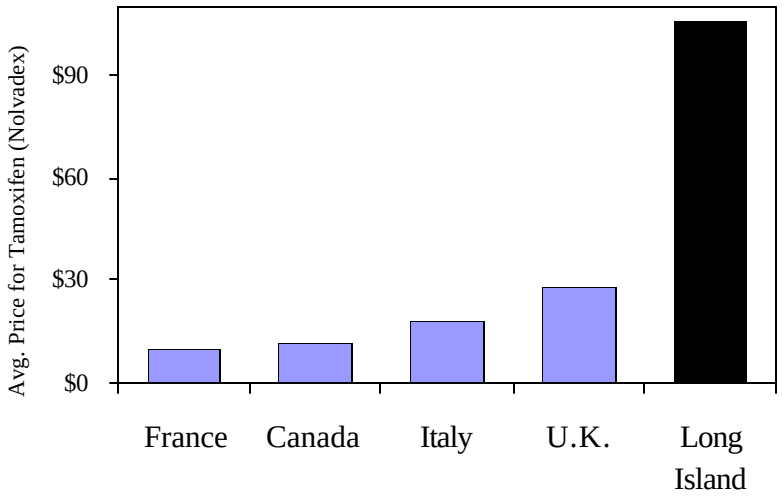
The report finds:

C **Breast cancer drugs are more expensive in Long Island than in other countries**. For a Long Island woman with breast cancer who does not have prescription drug coverage, the average price for the five commonly used breast cancer drugs is 133% higher than the average price in Canada, the U.K., France, and Italy. This means that these five breast cancer drugs cost women on Long Island more than twice as much as they do women in other countries.

• **Breast cancer drugs are, on average, over three times more expensive on Long Island than in Canada and France.** Among the four foreign countries surveyed, Canada and France have the lowest prices for the five breast cancer drugs. For a Long Island woman with breast cancer who does not have prescription drug coverage, the average price for the five breast cancer drugs is 3.2 times higher than the price in Canada and 3.6 times higher than the price in France.

C **The most widely used breast cancer drug has the highest price differential**. Tamoxifen, sold under the brand-name Nolvadex, is the most widely used breast cancer drug in the United States. It has the highest price differential of any of the five breast cancer drugs. Nolvadex costs over six times as much on Long Island as it does in other countries. A monthly supply of Nolvadex costs Long Island women without prescription drug coverage $105.87. In Canada, the same amount of the drug costs only $12.00 -- a price differential of almost 800%. In France, a monthly supply of Nolvadex costs only $10.20, a price differential of 938% (Figure 1).

Figure 1: Long Island Women Without Prescription Drug Coverage Pay More for Breast Cancer Drugs Than Women in Other Countries



- **The price differences are substantial in dollar terms.** A patient who is diagnosed with breast cancer will typically take prescription drugs each day for up to five years in order to prevent the growth and spread of cancer. For a full five-year course of treatment with tamoxifen, sold under the brand-name Nolvadex, a Long Island breast cancer patient who does not have prescription drug coverage must spend over $6,300. This is over $5,600 more than a woman in Canada would spend on the same drug. For Arimidex, another breast cancer treatment, Long Island women without prescription drug coverage must pay an average of almost $1,000 more each year than women in Canada.

I. BREAST CANCER TREATMENT AND INCIDENCE

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]

Women on Long Island are at particular risk for breast cancer. Long Island has one of the highest incidences of breast cancer in the United States. The breast cancer mortality rate on Long Island is over 20% higher than the national average.[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]

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[1]Cancer 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.

[2]Katrina 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]National Cancer Institute, *The Long Island Breast Cancer Study Project* (1999) (online at http://www-dccps.ims.nci.nih.gov/LIBSCP/Stats.html).

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

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

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

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 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. Nationwide, approximately 15% of women younger than 65 -- approximately five million women -- have no health insurance coverage at all.[10] 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.[11]

For women with breast cancer who must pay for their own prescription drugs, the costs can be staggering. Because of the high costs of diagnosis and treatment, many women with breast cancer are forced to delay diagnosis and treatment or forego appropriate care.[12]

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

[8]Although Medicare beneficiaries can purchase supplemental "Medigap" insurance privately, these policies are often prohibitively expensive or 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).

[9]HCFA, Unpublished Medicare Current Beneficiary Survey Data Provided Upon Request to Rep. Henry A. Waxman (Oct. 1999).

[10]U.S. Census Bureau, *Health Insurance Coverage 1998* (Oct. 1999).

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

[12]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).

II. OBJECTIVE OF THE REPORT

In the United States, drug manufacturers are allowed to discriminate in drug pricing. As the Congressional Budget Office reported, "[d]ifferent buyers pay different prices for brand-name prescription drugs. ... In today's market for outpatient prescription drugs, purchasers that have no insurance coverage for drugs ... pay the highest prices for brand-name drugs."[13] The Federal Trade Commission has reached the same conclusion, reporting that drug manufacturers use a "two tiered pricing structure" under which they "charge higher prices to ... the uninsured."[14]

In Canada, the U.K., France, and Italy, however, consumers are protected from manufacturer price discrimination. In Canada, the country's Patented Medicine Prices Review Board requires that the prices of new, brand-name drugs not exceed the average price of the drug in seven other industrialized countries.[15] In Italy, the government uses a similar approach, refusing to reimburse manufacturers for a drug if its price exceeds a twelve country European average price.[16] In France, the Drugs Economic Committee establishes a maximum price for each drug based on its therapeutic value and the price of the drug in other countries.[17] In the U.K., drug companies are free to establish their own prices on individual drugs. However, under the country's pharmaceutical laws, the maximum profit that drug manufacturers can earn on sales in the U.K. is limited to 17%.[18]

Because of these differences among the United States and other countries, Rep. McCarthy asked the minority staff of the Government Reform Committee to conduct an international comparison of the prices of breast cancer drugs. She requested that the staff compare the prices paid for prescription drugs by breast cancer patients in her district with the prices paid by women in Canada, the U.K., France, and Italy for the same drugs. In particular, she requested an examination of whether the drug manufacturers have adopted pricing strategies that force breast cancer patients on Long Island to pay higher prices for breast cancer drugs than women in the other countries.

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

[14]Federal Trade Commission, *The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change*, 75 (Mar. 1999).

[15]*See* Patented Medicine Prices Review Board, *Eleventh Annual Report for the Year Ending December 31, 1998* (1999).

[16]*See* Health Policy, *The New Pharmaceutical Policy in Italy*, 46, 21-41 (1998).

[17]*See* Congressional Research Service, *Determination of Prescription Drug Prices in France, the United Kingdom, and Italy* (Sept. 11, 2000).

[18]*Id.*

This report presents the results of the investigation requested by Rep. McCarthy. It is the first report to compare the prices of breast cancer drugs on Long Island with the prices of breast cancer drugs in other countries.

III. METHODOLOGY

A. Selection of Drugs

This report focuses on five leading brand-name drugs that are approved by the Food and Drug Administration (FDA) for breast cancer treatment.[19] All five drugs are used as out-patient hormonal therapies.[20] These drugs are:

- Tamoxifen, a hormone therapy manufactured by AstraZeneca and sold under the brand-name Nolvadex. 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 1999 were $573 million.[21]

- Arimidex, a hormone therapy manufactured by AstraZeneca. Arimidex was recently approved as a first-line treatment option for breast cancer in post-menopausal women and is

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[19]The report focuses on brand-name drugs because manufacturers of brand-name drugs have greater control over drug pricing than manufacturers of generic drugs. Consumers who purchase generic drugs often pay less than those who purchase brand-name drugs, but 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 13. Among the drugs included in this study, one drug (Megace) is available in a generic version, and a second drug (Nolvadex) is available as a licensed generic through a patent claim settlement that gave one generic manufacturer the exclusive rights to distribute the generic version.

[20]This 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.

[21]Zeneca, *Annual Report and Form 20-F 1999* (2000) (available online at http://www.astrazeneca.com/Investors/annualrep1999/contents/c19.htm).

also used as a second-line therapy when treatment with tamoxifen has failed. Total sales of Arimidex are approximately $120 million annually.[22]

- 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 are approximately $150 million annually.[23]

- 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 are approximately $114 million annually.[24]

- Fareston, sold in the United States by Schering-Plough. Fareston is a first- or second-line treatment for advanced breast cancer. Total sales of Fareston are approximately $13 million annually.[25]

B. Determination of Prices on Long Island

In order to determine the prices that women without drug coverage are paying for these breast cancer drugs on Long Island, the staff of Rep. McCarthy's office conducted a survey of nine drug stores -- including both independent and chain stores -- on Long Island. Rep. McCarthy represents the 4th Congressional District in New York, which is located on Long Island and includes the towns of Freeport, Hempstead, and Mineola. Average drug prices on Long Island were estimated by averaging the prices obtained from these drug stores.

C. Determination of Prices in Canada, the U.K., France, and Italy

Prices for prescription drugs in Canada, the U.K., France, and Italy were determined via a survey of pharmacies in these countries. At the request of the minority staff of the Committee on Government Reform, the surveys were conducted by the Office of NAFTA and Inter-American Affairs of the U.S. Department of Commerce in August 2000. All prices were obtained in local

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[22]Zeneca, *Annual Report and Form 20-F 1998* (1999).

[23]Forbes, *A New Career for Dr. Vasella* (Feb. 9, 1998).

[24]Bristol-Myers Squibb, *Annual Sales History for Bristol-Myers Squibb Major Products* (2000) (available online at www.shareholder.com/bmy/financials.cfm).

[25]Orion Group, *Orion Group Annual Report 1999* (2000) (available online at http://www.orion.fi/ewww/index.html).

currency and converted to U.S. dollars using commercially available exchange rates.

D. 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. Eight Megace tablets are taken daily, and 240 tablets represent a monthly dose of this drug. The dosages, forms, and package sizes used in the study are shown in Table 1.

In Canada, Fareston was not available, but the other four prescription drugs surveyed in this report were available in the same dosage as in the United States. In France, Italy, and the U.K., all five drugs were available, but Megace was not sold in the 20 mg. dosage available in the United States. In France and Italy, Megace was only sold in 160 mg. tablets. Because this dosage size was eight times larger than the U.S. size, it was not included in the price comparison.[26] In the U.K., Megace was available in a 40 mg. dosage and was included in the comparison. For this comparison, prices of equivalent quantities were used for the comparison. The price of two 20 mg. tablets in the United States was compared to the price of one 40 mg. tablet in the U.K.

IV. FINDINGS

A. Breast Cancer Drugs Are More Expensive on Long Island Than in Foreign Countries

The prices for the five breast cancer drugs paid by Long Island women without prescription drug coverage are significantly higher than the prices paid by women in other countries. For a woman with breast cancer who pays for her own drugs, the average price of these drugs on Long Island is 133% higher than the average price in the four foreign countries. This means that, on average, the drugs cost over twice as much on Long Island than they do in the other countries (Table 1).

Table 1: Long Island women without prescription drug coverage pay higher prices for breast cancer drugs than women in other countries.

Drug	Manufacturer	Quantity	Avg. Foreign Price	Long Island Price	Price Differential	
					Dollar	Percent
Tamoxifen (Nolvadex)	AstraZeneca	10 mg, 60 tab.	$17.10	$105.87	$88.77	519%
Arimidex	AstraZeneca	1 mg, 30 tab.	$149.78	$194.88	$45.10	30%
Femara	Novartis	2.5 mg, 30 tab.	$152.40	$190.94	$38.54	25%
Fareston	Schering-Plough	60 mg, 30 tab.	$55.50	$93.17	$37.67	68%

[26]If the price of Megace in 160 mg. tablets had been included in the analysis, it would have increased the observed price differential between drug prices on Long Island and drug prices in the four foreign countries.

Megace	Bristol Myers Squibb	20 mg , 240 tab	$145.80	$178.72	$32.92	23%
Average						**133%**

B. Breast Cancer Drugs Are Over Three Times More Expensive on Long Island Than in Canada and France

In each of the four other countries, prices for the five breast cancer drugs are lower than on Long Island. Canada and France have the lowest prices of the four foreign countries. The average price differential between the prices in Canada and the prices on Long Island is 223%. This means that women on Long Island who pay for their own drugs must pay 3.2 times more for breast cancer drugs than women in Canada. The average price differential between the prices in France and the prices on Long Island is 256%. This means that women on Long Island must pay 3.6 times more for breast cancer drugs than women in Canada.

The differentials between the prices on Long Island and the prices in the U.K and Italy are also large. The prices for the five breast cancer drugs are on average 172% higher on Long Island than in Italy and 114% higher than in the U.K. Prices for a monthly supply of the individual drugs in the four foreign countries can be seen in Appendix 1.

C. The Most Widely Used Breast Cancer Drug Has the Highest Price Differential

Tamoxifen, sold under the brand-name Nolvadex, is the most widely used breast cancer drug in the United States, with over 100,000 prescriptions filled in 1999. Nolvadex has the highest price differential of any of the five drugs in this survey, costing over six times as much on Long Island as it does in other countries. The average differential between the price of Nolvadex on Long Island and the price of this drug in Canada, the U.K., France, and Italy is 519%.[27]

A monthly supply of Nolvadex costs Long Island women without prescription drug coverage $105.87. In Canada, a woman can buy the same amount of the drug for only $12.00. This is a price differential of 782%. In France, this same amount of the drug costs $10.20, a price differential of 938%.

The drug with the second highest price differential in percentage terms is Fareston. The price differential for Fareston is 68%. A monthly supply of the drug Fareston costs Long Island women who pay for their own drugs $93.17. In Italy, a monthly supply of this drug costs $33.00, a price difference of 182%. In the U.K., a monthly supply of this drug costs $59.10, a price differential of 58%.

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[27]Tamoxifen is also available in the United States as a licensed generic, sold by Barr Laboratories. A survey of pharmacies in Rep. McCarthy's district found no significant difference between the price of this licensed generic version of tamoxifen and the brand name drug.

D. Price Differentials Are Substantial in Dollar Terms

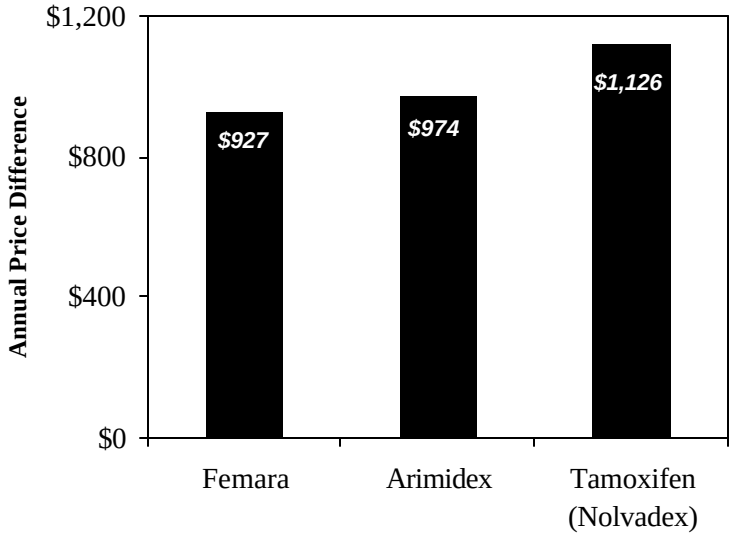
These price differences translate into large sums in dollar terms. A woman who is diagnosed with breast cancer and undergoes therapy involving prescription drugs will typically take hormonal therapies daily for up to five years. Over the course of treatment, a woman on Long Island with breast cancer who lacks prescription drug coverage could be forced to pay thousands of dollars more for these drugs than women in other countries.

A monthly prescription for Nolvadex, the brand-name version of tamoxifen, costs a Long Island woman without prescription drug coverage $93.87 per month more than a woman in Canada. On an annual basis, this represents a price difference of over $1,100. For a full five-year course of treatment, a Long Island breast cancer patient without drug coverage would spend almost $6,300 on Nolvadex -- over $5,600 more than a woman in Canada.

Tamoxifen is a first-line hormonal therapy for breast cancer. Some women who initially begin taking tamoxifen have a recurrence of the disease and switch to second-line therapies such as Arimidex. These women also face high prices. A woman with breast cancer on Long Island without prescription drug coverage pays over $80 more than a woman in Canada for a monthly prescription of Arimidex. For one year of treatment, a woman with breast cancer on Long Island would pay over $2,300 for Arimidex, compared to only $1,364 in Canada. This is an annual price difference of almost $1,000.

Femara also has a high price difference in dollars. A breast cancer patient on Long Island who pays for her own drugs would pay over $900 more than a woman in Canada for a one year supply of Femara (Figure 2).

Figure 2: Women on Long Island Pay Hundreds of Dollars More Per Year for Breast Cancer Drugs than Women in Canada



V. CONCLUSION

This report finds that women without prescription drug coverage on Long Island pay higher prices for breast cancer drugs than women in other countries. While consumers in other countries are protected from price discrimination by drug manufacturers, Long Island women who lack drug coverage have no such protection. As a result, drug manufacturers charge low prices for breast cancer drugs in other countries, but high prices for the same drugs on Long Island. The women with breast cancer on Long Island who can least afford high drug costs, such as women on Medicare and younger women without prescription drug coverage, are being forced to pay the most for the drugs that they need to survive.

Appendix 1: Prices of Individual Drugs on Long Island and in Canada, the U.K, France, and Italy

Drug	Quantity, Dosage	Long Island Price	Canadian Price	U.K Price	French Price	Italian Price	Average Foreign Price
Megace	20 mg., 240 tab.	$178.72	$232.80	$58.80*	Not. Avail.*	Not. Avail.*	$145.80
Fareston	60 mg, 30 tab.	$93.17	Not Avail.	$59.10	$74.40	$33.00	$55.50
Arimidex	1 mg, 30 tab.	$194.88	$113.70	$167.10	$143.70	$174.60	$149.78
Femara	2.5 mg, 30 tab.	$190.94	$113.70	$167.10	$150.60	$178.20	$152.40
Nolvadex	10 mg, 60 tab.	$105.87	$12.00	$28.20	$10.20	$18.00	$17.10

* Because Megace is not available in the U.K. in the 20 mg. size, this price comparison is based upon 120 40 mg. tablets. Megace is approved for use in France and Italy, but is not sold in a comparable size and thus was not included in this analysis.