

# Helping Improve Women's Health Today and Tomorrow



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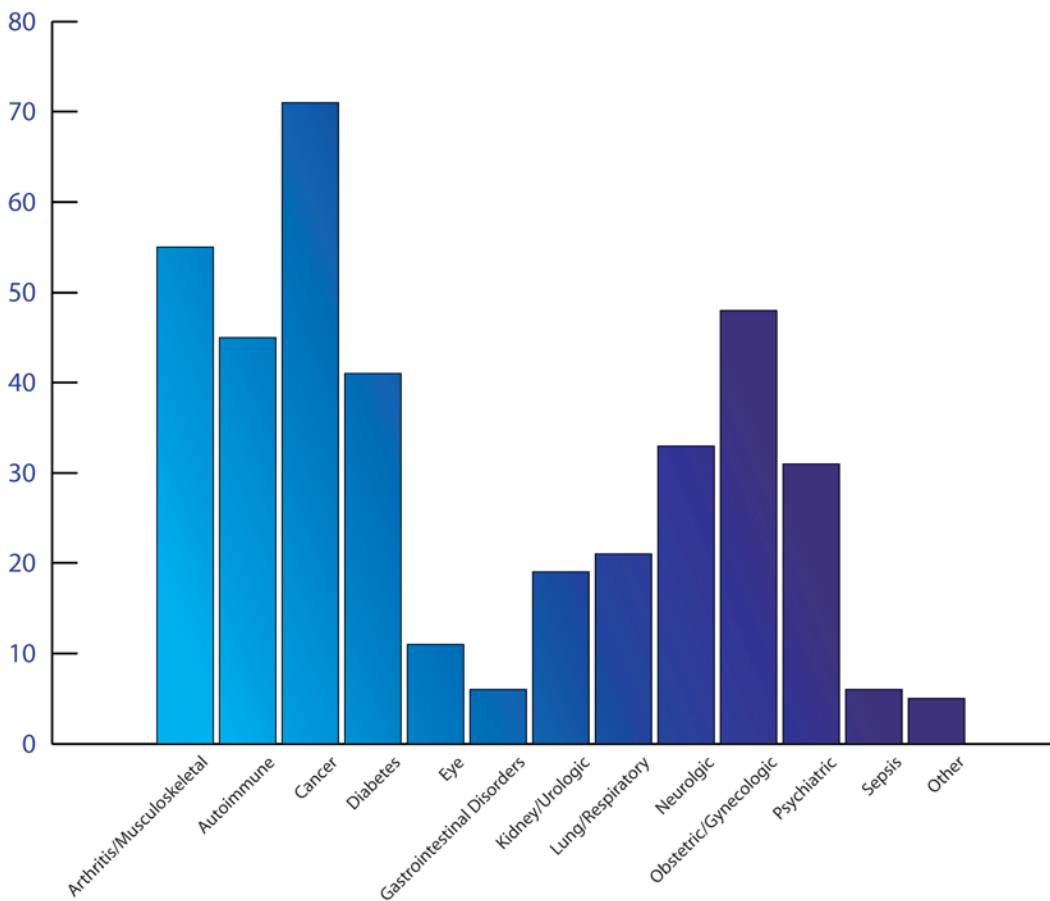
***P*hRMA**

## NEW MEDICINES IN THE PIPELINE FOR WOMEN

Every day millions of women across America are hoping for new treatments to help them fight the battle against such diseases as breast cancer, Alzheimer's and multiple sclerosis. The good news is that bio-pharmaceutical researchers are joining women in this fight for life by researching and developing new life-saving and life-enhancing medicines.

Today, more than 370 new medicines and vaccines that can help women lead longer, healthier lives are in the pipeline. These new medicines in development for women are either in clinical trials or awaiting approval by the Food and Drug Administration.

Medicines and Vaccines in Development for Women



*New medicines include:*

- 71 for cancer. This includes, but not limited to 41 for breast cancer, 34 for ovarian cancer and 10 for cervical cancer.
- 55 for arthritis/musculoskeletal disorders. Arthritis affects 41 million women, while musculoskeletal disorders cost the economy nearly \$125 billion annually in direct expenses, lost wages, and reduced productivity.
- 48 for obstetric/gynecologic conditions, which affect more than 4.5 million women ages 18 to 50 each year.
- 45 for autoimmune diseases, the fourth highest cause of disability among American women, who are 2.7 times more likely to be affected by such a disease than men.
- 41 for diabetes, which is reaching epidemic proportions, particularly among women and minorities. Almost 9 percent of women over the age of 20 have diabetes, including one-third who do not know it.
- 23 for depression. Almost twice as many women as men suffer from major depressive disorder.
- 21 for Alzheimer's disease, which affects two to three times as many women as men, including 50 percent to 70 percent of women over the age of 80.
- 20 for asthma, which affected more than 31 million Americans in 2001, with the prevalence rate for women being 30 percent higher than for men.

## PARTNERSHIP FOR PRESCRIPTION ASSISTANCE

Pharmaceutical researchers and manufacturers understand that the benefits of their products are only as real as the ability of patients to obtain them. The Partnership for Prescription Assistance matches patients to programs that may be able to provide them free and deeply discounted prescription medications. The PPA program has successfully helped America's working people, those without jobs, students, families, seniors, and retirees, including 41% of uninsured women who say they can not afford to fill prescriptions.

PPA cuts through the red tape. It offers a single point of access to more than 475 public and private patient assistance programs, including more than 150 programs offered by pharmaceutical companies. PPA is a partnership between America's research-based biopharmaceutical companies and 60 national healthcare organizations and community groups.



Since the national launch of PPA four months ago (Spring 2005), over 700,000 Americans who contacted PPA have been matched to at least one program. Low-income women across America who are looking for help accessing affordable medicines, should contact the Partnership for Prescription Assistance to see if they qualify (toll free 1-888-4PPA-NOW, or 1-888-477-2669. [www.pparx.org](http://www.pparx.org)).

## MEDICARE PRESCRIPTION DRUG BENEFIT

Women (56%) are more likely than men (42%) to use a prescription medicine on a regular basis, and also are more likely to report difficulties affording their medications. Many of these women are among the seniors and disabled patients who have waited for a long time for better access to prescription drugs, including more and better prescription drug coverage. Fortunately, this was finally resolved with the enactment of the Medicare Modernization Act with its new drug benefit.

The drug benefit, which begins January 1, 2006, is the single-most important enhancement to Medicare since its creation 40 years ago. It could give 10 million people coverage for the first time and another 14 million with modest incomes prescription drug coverage with low copayments of \$2 to \$5 per prescription. The new benefit also protects everyone in Medicare from catastrophic prescription drug expenses.

Caregivers will also want to take note of this new benefit: One in 10 women (12%) care for a sick or aging relative, and will likely be helping that relative to enroll. Enrollment begins November 15, 2005.

**Medicare Rx**  
EDUCATION NETWORK 

**PhARMA**

## WOMEN LIVING LONGER, HEALTHIER LIVES NOW MORE THAN EVER



According to recent reports, every 12 minutes a woman in America dies of breast cancer. Every year over 40,000 women die from this disease. Clearly, breast cancer is still one of the most common forms of cancer in women.

The good news is that over the past twenty years, there have been major advances in the diagnosis and treatment of breast cancer. New medicines are making possible significant improvements in the outlook for women with breast cancer, new research shows. Currently, there are 41 new medicines in the pipeline to help fight breast cancer.

As a result of advancements in medicine, overall mortality for breast cancer has fallen from 32.3 deaths per 100,000 women in 1980 to 25.4 deaths in 2000, according to a report by MEDTAP International, "The Value of Investment in Health Care." In the same time period, the risk for a 54 year-old woman with breast cancer of developing the aggressive metastatic form of the disease has decreased from 40% to 15%.

The 2004 MEDTAP report also calculated the value of the improvements reflected in these statistics, finding that for every additional dollar invested in breast cancer treatment, \$4.80 in health gains resulted. The report highlights some of the new medicines that play a key role in achieving these health gains.

More than ever before, medicines offer hope to those with breast cancer. Tamoxifen has been an effective part of cancer treatment for over 20 years and recently, it was approved for a new indication to help prevent breast cancer in women at high risk for the disease. Research found a 49% reduction in invasive breast cancer and a 50% reduction in non-invasive breast cancer in women on tamoxifen. This new indication is in addition to its established use in patients for five years after breast cancer surgery, reducing the risk of recurrence by 47%.

Additional advances are continuing to improve the odds for women with breast cancer. Patients who follow-up standard tamoxifen treatment with a new medicine, letrozole, cut their risk of a recurrent breast cancer by an additional 43%, a recent study in the New England Journal of Medicine shows. On this medicine, nearly half

as many women lost their lives to breast cancer. In fact, letrozole was so effective in reducing the risk of recurrence and death that researchers ended the study early to make the medicine available to all participants.

Other new medicines are also making it possible for more women to conquer breast cancer. Trastuzumab, a new medicine used in combination with chemotherapy, fights an aggressive, deadly type of breast tumor that produces excessive amounts of a protein called HER-2. This treatment has been found to reduce the risk of death within one year by one-third, and significantly improves patients' quality of life.



Remember, on October 21 our nation will celebrate National Mammography Day. Women across America should honor this day by getting a mammogram.

## U.S. Prescription Drug Safety: The World's Standard

The U.S. Food and Drug Administration (FDA) is responsible for assessing the efficacy and safety of drugs before they reach patients. Most experts regard FDA's extensive review as the "world's gold standard." In fact, fewer than 3 percent of approved prescription medicines have been withdrawn from the market over the last 20 years. Of the more than 10,000 prescription medicines on the market, the vast majority are working well and helping patients live productive, healthier lives.

Of course, all prescription drugs have some risk associated with their use. These are powerful treatments and patients should always discuss the risks and benefits of their medicines with their physician.

*Marketed prescription medications must have FDA approval which rests on the answers to two basic questions:*

- Do the results of well-controlled studies provide substantial evidence of effectiveness?
- Do the results show that the product's benefits outweigh its risks under the conditions of use described in the label?

*Consider the following:*

- For every 10,000 compounds that could become drugs only five ever make it to a clinical study (Phase III) on human patients, and only one is ever approved for sale.
- Pharmaceutical companies are required to provide the FDA with access to 100% of the data generated in clinical trials which include thousands of patients. In addition, all major observed side effects are promptly shared with the FDA.
- The FDA review typically requires 13-person years to examine the data and ensure that a medication's maker has met all of the regulatory and procedural requirements.
- Information about very rare safety issues of a medication and its appropriate use might only emerge once a drug has entered the market and has been used by a wider patient population. In other words, some risks and patient

reactions may not be determinable until a medication is used by hundreds of thousands of patients.

- Companies continue to track safety issues that might arise from use of their products once they are on the market.
- Companies have both a regulatory and an ethical obligation to monitor ongoing safety concerns and to report them to the FDA. In addition to reporting to the FDA, should new safety information be discovered, companies and the FDA work towards changing the drug label to reflect this new information. Important new information is always communicated to the medical community in a timely manner, for example via “Dear Doctor” letters.

## IMPORTATION AND WOMEN'S HEALTH

Just last year, the Food and Drug Administration warned women across America that counterfeit contraceptive patches were being sold by a rogue foreign Internet site. This Internet site, which posed as an American business but purportedly operated out of New Delhi, India, was selling fake patches that contained no active ingredient whatsoever and were incapable of providing protection against pregnancy.



In recent testimony before the Senate, the FDA highlighted the danger in imported drugs that lack effectiveness. An FDA official told the Senate Judiciary Committee last year about a patient with breast cancer who purchased breast cancer medication over the Internet from a Canadian pharmacy. According to the FDA official, "They did not give her Tamoxifen [a breast cancer medicine]. They gave her something different. And she continued to take it, her breast cancer continued to grow. And she didn't know she had been defrauded by this Canadian drugstore."

Authentic Ortho Evra®  
Transdermal Patch

Women in particular should be concerned that rogue online pharmacies are selling counterfeit drugs -- such as fake contraceptive patches -- to American consumers. Many consumers find out the hard way that purchasing foreign drugs over the Internet is unsafe and in some cases dangerous.

Americans are mistaken if they believe that most Canadian online pharmacies are really distributing medicines from Canada. According to a recent survey by Cyveillance, a company hired by the FDA to monitor thousands of websites claiming to be Canadian pharmacies, a majority of those sites were not actually Canadian and few actually sell drugs.



Counterfeit  
Contraception Patch

Some women might also assume that if Congress were to legalize importation of prescription drugs that they would only come from Canada. The truth is that Congress is considering legislation that could open America's borders to potentially dangerous, unsafe counterfeit drugs from over 25 countries around the world.

Just imagine how many more counterfeits could enter America if Congress were to open the floodgates to drugs made in countries without strict safety regulations, such as Latvia, Slovakia and Slovenia. These are just a few nations that would be allowed to legally import drugs to America if importation legislation were to pass.

Would you want to buy prescription drugs that were made in Pakistan, shipped to France and then imported to America through Canada? Would you want to receive your prescription drugs from a country with documented counterfeiting, such as South Africa, where according to reports 20% of the medicines are fake or stolen? Playing Russian roulette is not the answer to more affordable drugs.

Women who are looking for a safe option here at home and need help accessing affordable life-saving prescription drugs should contact the Partnership for Prescription Assistance (PPA). This one-stop shop provides access to information about hundreds of patient assistance programs that offer deeply discounted or free medicines for those low-income Americans who need them the most. To learn about these programs, you can contact PPA at either 1-800-PPA-NOW or [www.pparx.org](http://www.pparx.org).

To find more information about the dangers of purchasing drugs on foreign websites, visit [www.buysafedrugs.info](http://www.buysafedrugs.info).

**BuySafeDrugs.info**

*Think your drugs are from Canada? Think Again.*

