

Women



More Than **600** Medicines in Development for Diseases Impacting Women

While women and men often face many similar health issues, women are confronted with unique health challenges due to biological differences as well as environmental and societal factors. Due to these factors, disease can affect women differently than men which can result in different health outcomes. For example, women are less likely to suffer from coronary artery disease, leading to heart attack and heart failure. But the women who do develop the disease face worse outcomes than men, many times due to early misdiagnoses.⁶ Many women also face higher incidence of certain diseases relative to men, but experience similar outcomes. For example, thyroid cancer affects women nearly three times more than men, yet death rates are similar.⁷

Life expectancy among all Americans differs depending on race, ethnicity and societal factors. Unfortunately, after years of increasing, life expectancy for all Americans has declined in recent years due to a multitude of factors. Women still live longer

JUST THE FACTS

In 2019,

heart disease, cancer and stroke were the leading causes of death in women.¹

38%

of women suffer from one or more chronic diseases.²

5.7 years

Women live on average 5.7 years longer than men.³

754 | 50,000

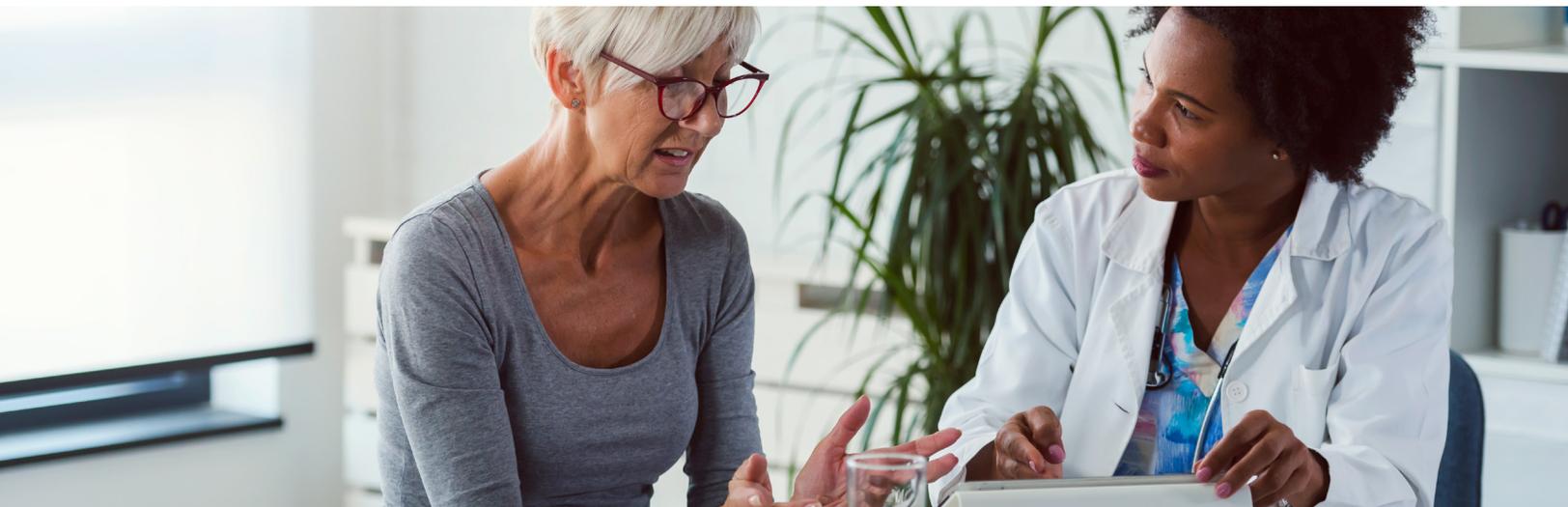
In 2019, 754 women died during pregnancy in U.S.,⁴ another 50,000 experienced severe pregnancy complications.⁵



than men - 79.9 years for women compared to 74.2 years for men in 2020 - but female life expectancy has decreased to its lowest level since 2003.^{3,8} Women continue to live longer than men after age 65, with women living 19.8 years compared 17 years for men.³ In 2019, after age 85, women outnumbered men 2 to 1.⁹

But women from different racial and ethnic backgrounds also face key differences in the three leading causes of death:¹

- For American Indian and Alaska Native women, accidents were the third leading cause of death compared to stroke for women overall.
- Cancer was the leading cause of death for Asian, Native Hawaiians/Pacific Islander and Hispanic women. However, cancer is the second leading cause of death for women overall.
- Chronic lower respiratory diseases were the third leading cause in non-Hispanic white women, while for women overall the third leading cause of death was stroke.



This report on medicines in development for women explores diseases that only affect women or diseases that disproportionately impact them. To address the need for new treatments, specifically for women and for diseases that are of major concern to them, America's biopharmaceutical research companies are developing **625** medicines targeting diseases that disproportionately or solely affect women.¹⁰ These medicines are either in clinical trials or under review by the U.S. Food and Drug Administration (FDA) and include:

- **200** for cancers primarily affecting women, including **119** for breast cancer, **66** for ovarian cancer, **4** for uterine cancer and **22** for cervical cancer. It is estimated that all together these cancers will kill more than 76,000 women in 2022.⁷
- **133** for neurologic disorders, including **90** for Alzheimer's disease of which two-thirds of the 6.2 million Americans living with Alzheimer's today are women;¹⁵ **13** for migraine which affects about 29 million Americans, of which 3 of 4 are women;¹⁴ and **25** for multiple sclerosis which is three times more common in women than men.¹⁶
- **87** for autoimmune diseases, which have a greater prevalence among women, occurring at a rate of 2 to 1.¹³ Some of the diseases targeted by these medicines include, **37** for lupus where 9 of 10 diagnosed adults are women;¹¹ **15** for myasthenia gravis, a disease causing weakness and fatigue of the muscles under voluntary control in the body, which is more common in women under 40 than older women;¹⁴ **12** for scleroderma, a condition which causes hardening of the skin due to abnormal growth of connective tissue; and **13** for Sjogren's syndrome, a diseases which results in dryness in the eyes and mouth caused when the immune system attacks the glands that make tears and saliva, both affecting more women than men.¹³

- **45** for mental illness, including anxiety disorders, depression, postpartum depression and eating disorders. Almost twice as many women as men suffer from anxiety, depression and eating disorders.¹⁴
- **43** for respiratory diseases, including asthma and chronic obstructive pulmonary disease, both of which disproportionately affect women.¹⁴
- **37** for arthritis and musculoskeletal disorders disproportionately affecting women. These include **5** for fibromyalgia, where two-thirds of people with the condition are women;¹¹ **4** for osteoporosis, which affects 1 in 2 women or 80% of all people with osteoporosis;¹² and **28** for rheumatoid arthritis which affects women three times more than men.¹¹
- **34** for eye diseases, including dry eye disease. Women are more likely to develop dry eye disease due to hormonal changes.
- **33** for obstetric/gynecologic health issues, including endometriosis, menopausal symptoms, polycystic ovarian syndrome, pregnancy complications and uterine fibroids.
- **23** for infectious diseases, including candidiasis, chlamydia, genital herpes and urinary tract infections. These infectious diseases affect more women than men.
- **14** for other disabling diseases that disproportionately affect women, including chronic fatigue syndrome, interstitial cystitis, irritable bowel syndrome and urinary incontinence.

America's biopharmaceutical research companies continue to make exciting progress in the search for new treatments and cures for diseases that disproportionately impact women. We live in an era when we understand more about the difference between genders and their health care needs. These **625** medicines in development may one day help bridge the health care disparity gap experienced by women and increase the likelihood that all Americans will share in the benefits of innovation and medical progress.



Unique Health Challenges for Women

Women experience unique health challenges throughout their lifetime. They are more likely to be diagnosed with certain diseases than men – such as autoimmune diseases, depression, osteoporosis, Alzheimer's disease and more. Yet, due to gender bias in health care, women can also be misdiagnosed, which delays proper care and treatment. Nearly 40% of women will be diagnosed with a chronic disease, compared to 30% of men.² Even among women, health challenges can differ by race and ethnicity.

Overall, the U.S. has the highest rate of maternal mortality due to complications from pregnancy or childbirth compared to 10 other high-income countries.³ But maternal mortality affects women at different rates. Black women die at 2.5 times the rate of non-Hispanic white women and at 3.5 times the rate of Hispanic women.⁵ There are several factors that contribute to this disparity, such as access to quality health care, underlying chronic conditions, systemic racism and bias.

Hispanic women are 40% more likely to have cervical cancer and 20% more likely to die from the disease than non-Hispanic white women.¹⁷ More women suffer from depression than men and suicide attempts by adolescent Hispanic girls is 40% higher than adolescent non-Hispanic white girls.¹⁷ Nationally, about 1 in 8 women experience symptoms of postpartum depression, but the number of women affected differ by age, race, ethnicity and state of residence.¹⁸

Women and Caregiving

While the COVID-19 pandemic has had a negative impact on the mental health of all Americans, women are reported to bear a disproportionate share. Gender roles, family caregiving responsibilities for children and elderly family members, combined with workforce participation contribute to the unique mental health challenges faced by women.¹⁹

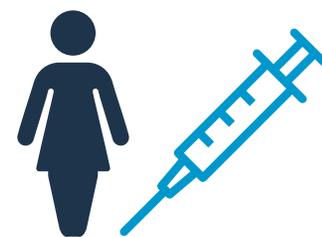
Not only are women affected by Alzheimer's disease at greater numbers than men, they also tend to be the primary caregiver for Alzheimer's patients. Nearly half of all caregivers who provide help to older adults do so for someone living with Alzheimer's or another dementia-related condition.¹⁵ About two-thirds of those caregivers are women and more than one-third are daughters.¹⁵



Biopharmaceutical Progress for Women

While the challenges are considerable, biopharmaceutical company research has led to innovations that have achieved progress against diseases affecting women. For example:

- Breast cancer, the 2nd leading cause of cancer death in women, has seen death rates fall 42% from 1989 through 2019.²⁰ Overall, the decline in breast cancer deaths is attributed to improved treatments and earlier detection through screenings, such as mammography. Unfortunately, during COVID-19 many health screenings have been delayed.
- It is estimated that more than 14,000 new cases of cervical cancer will be diagnosed in 2022 and 4,280 women will die from this deadly disease. Cervical cancer is almost always caused by the human papillomavirus (HPV). HPV vaccination has been shown to dramatically reduce the risk of invasive cervical cancer.²¹ Today, HPV vaccines help to produce immunity against several HPV types that cause about 90% of cervical cancer cases. Widespread use of the HPV vaccine has driven down prevalence of HPV infection in teenage girls by 86% and 71% in young adult females since the vaccine has been in use in the United States.
- Endometriosis is a painful condition caused when tissue similar to the lining of the uterus grows outside of the uterus. It affects more than 11% of American women between the ages of 15 and 44 years.¹⁴ It is especially common among women in their 30s and 40s and may make it more difficult to conceive.¹⁴ The first oral treatment for gynecological pain associated with endometriosis was approved in 2018.²² Prior to this approval, the only treatments available in the U.S. were injectable hormones or surgery.



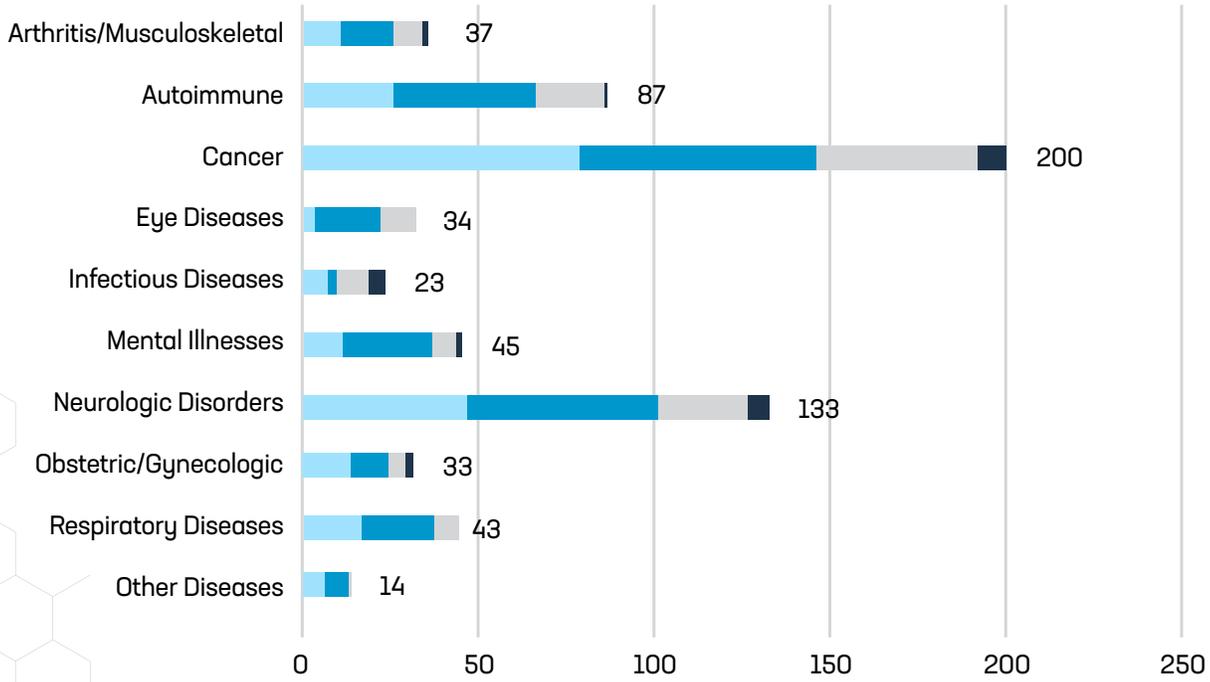
Innovative Medicines in the Pipeline

Some of the **625** medicines in development utilize expanded scientific knowledge and cutting-edge technology to target diseases in different ways and many offer new ways to treat or prevent disease. Examples of medicines being developed for diseases that exclusively or disproportionately impact women include:

- A next-generation GABA-A receptor modulator is in development to treat **postpartum depression** and **major depressive disorder**. The GABA system contributes significantly to regulating brain function, helping to reduce fear, anxiety, and stress. Low levels of GABA have been linked to increased risk of anxiety and depression and next generation GABA-A modulators are being developed to activate the GABA receptor pathway.
- An oral combination medicine is in development to treat **endometriosis** and to provide **contraception efficacy**. The medicine is a combination of an oral gonadotropin-releasing hormone (GnRH) receptor antagonist that reduces the amount of estrogen (and other hormones) produced by the ovaries, a hormone that stimulates the growth of endometriosis; estradiol (an estrogen) which may reduce the risk of bone loss; and norethindrone, which is necessary when women with a uterus take estrogen.
- A human monoclonal antibody that inhibits granulocyte-macrophage colony-stimulating factor (GM-CSF), is in development for **rheumatoid arthritis**. GM-CSF is a protein that plays a key role in immune-mediated diseases, such as rheumatoid arthritis, by stimulating immune cells (macrophages) leading to inflammation, joint damage and pain. The antibody neutralizes the function of GM-CSF by blocking the interaction of GM-CSF and macrophages.
- A medicine in development to treat **triple negative breast cancer** binds to and inhibits AKT proteins. AKT helps to regulate cellular processes, such as cell division, cell death, and glucose and fatty acid metabolism. Mutations in the PI3K/AKT/mTOR signaling pathway can promote several types cancer, including breast cancer, because normal cellular processes are disrupted. The medicine works by inhibiting AKT in cancer cells and is being tested in combination with paclitaxel, an approved chemotherapy treatment.
- Several of the **90** medicines in development for **Alzheimer's disease** are disease-modifying treatments that may stop or slow disease progression by targeting one or more of the changes in the brain associated with the disease. These targets include beta-amyloid plaques that appear between nerve cells, tau protein tangles that damage and kill brain cells and a receptor that decreases a neurotransmitter necessary for the brain to think and function normally. Other research targets neuroinflammation, immune response and metabolic changes. One monoclonal antibody medicine in development is a Tau protein inhibitor designed to block and reduce the spread of Tau from neuron to neuron and potentially from forming damaging Tau tangles.



Medicines in Development for Women*



* Some medicines may be in more than one category. ■ PHASE I ■ PHASE II ■ PHASE III ■ APPLICATION SUBMITTED



Women and Clinical Trials

Historically, women have been excluded from clinical research studies, often resulting in a male bias in medical treatments. But research into women's health is vital and necessary. It was in the 1990s that there was a real push to include women in clinical trials.

This is important because advances in research revealed how diseases can manifest differently in women than in men and women can react differently to medicines. Factors such as genetics, hormones, sex-specific physiology, diet, sociocultural issues and the environment can influence how women will respond to specific treatments. Additionally, the inclusion of women, of all ages, races and ethnicities is important to finding optimal dosing of medicines, distinguishing any side effects specific to sex and understanding how adverse reactions can differ in women from men.

Pregnancy and Clinical Trials

It is important that medicines used by pregnant or lactating women are studied to see how treatments will affect women and their children, both born and unborn, while ensuring appropriate ethical protections. In the 1960s, in reaction to the thalidomide tragedy, pregnant women and women of child-bearing age were excluded from pharmaceutical clinical trials and to this day are categorized as a vulnerable population under human subject protection regulations. Even though pregnant women are in general excluded from clinical trials, in certain situations, it may be scientifically and ethically appropriate to include pregnant women in a clinical trial. For example, nearly 94% of pregnant women take at least one prescription or over-the-counter medication during pregnancy.²³

The 21st Century Cures Act, which was signed into law in December 2016, established the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC). PRGLAC offered a list of recommendations and an implementation plan to the U.S. Health and Human Services Secretary to promote the inclusion and integration of pregnant women and lactating women into clinical research, increase the dissemination of knowledge about safety and efficacy of products used by pregnant and lactating women and develop programs to help drive the R&D of therapeutics for conditions specific to pregnant and lactating women.

Additionally, in 2018, the FDA published draft guidance²⁴ for industry for the inclusion of pregnant women into clinical trials - "Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials." The guidance provides recommendations about how and when to include pregnant women in drug development trials. Furthermore, in addition, to support implementation of a standardized process for determining necessity and type of pregnancy post marketing studies, the Prescription Drug User Fee Act reauthorization (PDUFA VII) includes new Sentinel demonstration projects for assessing pregnancy outcomes in women exposed to drugs and biological products.



Chronic Disease and American Women



Heart Disease¹

The leading cause of death for women with more than 300,000 deaths in 2019



Cancer²

More than 930,000 new cases will be diagnosed and more than 287,000 deaths in women in 2022



Migraine⁷

About 3 out of 4 people with migraine are women



Diabetes²

The 7th leading cause of death for women with more than 38,000 deaths in 2019



Depression^{3,4}

Women are 2x more likely to experience depression and about 1 in 8 women experience postpartum depression



Asthma⁷

After age 15, asthma is more common in females than males and symptoms can be exacerbated during certain times in the menstrual cycle



Alzheimer's Disease⁵

Of the 6.2 million people 65 and older with Alzheimer's, 3.8 are women



Arthritis⁶

Nearly 3x as many women have rheumatoid arthritis as men

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