Part I:
Women’s Health Research

Alcohol/Fetal Alcohol Syndrome

Alcoholism and diseases related to alcohol abuse are not commonly considered women's health issues. It is true that alcohol use is lower among women than among men, both in terms of the number of women who drink and the amount of alcohol they consume. However, particularly for the heaviest drinkers, drinking comparable amounts of alcohol has more severe effects on women than on men.

- Female alcoholics develop alcohol-induced liver disease over a shorter period of time and after consuming less alcohol, compared with men.[1]
- Women are more susceptible to interpersonal violence as a result of alcohol abuse. According to the National Institute on Alcohol Abuse and Alcoholism (NIAAA) at the National Institutes of Health (NIH), one survey of female college students found a significant relationship between the consumption of alcohol the women reported drinking each week and their experiences of sexual victimization.[2]
- Women are more likely to develop alcoholic hepatitis and to die from cirrhosis than men with similar drinking histories.[3]
- Heavy alcohol use increases the risk of death from cardiovascular disease for women aged 55 and younger.[4]

Alcohol use during pregnancy is the leading cause of mental retardation in newborns and the leading preventable cause of birth defects.

According to the Centers for Disease Control and Prevention, 1 out of 8 women of childbearing age report risk drinking, which is defined as consuming seven or more drinks per week, or five or more drinks on any one occasion. Additionally, 1 out of every 29 women who know they are pregnant reports risk drinking.[5]

Alcohol use during pregnancy is the leading cause of mental retardation in newborns and the leading preventable cause of birth defects. It can cause head and facial deformities, organ dysfunction, growth retardation, learning disabilities, low IQ, behavioral problems, short attention span, poor coordination, and hyperactivity. This set of irreversible mental and physical birth defects is known as Fetal Alcohol Syndrome (FAS) and affects between 1,300 and 8,000 babies each year.[6] Fetal Alcohol Effects (FAE) is a term that has been used to describe a less severe condition in which a child exhibits some but not all of the components of FAS. However, other diagnostic terms, such as alcohol-related birth defects (ARBD) and alcohol-related neurodevelopmental disorder (ARND) are now more commonly used.[7] The National Organization on Fetal Alcohol Syndrome estimates that the lifetime institutional and medical costs for one child with FAS total $1.4 million.[8]

Advocates believe that FAS is misdiagnosed and underdiagnosed due to a lack of health care provider training. Less than 10 percent of medical schools require training on the diagnosis and referral of individuals with alcoholism.[9]

FAS affects all races and socioeconomic groups. One of its puzzling aspects is that the occurrence of FAS among African Americans is 6 times higher than among Caucasians, even when the mothers have similar drinking habits during pregnancy.[10] The occurrence is 33 times higher among some Native American tribes.[11] Smokers, single women, young women, and less educated women—all of whom already face an increased risk of pregnancy complications—are more likely to drink alcohol during pregnancy and are therefore at a higher risk of having babies with FAS.

Researchers are exploring gender differences in the physiological effects of alcohol. For example, hormonal changes throughout the menstrual cycle may influence the metabolism of alcohol in women. Alcoholic women have higher rates of amenorrhea, miscarriage, early menopause, gynecologic surgery, and infertility than other women, but the mechanisms by which alcohol affects the female reproductive system are not well understood.[12]

Further Research Needed

The Health Resources and Services Administration at the Department of Health and Human Services estimates that less than 10 percent of American women are dependent on alcohol. Prevalence rates are highest

among Caucasian women, followed by African-American and Hispanic women.[13] However, quantifying the prevalence of alcohol problems among women is hampered by the lack of data. Women have historically been underrepresented in studies of alcohol use and abuse, thus prevention, diagnosis, and treatment methods have been developed largely through studies of men.

Women react differently to treatment and intervention messages than men. The social stigma against women who drink heavily acts as a major barrier to treatment. Other barriers include lack of access to services, transportation, lack of culturally sensitive services for racial and ethnic minorities, responsibility for children, cost, and fear of removal of their children. Studies show that women who receive treatment improve their health, productivity, parenting ability, and the health and well-being of their children.[14] Researchers are continuing to look at the most effective gender-appropriate methods to prevent and treat alcohol abuse in women.

In FY1999, the NIAAA allocated roughly $46 million to research on women and alcohol.[15] The Institute has identified a broad list of research opportunities concerning women and alcohol. Continued research will help identify patterns of alcohol use and abuse among women, differences in the physiological and social effects of alcohol on women and men, and the prevention and treatment strategies that will be most effective for women. Additionally, the NIAAA will continue its focus on preventing maternal consumption of alcohol during pregnancy.[16]

Congressional Action

During Senate consideration of the FY2001 Labor, Health and Human Services, and Education appropriations bill (S. 2553), the Senate adopted an amendment that would provide an additional $10 million for education on, and prevention and detection of, FAS and FAE, bringing total funding to $15 million. The final measure (P.L. 106-554) included the amendment.

Committee report language accompanying the House-passed FY2001 Labor, Health and Human Services, and Education appropriations bill (H.R. 4577) encouraged the NIAAA to begin implementing a plan to establish a national clearinghouse on alcohol-related birth defects.

Notes

1 National Institute of Alcohol Abuse and Alcoholism (NIAAA), "Alcohol Alert: Are Women More Vulnerable to Alcohol's Effects?" <http://www.silk.nih.gov/silk/niaaa1/publication/aa46.htm> (1/18/00).

2 Ibid.

3 Ibid.

4 NIAAA, *10th Special Report to the U.S. Congress on Alcohol and Health* (Bethesda: NIAAA, 2000), p. 253.

5 Centers for Disease Control and Prevention, Division of Birth Defects, Child Development, and Disability and Health, "Fetal Alcohol Syndrome" <http://www.cdc.gov/nceh/programs/cddh/fas/fasfact.htm> (1/18/00).

6 Ibid.

7 NIAAA, *10th Special Report*, p. 286.

8 The National Organization on Fetal Alcohol Syndrome, "What is Fetal Alcohol Syndrome?" <http://www.nofas.org> (6/26/00).

9 Ibid.

10 NIAAA, "FY2001 Congressional Budget Justification" <http://silk.nih.gov/silk/niaaa1/about/cj_aa01.htm> (8/10/00).

11 Ibid.

12 NIAAA, "Alcohol Alert: Are Women More Vulnerable to Alcohol's Effects?"

13 Health Resources and Services Administration, "Effects of Drug and Alcohol Use on Perinatal and Women's Health" (fact sheet, 1998), p. 1.

14 Ibid., p. 3.

15 Nancy Brennan of the NIAAA Budget Office, telephone interview with Women's Policy, Inc., June 26, 2000.

16 NIAAA, "NIAAA Research Accomplishments and Initiatives Concerning Alcohol Abuse and Alcoholism Among Women Fiscal Years 1997-1998"; NIAAA, *10th Special Report*, p. 255.

Autoimmune Diseases

Autoimmune diseases encompass more than 80 different chronic diseases whereby the body inexplicably develops antibodies to its own system, which is subsequently attacked by its own immune cells. Roughly 12 million Americans suffer from an autoimmune disease, and women are disproportionately affected by these diseases. Autoimmune diseases traditionally strike women during their working and childbearing years.[1] Examples of autoimmune diseases include rheumatoid arthritis, lupus, multiple sclerosis, scleroderma, Type I diabetes, Graves' disease, and Sjogren's syndrome.

Autoimmune diseases are particularly difficult to diagnose because of the vagueness of symptoms. Often women are sent from specialist to specialist, taking years before they are diagnosed. A study by the American Autoimmune Related Diseases Association (AARDA) found that 65 percent of patients were labeled hypochondriacs or chronic complainers by their physicians when they were actually in the early stages of the disease.[2] The emotional, physical, and economic cost for individuals seeking an explanation for their symptoms is significant. According to the AARDA, direct medical costs associated with autoimmune diseases total roughly $86 billion per year.[3]

Research

Research into autoimmune diseases is just beginning. There is no known cause or cure for many of the diseases. Some experts believe that the hormone estrogen plays a role because of the disproportionate number of women afflicted with autoimmune diseases. However, many questions remain, such as why certain diseases, for example, multiple sclerosis and rheumatoid arthritis, become less severe during pregnancy when there are high levels of estrogen in the body, and yet other diseases, such as lupus, become worse.[4]

Additionally, there appears to be a genetic predisposition to autoimmune diseases. While no one gene has been identified, there is evidence that clusters of genes may increase an individual's susceptibility. It is not uncommon for several individuals within a family to have a number of different autoimmune diseases. Outside triggers, such as strep throat, rheumatic fever, and sunlight may contribute to disease onset or worsen a disease's progression. Research is needed on the etiology of autoimmune diseases in an effort to discover a root cause for the diseases. Currently, there are several treatments undergoing Phase III clinical trials, which test a new drug or treatment against the standard method of treatment.[5]

Researchers at the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health (NIH) are currently investigating the immune system during disease progression, the influence of genetics, the role of infectious agents, and the effects of therapeutic interventions.[6] In FY1999, the NIAID, the lead federal agency on autoimmune disease research, spent $30 million on such research and the NIH as a whole spent $393 million.[7]

Congressional Action

Committee report language accompanying both the House-passed and the Senate-passed FY2001 Labor, Health and Human Services, and Education appropriations bills (H.R. 4577/S. 2553) commended the NIH for creating an Autoimmune Diseases Coordinating Committee to develop a consensus research agenda.

The 106th Congress enacted legislation (P.L. 106-310) pertaining to children's health that included an autoimmune diseases initiative at the NIH. Under the new law, the NIH Director is required to expand, intensify, and coordinate research on autoimmune diseases at the

Legislation

NIH Office of Autoimmune Diseases Act of 1999 (H.R. 2573/S. 1897)—Reps. Henry Waxman (D-CA) and Connie Morella (R-MD) and Sen. Joseph Biden (D-DE)

H.R. 2573/S. 1897 would authorize $950,000 to establish an Office of Autoimmune Diseases within the Office of the Director at the NIH. The Office of Autoimmune Diseases would recommend an agenda for conducting and supporting research on autoimmune diseases, as well as promote coordination and cooperation among the research institutes at the NIH.

NIH. The law requires the NIH to report to Congress biennially on research, education, and other activities on autoimmune diseases conducted or supported by the NIH. The language is similar to bills sponsored by Reps. Henry Waxman (D-CA) and Connie Morella (R-MD) and Sen. Joseph Biden (D-DE).

Rheumatoid Arthritis

Rheumatoid arthritis (RA) is an autoimmune disease in which the immune system attacks the lining of various joints, causing pain, swelling, and stiffness. RA affects 2.1 million Americans, of whom 1.5 million are women.[8] Earnings lost annually by women with rheumatoid arthritis-like symptoms are estimated at $8.9 billion.[9]

Researchers are investigating the role that genetic factors play in RA. Scientists have been able to discover that more than one gene is involved in the development of the disease; however, some people who carry these genes do not develop RA while others do.[10] Additionally, the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) at the NIH has partnered with the Arthritis Foundation to support the North American Rheumatoid Arthritis Consortium. The consortium will collect medical information and genetic material from 1,000 families in which two or more siblings have RA.[11]

Researchers believe that some incident triggers the onset of RA in people who are genetically predisposed to the disease. As a result, the NIAMS is undertaking research on environmental factors and RA. In an effort to better understand why women are more affected by RA than men, researchers also are studying male and female hormones, as well as other gender differences.[12]

Current treatment for RA involves an integrated approach. In addition to prescribing medication, many health care providers also address lifestyle issues, such as diet, exercise, and stress levels. Certain medications are aimed at reducing the inflammation of the joints, while other more powerful disease-modifying antirheumatic drugs are used to slow disease progression.[13] Non-steroidal anti-inflammatory drugs such as aspirin, ibuprofen, naproxen, and a number of other drugs are commonly used to treat rheumatoid arthritis; however, these medications often have gastrointestinal side effects that can be quite severe in some cases. While the Food and Drug Administration (FDA) approved a new painkiller for RA in January 1999, the FDA declared that there was no proof that the drug had fewer side effects than other drugs on the market.[14]

In an effort to raise awareness about RA, the Centers for Disease Control and Prevention launched the National Arthritis Action Plan in November 1998. The plan was created to serve as a blueprint for health professionals, organizations, academic institutions, communities, and others for the prevention and control of arthritis.[15]

Multiple Sclerosis

Multiple Sclerosis (MS) is an autoimmune disease in which the immune system attacks nerve tissues of the central nervous system. Symptoms of the disease include difficulty in walking; abnormal sensations, such as numbness or tingling; impaired vision; weakness and fatigue; and equilibrium difficulties. An estimated 250,000 to 350,000 Americans are affected by MS, and it is twice as common in women as in men.[16]

Treatments for MS can include occupational, physical, and speech therapy, in addition to medication aimed at alleviating MS symptoms and preventing relapses.

Like many autoimmune diseases, there is no known cause of, or cure for, MS. However, researchers believe that there are immunologic, environmental, viral, and genetic factors that contribute to disease onset. Certain geographic areas have higher prevalence rates of MS than others, suggesting a possible environmental agent.[17] While no MS gene has been identified, studies show that an individual's risk for MS increases if she/he has a first-degree relative, such as a parent or sibling, diagnosed with MS.[18]

Scientists have been able to identify the cells that attack myelin, a fatty layer that surrounds nerve fibers.[19] Destruction of the myelin causes nerve impulses to be slowed or halted altogether, thereby causing MS symptoms. In November 1999, the *Journal of Neuroscience* reported a study that isolated cells (oligodendrocyte progenitor cells) in the brain that have the potential to repair myelin that has been destroyed by MS.[20]

As research into a cause, better treatments, and a cure continues, the NIH has increased the resources devoted to MS research. In 1990, $40.5 million was allocated for research; in FY1999, the NIH spent $96.3 million

and was expected to spend $107.4 million in FY2000 and $110.5 million in FY2001.[21]

Congressional Action

The House on October 19 approved a resolution (H. Con. Res. 271) supporting increased awareness of MS. Sponsored by Rep. Bob Weygand (D-RI), the resolution expressed the sense of Congress that all Americans should play an active role in fighting multiple sclerosis. The resolution commended the work of national and community organizations, as well as health care professionals. Finally, the resolution stated that the federal government has a responsibility to continue to fund research, to consider ways to improve access to, and quality of, health care services, to raise public awareness, and to raise health care professionals' awareness about treatments. The Senate did not consider a similar resolution (S. Con. Res. 97), sponsored by Sen. Jack Reed (D-RI), prior to adjournment.

Lupus

Lupus is an autoimmune disease in which the immune system attacks organs and tissues. Lupus affects 1 out of every 185 Americans, 90 percent of whom are women; 1 out of every 102 women is affected by lupus.[22] African-American women are three times more likely than Caucasian women to develop the disease.[23]

There are several forms of lupus—discoid, systemic, drug-induced, and neonatal. Discoid lupus is limited to the skin only and is characterized by a rash. Systemic lupus erythematosus (SLE), the most severe form, affects the joints, skin, kidneys, lungs, heart, nervous system, and blood vessels. Drug-induced lupus is most commonly associated with certain drugs used to treat high blood pressure and irregular heart rhythms, and its symptoms are similar to systemic lupus. Neonatal lupus is a very rare form of lupus that can affect the newborn babies of women with SLE. Neonatal lupus is characterized by skin rash, liver abnormalities, low blood counts, and sometimes a heart defect. Although the disease affects each individual differently, it is characterized by periods of onset and remission. There is no cure for the disease, and it is a lifetime affliction that can be life-threatening.[24]

Although up to two million people have been diagnosed with lupus, patient advocacy groups argue that too little is spent on research. According to the Lupus Foundation of America, less federal money is spent on lupus research per patient than for AIDS, leukemia, multiple sclerosis, muscular dystrophy, or cystic fibrosis.[25] In FY1999, the NIH allocated $46.1 million for lupus research and is expected to spend $52.4 million in FY2000 and $55.2 million in FY2001.[26]

Because lupus is 10-15 times more likely to occur in adult women than in adult men, it is frequently referred to as a "woman's disease." The onset of lupus is most likely to occur during a woman's childbearing years. This can limit birth control choices. Women with lupus are discouraged from taking oral contraceptives containing estrogen because estrogen has been linked to increased disease activity. Currently, the NIAMS, the NIH Office of Research on Women's Health, and the NIH Office of Research on Minority Health are funding a study to look at the safety of estrogen for women with SLE.[27]

Although there is no cure for lupus, there are numerous treatments if the disease is detected early. However, side effects from medication, especially on postmenopausal women, can be debilitating. Women treated with corticosteroids—the most common and effective form of treatment—are more likely to develop osteoporosis or cardiovascular disease. The use of corticosteroids can also lead to high blood pressure and high cholesterol. As the disease develops, the inflammation of joints and organs is increasingly pronounced, becoming a disabling condition for many women.[28]

The origin of lupus remains largely a mystery. Researchers believe that environmental, genetic, and hormonal factors contribute to the disease. Genetic studies have been ongoing, and in 1997 a study funded by the NIAMS discovered a gene that predisposes people to SLE. According to the NIAMS, the gene appears to cut across ethnic groups and may be found in Caucasians, Asians, and African Americans. The NIAMS also has established a lupus registry to track the prevalence of the disease among families.[29]

Congressional Action

Congress enacted legislation (P.L. 106-505) to authorize and expand research on, and services for, lupus. The bill (H.R. 762), sponsored by Rep. Carrie Meek (D-FL), was incorporated into an omnibus health research package (H.R. 2498). The new law authorizes an unspecified amount of funding to expand and intensify research on lupus at the NIH. Additionally, the

new law authorizes an unspecified amount of funding for programs that deliver services to individuals afflicted by lupus and their families. A similar bill (S. 1163) was sponsored by Sen. Robert Bennett (R-UT).

Additionally, committee report language accompanying both the House-passed and the Senate-passed FY2001 Labor, Health and Human Services, and Education appropriations bills (H.R. 4577/S. 2553) encouraged the NIAMS to enhance research efforts at developing safer and more effective treatments for lupus.

Committee report language accompanying the final FY2001 Labor, Health and Human Services, and Education spending bill (P.L. 106-554) urged the Centers for Disease Control and Prevention to continue its "research, surveillance, and health communication efforts, including the impact of lupus on women, within the framework of the National Arthritis Action Plan."

Notes

1 National Institute of Allergy and Infectious Diseases (NIAID), *Understanding Autoimmune Diseases* (Bethesda: 1998), p. 2.
2 American Autoimmune Related Diseases Association (AARDA), "Autoimmunity: A Major Women's Health Issue" <http://www.aarda.org/women_health_art.html> (8/10/00).
3 AARDA, "Autoimmunity: Frequently Asked Questions" (press backgrounder, no date).
4 Claudia Kalb and Joan Raymond, "Autoimmune Diseases," *Newsweek*, Spring/Summer 1999, pp. 56-58.
5 National Cancer Institute, "An Introduction to Clinical Trials" <http://cancertrials.nci.nih.gov/understanding/basics> (8/10/00).
6 National Institutes of Health (NIH), "Report of the Autoimmune Diseases Coordinating Committee," June 2000, pp. 15-17.
7 Ibid., pp. ii, 3.
8 Arthritis Foundation, "Women and Arthritis Fact Sheet" <http://www.arthritis.org/resource/fs/women.asp> (1/18/00).
9 Ibid.
10 National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), "Rheumatoid Arthritis" <http://www.nih.gov/niams/healthinfo/rahandout> (1/18/00).
11 Ibid.
12 Ibid.
13 Ibid.
14 Lauran Neergaard, "FDA Approves First of New Painkillers for Arthritis," *Washington Post*, Jan. 1, 1999, A12.
15 Centers for Disease Control and Prevention, "Arthritis" <http://www.cdc.gov/nccdphp/arthritis.htm> (8/10/00).
16 National Multiple Sclerosis Society, "Factual Answers to the Public's Most Frequently Asked Questions" <http://www.nmss.org> (1/19/00).
17 Ibid.
18 Ibid.
19 Ibid.
20 Neeta Singh Roy, et al., "Identification, Isolation, and Promoter-Defined Separation of Mitotic Oligodendrocyte Progenitor Cells from the Adult Human Subcortical White Matter," *Journal of Neuroscience* 19 (1999) 2: 9939-9952.
21 NIH, Office of the Director, Office of Financial Management funding chart <http://www4.od.nih.gov/ofm/diseases/index.stm> (8/10/00).
22 NIAMS, "Systemic Lupus Erythematosus" <http://www.nih.gov/niams/healthinfo/slehandout> (1/18/00).
23 Ibid.
24 Ibid.
25 Lupus Foundation of America, "LFA Funded Research Projects" <http://www.lupus.org/info/funded.html> (12/11/00).
26 NIH, Office of the Director, Office of Financial Management funding chart <http://www4.od.nih.gov/ofm/diseases/index.stm> (8/10/00).
27 NIAMS, "First Clinical Trial on the Safety of Estrogen in Lupus Erythematosus Begins" (press release, Jan. 15, 1996).
28 NIAMS, "Systemic Lupus Erythematosus."
29 Ibid.

Breast Cancer

Breast cancer is the most common form of cancer in women and the second leading cause of cancer death in women. There are 2.6 million women living with the disease in the United States today.

- The American Cancer Society estimated that 182,800 new cases of breast cancer would be diagnosed in the United States in 2000, with an estimated 41,200 deaths.[1]
- While Caucasian women are more likely to develop breast cancer, African-American women are 12 times more likely to die from it. The five-year survival rate for African-American women is 71 percent, compared with 86 percent for Caucasian women.[2]
- The risk of breast cancer increases significantly with age. Roughly 77 percent of women with breast cancer are over 50, and 84 percent of breast cancer deaths occur in women over 50.[3]

Research funding for breast cancer has increased 600 percent since 1990.

Background

The public policy response to breast cancer in recent years has been more urgent and energetic than to any other women's health issue. Since 1994, federal efforts have included the National Action Plan on Breast Cancer, a public-private partnership designed to coordinate the research, treatment, and education activities of government and non-governmental organizations. The action plan was developed in response to a National Breast Cancer Coalition petition calling for a comprehensive strategy to end breast cancer. The plan's top priorities include expanding research on breast cancer, enhancing the quality of life for persons with breast cancer, improving survival, and increasing the involvement of diverse partners, such as consumer advocates, in research decisions.[4]

One of the primary goals of the breast cancer advocacy community is to increase the federal investment in breast cancer research. As a result, research funding has increased 600 percent since the beginning of the decade—from less than $90 million in 1990 to more than $660 million in 1999.[5] These figures include programs at both the National Institutes of Health (NIH) and the Department of Defense (DoD).

The National Cancer Institute (NCI) at the NIH is the lead federal agency on breast cancer research. Breast cancer research receives the majority of the funds spent by the NCI on cancers in women. The NCI's work includes basic cancer research, to which approximately half of its breast cancer funds are directed, as well as research on prevention, treatment, and diagnostic technology. The NCI is also funding studies on breast cancer risk factors, including diet and obesity, estrogen replacement therapy, stress, and environmental factors. In October 2000, the NCI awarded $12.7 million in first-year funding for five Specialized Programs of Research Excellence to research breast and prostate cancer.[6]

Breast cancer research also is conducted by several other NIH institutes, including the National Institute of Child Health and Human Development and the National Institute of Environmental Health Sciences. Total NIH funding for breast cancer in FY1999 was $474.7 million, and the NIH estimated that it would spend $523.8 million in FY2000 and $553 million in FY2001.[7] Additionally, Congress enacted the Women's Health Reauthorization Act (P.L. 105-340) in 1998. The act reauthorized NIH's breast cancer research program through the year 2003 but did not provide specific dollar amounts for the program.

In addition to the NIH, the Department of the Army administers a peer-reviewed breast cancer research program, which was started in FY1992 with a two-year $210 million appropriation. In FY2001, the program is funded at $175 million, the same amount as FY2000, but up from $135 million in FY1999. In recent years, the well-regarded program has focused its research on innovative scientific ventures that represent unattempted avenues of investigation or novel applications of existing technologies.[8] Breast cancer advocates believe that the DoD program has fostered a positive competition with the NCI, challenging each institution to be innovative about finding a cure for breast cancer.

In addition to the growth in federal funding for medical research, the 105th Congress voted overwhelmingly in 1997 to establish a special stamp to raise money for breast cancer research when it enacted the Stamp Out

Breast Cancer Act (P.L. 105-41). Authorization for that stamp was due to expire on July 29, 2000, but the 106th Congress extended authorization for the stamp for an additional two years under the Semipostal Authorization Act (P.L. 106-253).

Currently, the NIH receives 70 percent of the revenues raised when consumers purchase the alternative first-class stamp, and the DoD receives 30 percent. The 40-cent stamp went on sale to the public in August 1998. As of August 2000, 223 million stamps had been sold, raising $15.7 million for research. The sale of the stamp has been so successful that the U.S. Postal Service announced it would print an additional 85 million stamps, bringing the total to 415 million stamps.[9] In October 2000, the NCI announced that it had awarded $6.9 million in two-year Insight Awards to Stamp Out Breast Cancer grants, as a result of the money raised through the sale of the stamp. According to the NCI, the grants programs will focus on research in biology, etiology, genetics, prevention, detection, diagnosis and prognosis, treatment, control, and outcomes.[10]

Genetics

The federal investment in research has resulted in important advances in our understanding of the biology of breast cancer and treatment of the disease. Researchers have discovered over 100 alterations in the inherited BRCA1 and BRCA2 genes, known to cause breast cancer. While the discovery has answered some questions about the biology of breast cancer, there are still many unanswered questions, particularly since only 5 to 10 percent of all breast cancers are hereditary. However, scientists believe that BRCA1 and BRCA2 mutations account for 30 to 70 percent of all inherited breast cancer cases.[11] Women who have inherited the BRCA1 mutation have a 50 to 85 percent risk of developing breast cancer in their lifetimes.[12] The NCI estimates that BRCA1 is responsible for 45 percent of breast cancers in families with multiple cases of the disease, and BRCA2 mutations represent 35 percent of breast cancers in such families.[13]

An August 2000 study published in the *Journal of the National Cancer Institute* also found that European families that have a mutation in the CDKN2A gene have an increased risk for breast cancer.[14] Researchers continue to examine the genetic factors associated with breast cancer.

New Treatments

Additionally, several advancements have been made in the treatment of breast cancer. In early 1998, the NCI and the National Surgical Adjuvant Breast and Bowel Project (NSABP) announced the results of a study documenting the efficacy of tamoxifen in reducing the risk of breast cancer in high-risk women. Although the study demonstrated a 45 percent reduction in breast cancer incidence among trial participants who took the drug, some women experienced potentially life-threatening side effects, including uterine cancer, blood clots, and stroke.[15] For example, the chances of developing uterine cancer were doubled from 1 in 1,000 to 2.3 in 1,000. The Food and Drug Administration (FDA) approved tamoxifen as a treatment to reduce the incidence of breast cancer in October 1998.[16] However, tamoxifen cannot be marketed as a preventive measure due to concerns that women will falsely believe that the drug will offer them a lifetime immunity against breast cancer.[17]

Moreover, a Dutch study published in *The Lancet* in September 2000 showed that women who took tamoxifen for two or more years experienced a greater risk of endometrial cancer.[18] Researchers will continue to examine the safety and effectiveness of long-term tamoxifen use.

The NCI began another study—the Study of Tamoxifen and Raloxifene (STAR)—in 1999. The STAR study is examining whether the drug raloxifene is as effective as tamoxifen in reducing the risk of breast cancer.[19] After the first year of the trial, over 6,000 women were enrolled, and the NCI is searching for an additional 16,000 participants.[20] Raloxifene has been approved by the FDA for the prevention of osteoporosis.

In September 1998, the FDA approved herceptin, a drug that can be used to treat women with advanced breast cancer only.[21] The drug targets the HER2 gene, which produces a protein that causes cells to divide, multiply, and grow. Normal cells contain two copies of the HER2 gene, but some women have extra copies of the gene. These extra copies then overproduce the protein—known as HER2 overexpression—leading to a more aggressive form of breast cancer.[22] Herceptin targets the HER2 protein by directing the protein to stop growing. Studies show that the drug may help 25 to 30 percent of breast cancer patients.[23]

Early Detection

Efforts to develop improved technology for the early detection of breast cancer may further reduce cancer mortality rates in years to come. In April 1999, the FDA approved a hand-held imaging device for use in the diagnosis of breast cancer.[24] Clinical studies showed improved diagnostic accuracy for women with ambiguous mammogram results. Additionally, the first digital mammography system (Senographe 2000D) was approved by the FDA in January 2000.[25] While the clinical trials that led to its approval did not demonstrate that digital images are better at detecting the disease than traditional film/screen images, digital images offer patients several advantages. These advantages include electronic storage and transfer of the images to facilitate quick evaluation, correction for under- or over-exposed films, and a large range that allows the entire breast to be photographed despite varying breast density.[26]

Since 1994, the Department of Health and Human Services has worked in collaboration with the DoD, the Central Intelligence Agency, and the National Aeronautics and Space Administration (NASA) to adapt missile detection technology for use in identifying breast cancer. The digital mammography system approved earlier this year was a result of this collaboration. Report language accompanying the House-passed FY2001 Labor, Health and Human Services, and Education appropriations bill (H.R. 4577) encouraged the NCI to pursue the development of advanced imaging technologies derived from the military and NASA.

Additionally, the 106th Congress enacted legislation (P.L. 106-391) to reauthorize NASA. The law includes a $2 million earmark for research and early detection systems for breast and ovarian cancer and other women's health issues.

Further Research Needed

Despite recent advances, little is known about how to prevent breast cancer. While the disease's mortality rates have slowly begun to decline, researchers are still unable to explain the steady increase in the incidence of the disease over the past 50 years. The lifetime risk of developing breast cancer has increased over the past two decades from 1 in 20 to 1 in 8 today.[27] Further research also is needed to understand disturbing racial, ethnic, and economic differences in breast cancer mortality rates. During the 1980s, mortality rates for African-American women with breast cancer were slightly lower than Caucasian women diagnosed with the disease. However, mortality rates for African-American women were 16 percent higher than Caucasian women in 1990 and 29 percent higher in 1995.[28] The role of environmental factors is also attracting increased attention in breast cancer research.

Consumer Involvement

The successful role played by consumers in the DoD's breast cancer research program has drawn attention to the importance of involving a broader range of perspectives in the grant review process.

When Congress first appropriated funds for the breast cancer research program in 1992, the DoD asked the Institute of Medicine (IOM) for guidance on how to best use funds to accelerate the pace of research advances. In this report, the IOM recommended the DoD focus on bringing new talent into the field of breast cancer research and on supporting innovative ideas and cross-cutting proposals that could shed light on fundamental questions concerning causation, prevention, detection, diagnosis, and treatment.[29] The IOM also helped the DoD create a peer-review process that would be better able to accommodate the goals of the innovative program being developed.

To meet the goal of funding new scientists with new ideas, the IOM recommended that the review panels include a mix of people drawn from a broad pool of reviewers representing different perspectives, expertise, career levels, and disciplines, and that women be strongly represented in the peer-review process, with a special effort made to include women of color.[30]

In accordance with the IOM recommendations, the DoD has placed breast cancer advocates as voting members on peer-review panels. Despite initial concerns in the scientific community, there is a general consensus among researchers that the program is working well and that broadening the perspectives represented on study panels has resulted in a better grant-making process.

Legislation

Consumer Involvement in Breast Cancer Research Act (S. 118/H.R. 1596)—Sen. Olympia Snowe (R-ME) and Rep. Nita Lowey (D-NY)

S. 118/H.R. 1596 would direct the NCI, to the extent practical, to increase the involvement of consumer advocates in breast cancer research decisions. An advocate is defined for purposes of the bill as an individual who is accountable to, represents, and reports back to organizations that represent those affected by breast cancer.

Breast Cancer Research Extension Act of 2000 (H.R. 4699)—Rep. Nita Lowey (D-NY)

H.R. 4699 would authorize $750 million for breast cancer research programs.

Notes

1 American Cancer Society (ACS), "Cancer Facts and Figures 2000" <http://www.cancer.org/statistics/cff2000/selectedcancers> (5/30/00).
2 ACS, "Breast Cancer Facts and Figures 1999-2000" <http://www.cancer.org/99bcff/> (6/26/00).
3 Ibid.
4 Public Health Service's Office on Women's Health, "OWH: Programs and Activities – Breast Health" <http://www.4woman.org/owh/prog/breast.htm> (1/19/00).
5 National Breast Cancer Coalition, "Overview of NBCC/NBCCF's Major Accomplishments Since Its Inception in 1991" <http://www.nbcc.org> (11/14/00).
6 National Cancer Institute (NCI), "NCI Announced SPORE Grants for Breast and Prostate Cancer Research" (press release, Oct. 2, 2000) <http://rex.nci.nih.gov/massmedia/pressreleases/spore.html> (10/18/00).
7 National Institutes of Health, Office of the Director, Office of Financial Management funding chart <http://www4.od.nih.gov/ofm/diseases/index.stm> (6/26/00).
8 Department of Defense, "The Breast Cancer Postage Stamp and the Involvement of the Department of Defense Breast Cancer Research Program" (information paper, Oct. 15, 1999).
9 U.S. Postal Service, "Postmaster General Orders Third Reprint of Breast Cancer Research Postage Stamp" (press release, Aug. 18, 2000) <http://www.usps.com> (11/14/00).
10 NCI, "NCI Awards Breast Cancer Research Grants Derived From Postage Stamp Sales" (press release, Oct. 6, 2000) <http://rex.nci.nih.gov/massmedia/pressreleases/stampawards/html> (10/18/00).
11 NCI, CancerNet, "Genetic Testing for Breast Cancer Risk: It's Your Choice" <http://www.cancernet.nci.nih.gov> (3/7/00).
12 Ibid.
13 Ibid.
14 Reuters News Service, "Additional Breast Cancer Susceptibility Gene Identified," Aug. 7, 2000 <http://www.4woman.gov/nwhic/News/Aug00/7aug00.htm> (8/7/00).
15 National Surgical Adjuvant Breast and Bowel Project, "Breast Cancer Prevention Trial Shows Major Benefit, Some Risk" (press release, Apr. 6, 1998).
16 Department of Health and Human Services, "Tamoxifen Approved for Reducing Breast Cancer Incidence" (press release, Oct. 29, 1998).
17 Susan Okie, "Tamoxifen Ads Won't Mention Prevention," *Washington Post*, Nov. 10, 1998, Health Section, 7.
18 Denise Grady, "Use of Breast Cancer Drug Questioned in Dutch Study," *New York Times*, Sept. 8, 2000.
19 NCI, "Study of Tamoxifen and Raloxifene To Open in Early 1999" (press release, Oct. 21, 1998).
20 NCI, "STAR Enrolls 6,139 Women in First Year; 16,000 More Women at Increased Risk of Breast Cancer Sought" (press release, July 27, 2000) <http://rex.nci.nih.gov/massmedia/pressreleases/year1.html> (8/10/00).
21 "Herceptin: Good News May Extend Beyond Advanced Breast Cancer," *Women's Health Advocate* 5 (Jan. 1999) 11: 7.
22 Genentech, Biooncology, "HER2 News – Issue Five," December 1999.
23 Herceptin Patient Website <http://www.herceptin.com> (3/1/00).
24 FDA, "FDA Approves New Breast Imaging Device" (FDA Talk Paper, Apr. 19, 1999).
25 FDA, "FDA Approves First Digital Mammography System" (FDA Talk Paper, Jan. 31, 2000).
26 Ibid.
27 NCI, Cancernet, "Lifetime Probability of Breast Cancer in American Women" <http://cancernet.nci.nih.gov/cgi-bin/srchcgi.exe?DBID=pdq&TYPE=search&SFMT=pdq_statement/1/0/0&ZUI=600056> (11/14/00).
28 Alexis Jetter, "Breast Cancer in Blacks Spurs Hunt for Answers," *New York Times*, Feb. 2, 2000, D5.
29 Institute of Medicine, *Strategies for Managing the Breast Cancer Program: A Report to the U.S. Army Medical Research and Development Command*, (Washington: National Academy Press, 1993).
30 Ibid.

Cardiovascular Diseases

Cardiovascular diseases are the leading causes of death and disability among American women.

- In 1997, cardiovascular diseases accounted for 49.1 percent of deaths in women.[1]
- More than a half million women died from cardiovascular diseases in 1997, and 97,227 women died from stroke in 1997, accounting for 60.8 percent of all stroke deaths.[2]
- Forty-two percent of women who have heart attacks die within one year compared with 24 percent of men.[3]
- More than one in five women has some form of heart or blood vessel disease.[4]
- Death rates for coronary heart disease for African-American women are 14.6 percent higher than those for Caucasian women. Death rates for stroke for African-American women are 31.4 percent higher than for Caucasian women.[5]
- In 1999, the cost of cardiovascular disease in the United States was estimated to be over $286 billion.[6]

Although half of the individuals with cardiovascular diseases are women, and nearly half of fatal heart attacks occur in women, cardiovascular diseases have long been perceived as primarily affecting men.

Gender Disparities

Although half of the individuals with cardiovascular diseases are women, and nearly half of fatal heart attacks occur in women, cardiovascular diseases have long been perceived as primarily affecting men. A 1997 study found that only 8 percent of American women believed that heart disease and stroke were the greatest health threat to them, and only 30 percent of those surveyed said that their doctors mentioned heart disease when discussing general health.[7]

Additionally, studies have shown that doctors are less likely to diagnose heart disease in women than in men with the same symptoms. In fact, a 1999 study published in the *New England Journal of Medicine* concluded that physicians contribute to race and sex disparities in heart disease treatment. Conducted by the Georgetown University Medical Center and funded by the Agency for Healthcare Research and Quality, the study found that the odds of African Americans and women presenting with chest pain being referred for cardiac catheterization were 60 percent less than Caucasians and men. The disparity was most dramatic for African-American women, whose odds of being referred for the procedure were 40 percent less than those of Caucasian men.[8]

The Centers for Disease Control and Prevention's (CDC) National Ambulatory Medical Care Survey, published in 1998, showed that women were counseled less often than men about exercise, nutrition, and weight reduction.[9] Another 1997 study found that women were less likely than men to enroll in cardiac rehabilitation after a heart attack,[10] and a 1999 study by Yale University demonstrated that middle-age women who have heart attacks were more likely to die from them than middle-age men.[11]

Studies also have shown that diagnostic tools are often less accurate in women than in men because the tests were originally designed for men. Biological differences between men and women can also cause diagnostic differences. A 1997 American Heart Association (AHA) statement on cardiovascular disease in women said that "gender-specific considerations related to diagnostic test performance may influence the choice of procedures used to evaluate chest pain syndromes in women."[12]

Current Prevention Efforts

Currently, the CDC is supporting efforts in three states—Arizona, Massachusetts, and North Carolina—to screen women for factors that increase their risk for cardiovascular disease. The screening is being conducted through the CDC's WISEWOMAN program and has evaluated more than 4,000 low-income and uninsured women aged 50 and older. In 1999, 50 percent of the women screened had either elevated cholesterol or high blood pressure, and more than 60 percent were overweight.[13]

Several medical associations, including the AHA, the American College of Cardiology, the American Medical Women's Association, the American College of

Nurse Practitioners, and the American College of Obstetricians and Gynecologists, have joined together in producing a *Guide to Preventive Cardiology for Women*. Issued in April 1999, the guide recommended that health professionals begin assessing a woman's risk during the preconception period and pregnancy in an effort to establish healthy behaviors that will reduce her risk.[14]

Many of the risk factors for heart disease are similar for women and men: smoking, high blood pressure, high cholesterol, obesity, and a sedentary lifestyle. However, some risk factors, such as diabetes, high levels of triglycerides, and low levels of HDL cholesterol appear to increase the risk more for women than for men. In fact, the AHA recommends that everyone aged 20 and older have their cholesterol checked. Under the recommendations, premenopausal women whose initial test is normal may wait five years before repeating the test, but postmenopausal women should have a cholesterol screening every one to three years.[15] In addition, women tend to develop heart attacks later in life than men—on average, 10 years later.

Evidence that short-term use of estrogen replacement therapy (ERT) and hormone replacement therapy (HRT) in postmenopausal women reduces the risk of heart disease is mixed. In 1995, the Postmenopausal Estrogen/Progestin Interventions (PEPI) Trial found that both ERT and HRT increased the level of HDL cholesterol, the "good" cholesterol.[16] Additionally, the Nurses' Health Study found that ERT and HRT reduced the risk of death from heart disease and stroke.[17] However, results from the Heart and Estrogen/Progestin Replacement Study (HERS), published in August 1998, found that the use of estrogen plus progestin in postmenopausal women with heart disease did not prevent further heart attacks or death from coronary disease.[18] Additionally, there are other health risks associated with ERT, such as an increased risk of endometrial or uterine cancer, and an increased risk of blood clots and gall bladder disease.

In fact, in April 2000, researchers involved with the HERS trial announced that women who had been taking estrogen as part of the study were at a slightly higher risk for heart attacks and strokes. However, officials at the National Heart, Lung, and Blood Institute (NHLBI) at the National Institutes of Health (NIH) cautioned that the results did not address the long-term benefits and risks of HRT and should not influence current medical practice.[19]

An August 2000 study published in the *New England Journal of Medicine* found that the use of estrogen alone or estrogen plus progestin did not affect the progression of heart disease in women who already had the disease. The study suggested that "women should not use estrogen replacement with an expectation of cardiovascular benefit."[20]

Another study found that a reduction in smoking, improvement in diet, and an increase in postmenopausal hormone use attributed to a decline in the incidence of coronary disease in women participating in the Nurses' Health Study.[21]

Research Initiatives

In FY1999, the NHLBI spent $180 million on research on cardiovascular disease and women. The NHLBI estimated that it would spend $207 million in FY2000.[22]

Despite increased spending on research on cardiovascular diseases and women, a recent study found that women made up only 38 percent of participants in mixed-sex studies on heart disease at the NHLBI. Additionally, women represented only 26 percent of participants in congestive heart failure studies.[23]

The NHLBI is currently supporting several clinical trials dealing with women and cardiovascular disease, including the Women's Health Initiative (WHI), the Women's Angiographic Vitamin and Estrogen (WAVE) Trial, the Women's Estrogen/Progestin and Lipid Lowering Hormone Artherosclerosis Regression Trial (WELL-HART), and the Estrogen Replacement and Artherosclerosis (ERA) Trial. These trials are slated for completion in 2005 and 2006.[24]

Congressional Action

While the NHLBI has historically pursued research on women and cardiovascular diseases, the institute did not have a congressionally authorized program for such research until 1998 when the 105th Congress authorized such a program under the Women's Health Reauthorization Act (P.L. 105-340). The law directs the NIH to expand, intensify, and coordinate research on heart attack, stroke, and other cardiovascular diseases in women. Research should include the underlying risks

for women, causes of the disease in women, differences between men and women, development of new diagnostic approaches for women, and educational campaigns. Despite the authorization, no money has been earmarked by Congress for the program since the law was enacted.

Committee report language accompanying the House-passed and the Senate-passed FY2001 Labor, Health and Human Services, and Education appropriations bills (H.R. 4577/S. 2553) encouraged the NHLBI to expand its research on cardiovascular diseases in women. The reports also encouraged the NHLBI to focus on the dissemination of educational materials to women and their providers.

Additionally, committee report language accompanying the final FY2001 Labor, Health and Human Services, and Education spending bill (P.L. 106-554) stated that adequate funding was provided to allow the CDC to expand its WISEWOMAN program to not more than 15 states. Sen. Bill Frist (R-TN) and Rep. Rosa DeLauro (D-CT) sponsored bills (S. 2635/H.R. 4606) to expand the WISEWOMAN program (see Mid-life and Older Women, p. 57).

Legislation

H. Res. 220—Rep. Juanita Millender-McDonald (D-CA)—The resolution expresses the sense of the House that public awareness of heart disease among women should be heightened.

Notes

1 American Heart Association (AHA), "Women, Heart Disease and Stroke Statistics" <http://www.americanheart.org/Heart_and_Stroke_A_Z_Guide/womens.html> (11/14/00).
2 Ibid.
3 Ibid.
4 Ibid.
5 Ibid.
6 Centers for Disease Control and Prevention (CDC), "Preventing Cardiovascular Disease: Addressing the Nation's Leading Killer At-A-Glance 1999" (fact sheet, 1999).
7 AHA, "Women and Heart Disease: A Study of Women's Awareness of and Attitudes Toward Heart Disease and Stroke," Aug. 1999 <http://women.americanheart.org/stroke/fs_overview.html> (1/11/00).
8 Georgetown University Medical Center, "Patient Race and Sex Influence Physician Recommendations for Key Heart Disease Diagnostic Procedure" (press release, Feb. 25, 1999).
9 "Missed Opportunities in Preventive Counseling for Cardiovascular Disease: United States, 1995," *Morbidity Mortality Weekly Report*, 47 (1998): 91-95.
10 R.J. Thomas, "National Survey on Gender Differences in Cardiac Rehabilitation Programs: Patient Characteristics and Enrollment Patterns," *Journal of Cardiopulmonary Rehabilitation* 16 (1996): 402-412.
11 David Brown, "A Gender Medical Mystery In Middle-Age, Women Likelier to Die of Heart Attack," *Washington Post*, July 7, 1999, A1.
12 AHA, "Cardiovascular Disease in Women: A Statement for Healthcare Professionals from the American Heart Association," *Circulation* 96 (1997): 2468-2482.
13 CDC, "Preventing Cardiovascular Disease."
14 Lori Mosca, M.D., Ph.D., et al., "Guide to Preventive Cardiology for Women," *Circulation* 99 (1999): 2480-2484.
15 National Women's Health Resource Center, "High Blood Cholesterol and Women's Health," *National Women's Health Report* 22 (2000) 4: 1-2.
16 National Heart, Lung, and Blood Institute (NHLBI), "Hormone Replacement Therapy and Heart Disease: The PEPI Trial," August 1995.
17 AHA, "Estrogen and Cardiovascular Diseases in Women" <http://www.americanheart.org> (1/11/00).
18 National Institutes of Health (NIH), "The HERS Study Results and Ongoing Studies of Women and Heart Disease" (press release, Aug. 18, 1998).
19 Gina Kolata, "Estrogen Use Tied to Slight Increase in Risks to Heart," *New York Times*, Apr. 5, 2000, A1.
20 David Harrington, et al., "Effects of Estrogen Replacement on the Progression of Coronary-Artery Atherosclerosis," *New England Journal of Medicine* 343 (2000) 8: 522-529.
21 Frank B. Hu, et al., "Trends in the Incidence of Coronary Heart Disease and Changes in Diet and Lifestyle in Women," *New England Journal of Medicine* 343 (2000) 8: 530-537.
22 Nga Nguyen of the NHLBI Budget Office, telephone interview with Women's Policy, Inc., Aug. 21, 2000.
23 "Women and Heart Studies," *Washington Post*, Aug. 17, 2000, A5.
24 NIH, "The HERS Study Results and Ongoing Studies of Women and Heart Disease."

Cervical Cancer/HPV

Evidence indicates a strong link between human papillomavirus (HPV)—the most common viral sexually transmitted disease (STD) in the United States—and cervical cancer, which the American Cancer Society estimated would be diagnosed in 12,800 women and claim 4,600 lives in 2000. The death rate for African Americans is more than twice the national average. In addition, Hispanics and Native Americans have higher than average death rates from cervical cancer.[1]

HPV refers to more than 70 types of viruses, only a few of which are associated with cervical cancer. It is estimated that as many as 80 percent of sexually active women are infected with HPV.[2] While some types of HPV cause genital warts, 95 percent are latent and can only be identified through DNA testing.[3]

It is estimated that as many as 80 percent of sexually active women are infected with HPV.

HPV infection is the major risk factor for cervical cancer. Based on a number of epidemiological studies, evidence of HPV has been found in 90 to 95 percent of cervical cancers. Most HPV infections, however, do not develop into cancer. In addition, the process of developing cancer from initial exposure to HPV takes at least a decade, which explains why cervical cancer is a disease most often affecting midlife and older women—even though HPV infection is most common in young women.[4]

A recent study suggests that genes also may play a role in a woman's risk of cervical cancer. According to the study, published in the *International Journal of Cancer*, more than one in four (27 percent) cervical cancers in Swedish women were attributed to genetics.[5] A woman's risk for cervical cancer was highest if her sister had cervical cancer. Additionally, the authors of the study also suggest that genes may make some women more vulnerable to HPV infection.[6]

Other risk factors for cervical cancer include unprotected intercourse at an early age; a large number of sexual partners; infection with other viruses, including HIV; cigarette smoking; and low socioeconomic status.[7] While condoms provide some protection, HPV can be transmitted by parts of the groin area that are not covered by condoms.[8]

Cervical cancer was once one of the most common causes of cancer death for women. However, between 1955 and 1992, deaths from cervical cancer declined by 74 percent. This shift was due mainly to the use of a simple and readily available screening method, the Pap test, that allows for early detection of cervical cancer. Diagnosed while it is localized, the disease has a 5-year survival rate of 91 percent.[9] According to the American Medical Women's Association, two-thirds of cervical cancers occur in women who have not been screened.[10]

In the past few years, several new screening techniques have been approved by the Food and Drug Administration (FDA), including improved versions of Pap testing and HPV DNA testing of cervical cells.[11] Because most HPV infections do not progress to cancer, treatment is mainly decided on a "wait and see" basis, with follow-up Pap testing.[12]

Two studies published in the *Journal of the American Medical Association* in January 2000 conclude that HPV DNA testing may improve screening for cervical cancer in some populations and also could provide a means to better reach underserved women. However, an editorial in the same issue contends that the question of whether HPV DNA testing is feasible or affordable, and whether it will actually lead to better outcomes and fewer cases of cervical cancer will require further study.[13]

One of the studies examined HPV DNA testing on a population at high risk for developing cervical cancer, a group of about 8,500 women in Guanacaste Province, Costa Rica, where cervical cancer rates are high. Investigators concluded that HPV DNA screening was more sensitive than the conventional Pap test, but less specific, and that HPV DNA screening could be a useful tool depending on the population and other factors.[14]

The other study's objective was to determine whether HPV DNA testing of self-collected vaginal swabs can be used for cervical cancer screening in women aged 35 years and older. Given the high rate of women with cervical cancer who have not been screened and the

limited access to such screening in less developed parts of the world, such testing could be effective for harder-to-reach populations. The study was conducted in outpatient clinics outside of Cape Town, South Africa, between January 1998 and April 1999. Investigators concluded that HPV DNA testing of self-collected vaginal swabs was as sensitive, but not as specific as Pap tests for detecting high-grade cervical disease in women aged 35 and older.[15]

The National Cancer Institute (NCI) at the National Institutes of Health is currently conducting a national study, the ASCUS/LSIL Triage Study or ALTS, to determine the best way to address abnormal Pap tests. The study is examining three approaches, including immediate colposcopic exam and biopsy (the current standard), repeat Pap tests every six months, and HPV DNA testing to determine which abnormalities indicate colposcopy and which would be better followed by repeat Pap testing. The study results are expected in the near future.[16] Guidelines for the use of HPV DNA testing are expected at the conclusion of the study.[17]

The NCI is currently working to develop a vaccine for HPV infection. In FY1998, the NCI spent $58 million on cervical cancer research, and in FY1999 the NCI spent $66.3 million.[18]

Congressional Action

During the closing moments of the 106th Congress, legislation (P.L. 106-554) was enacted to require the Centers for Disease Control and Prevention to conduct surveillance on HPV, research prevention strategies, and prepare and distribute educational materials on HPV. The law requires the Department of Health and Human Services to study existing condom labels to determine whether they are medically accurate with respect to the effectiveness or lack of effectiveness of condoms in preventing STDs. The final language, authored by Rep. Tom Coburn (R-OK), was included in the final version of the FY2001 Labor, Health and Human Services, and Education appropriations bill (H.R. 4577) after it was removed from a bill (H.R. 4386) to provide treatment to women diagnosed with breast or cervical cancer under the National Breast and Cervical Cancer Early Detection Program. The language is similar to a stand-alone bill (H.R. 3248) sponsored by Rep. Coburn.

Additionally, on October 3, 2000, the House approved a resolution (H. Con. Res. 64), sponsored by Reps. Juanita Millender-McDonald (D-CA) and Rick Lazio (R-NY), to call for a national cervical cancer public awareness and education campaign, recognize the need for early detection, recognize the importance of federally funded programs providing screening, and encourage all women to have regular Pap tests.

Notes

1 American Cancer Society (ACS), The Cervical Cancer Resource Center, "Cervical Cancer—Overview" <http://www3.cancer.org/cancerinfo/> (7/27/00).

2 American Medical Women's Association (AMWA), National Cervical Cancer Public Education Campaign, "Answers to Frequently Asked Questions About Cervical Cancer" (fact sheet, 1999).

3 Data provided by the National Institute of Child Health and Human Development at the National Institutes of Health, telephone interview with Women's Policy, Inc., July 2000.

4 Robert Burk, M.D., "Human Papillomavirus and the Risk of Cervical Cancer," *Hospital Practice*, Nov. 15, 1999.

5 Patrik K.E. Magnusson, et al., "Heretability of Cervical Tumours," *International Journal of Cancer* 88 (2000) 5:698-701.

6 Reuters News Service, "Genes predispose women to cervical cancers," Nov. 20, 2000 <http://www.4woman.gov/nwhic/news/Nov00/21Nov002.htm> (11/27/00).

7 ACS, "Cervical Cancer—Overview."

8 Burk, "Human Papillomavirus."

9 ACS, "Cervical Cancer—Overview."

10 AMWA, "Answers to Frequently Asked Questions."

11 The National Family Planning and Reproductive Health Association, *The Nickel-And-Diming of Women's Health* (Washington: NFPRHA, 1999), pp. 13-17; Food and Drug Administration, "New Devices Aim at Improving Pap Test Accuracy" <http://www.fda.gov/fdac/features/896_pap.html> (3/1/00).

12 Burk, "Human Papillomavirus."

13 Jack Cuzick, Ph.D., "Human Papillomavirus Testing for Primary Cervical Cancer Screening," *Journal of the American Medical Association* 283 (Jan. 2000) 1: 108-109 <http://jama.ama-assn.org/issues/v283nl/full/jed90104.html> (8/1/00).

14 Mark Schiffman, M.D., M.P.H., et al., "HPV DNA Testing in Cervical Cancer Screening," *Journal of the American Medical Association* 283 (2000) 1: 87-93 <http://jama. ama-assn.org/issues/v283nl/full/jto90018.html> (8/1/00).

15 Thomas Wright, Jr., M.D., et al., "HPV DNA Testing of Self-collected Vaginal Samples Compared with Cytologic Screening to Detect Cervical Cancer," *Journal of the American Medical Association* 283 (2000) 1: 81-86 <http://jama.ama-assn.org/issues/v283nl/full/joc91536.html> (8/1/00).

16 Burk, "Human Papillomavirus."

17 Edward L. Trimble, M.D. and Douglas Lowy, M.D. of the National Cancer Institute, "Women's Health: Raising Awareness of Cervical Cancer," testimony before the House Commerce Subcommittee on Health and Environment, Mar. 19, 1999, p. 7.

18 National Cancer Institute, Office of Financial Management funding chart <http://www.nci.nih.gov/admin/fmb/areas.html> (8/1/00).

DES

Developed in 1938, a drug called diethylstilbestrol (DES) was prescribed by doctors for nearly three decades to prevent miscarriage and other problems during pregnancy. It is estimated that four million pregnant women in the United States took the drug before it was removed from the market in 1971, exposing five to ten million individuals to the drug.[1]

Not only was DES found to be ineffective at preventing miscarriage, it also has been shown to increase health risks for the women who took the drug, as well as for their children. When DES was conclusively linked to clear cell vaginal adenocarcinoma in the daughters of women who had taken the drug, the Food and Drug Administration banned its use in pregnant women in 1971.[2]

This rare form of vaginal cancer is estimated to occur in 1 out of every 1,000 daughters of women who took DES, and it has an 80 percent survival rate.[3] It occurs most often in the late teens and early twenties, although recent research has documented cases in females aged 7-48, with an increase in cases in women aged 40-46. Researchers believe this may demonstrate a possible second peak of incidence.[4] In addition to vaginal cancer, DES daughters also face greater risks of ectopic pregnancy, premature labor, and infertility.

The effects on DES sons are still unclear, although some DES sons have higher rates of testicular abnormalities. Women who actually took DES have a 30 percent increased risk of breast cancer over women who did not take the drug.[5]

Further research is needed to define long-term health problems from DES exposure, including whether hormone replacement therapy is advisable for DES-exposed women and their daughters, and whether DES could have a genetic impact on the grandchildren of women who took DES.

Further research is needed to define long-term health problems from DES exposure, including whether hormone replacement therapy is advisable for DES-exposed women and their daughters, and whether DES could have a genetic impact on the grandchildren of women who took DES.

The National Institute of Environmental Health Sciences at the National Institutes of Health (NIH) published a study in 1998 that showed an increase in reproductive tract cancers in third-generation DES-exposed mice. The study, however, did not show signs of infertility in those mice.[6]

Detection and Education

Screening procedures can increase the early detection of DES-related health problems and help reduce the impact of DES exposure. Since the drug and similar compounds were marketed under a wide range of names, many women who used DES may not be aware of their exposure. As a result, many women and their now-grown children may not be receiving appropriate health care.

There is an ongoing need for education about the effects of the drug, as well as for improved access to clinical services for the DES population and increased outreach to those who may have been exposed.

National DES Education Program

In 1992, Congress passed legislation mandating the establishment of a national DES research and education campaign. As a direct result, the National Cancer Institute (NCI) at the NIH launched the National DES Education Campaign.

The program's objective is to design, implement, and evaluate expanded health information about DES exposure and to improve early diagnosis and treatment of conditions related to exposure. Grants were awarded in five regions for programs that targeted both the DES-exposed population and health care providers. Six consumer publications were created to raise public awareness about the issue. Research identifying DES grandchildren for studies of possible effects is now being conducted, as are studies placing DES in the broader

context of environmental estrogens, currently receiving increased scrutiny for their possible role as carcinogens.

Congressional Action

The 105th Congress passed legislation—the Women's Health Reauthorization Act (P.L. 105-340)—reauthorizing the DES research and education program through the year 2003.

During the 106th Congress, the Senate-passed FY2001 Labor, Health and Human Services, and Education appropriations bill (S. 2553) included committee report language noting that adequate funding had been allocated to the NCI to conduct the DES education campaign in conjunction with the Centers for Disease Control and Prevention. The House-passed version of the bill (H.R. 4577) included committee report language urging the NCI to ensure that public information pamphlets are readily available to consumers.

Notes

1 The DES Cancer Network, "DES Frequently Asked Questions" <http://www.descancer.org> (1/14/00).
2 Ibid.
3 Ibid.
4 DES Action USA, "Current Happenings: The DES Research Update 1999 Conference" <http://www.desaction.org> (1/18/00).
5 Ibid.
6 National Institute of Environmental Sciences, "'DES Daughters' Had Increased Rates of Cancer; An Animal Study Shows 'DES Granddaughters' May Too" (press release, Sept. 25, 1998).

Environmental Health

Most human disease is believed to be the product of a complex interaction between genetic and environmental factors. Over the past ten years, the mapping of the human genome has transformed biomedical research and the practice of medicine. However, research on environmental factors has lagged far behind.

Humans are exposed to a multitude of environmental agents from conception to death. From the food we eat, to the synthetic and naturally occurring chemicals in our environment, to physical agents such as sunlight, the impact of the environment on women's health is profound. There is disturbing evidence—both from laboratory experiments and epidemiological surveys—that certain chemicals mimic the biological effects of the female hormone estrogen.

These "environmental estrogens," like other environmental toxins, tend to accumulate in fat tissues. Because women have a higher percentage of body fat than men, they may build up greater stores of these compounds inside their bodies. In addition, when women's fat reserves are mobilized during pregnancy, lactation, and dieting, they may face secondary exposure to toxins.

Estrogen exposure has been implicated in the development of breast, ovarian, and endometrial cancers, which account for more than one-fifth of cancer deaths in American women.[1] Chemicals that can mimic the effects of estrogen include chlorinated hydrocarbons (such as DDT, PCBs, and dioxin), which are among the most widespread and persistent classes of pesticides.

The 1996 publication of *Our Stolen Future*, co-authored by two environmental scientists and a journalist, raised public concern about the possible human health effects of synthetic chemicals added to the environment in pesticides, detergents, plastics, and other products. Although the authors acknowledged that the scientific evidence is incomplete, they believe broader public awareness of the effects of environmental toxins on human health is needed. The chemicals they term "endocrine disruptors" may be responsible for the dramatic increase in breast and prostate cancer rates over the past three decades, declining sperm counts, and neurological problems in children exposed in utero.[2]

A number of federal agencies have jurisdiction over environmental health research and regulation, including the Centers for Disease Control and Prevention (CDC), the Environmental Protection Agency (EPA), the Food and Drug Administration, the National Institute of Environmental Health Sciences (NIEHS) at the National Institutes of Health (NIH), and the Occupational Safety and Health Administration. In 1994, the Public Health Service's Office on Women's Health convened a Federal Interagency Coordinating Committee on Women's Health and the Environment to promote collaboration between the various agencies with responsibility for environmental health issues.

Under the Food Quality Standards Act of 1996 (P.L. 104-170), the EPA was directed to establish a screening program for chemicals that mimic the biological effects of estrogen or other hormones, and report to Congress, within four years of enactment, on the human health effects of those chemicals. Additionally, the Safe Drinking Water Act Amendments of 1996 (P.L. 104-182) required the EPA to establish an estrogenic chemicals screening program. P.L. 104-182 also permitted the EPA to regulate such substances if they are found to pose a threat.

As a result of those two laws, the Endocrine Disruption Screening and Testing Advisory Committee at the EPA recommended that the congressionally mandated screening program expand its efforts to include chemicals that may affect the androgen and thyroid systems in both humans and wildlife, in addition to screening chemicals that may disrupt the endocrine system.[3] Implementation of the Endocrine Disruption Screening Program (EDSP), as required by law, will occur in two phases: the first phase will involve screening chemicals to determine whether they interact with hormone systems, and the second phase will involve a "two-tiered" test to determine the effects of that interaction on hormone systems. The program will focus on providing methods and procedures to detect and characterize endocrine activity of pesticides, commercial chemicals, and environmental contaminants.[4] The EDSP was established in August 1998 and the EPA is

currently in the process of implementing the program. The EPA anticipates that required screening of active ingredients in pesticides will begin in 2003.[5]

Also in 1999, the National Academy of Sciences (NAS) completed its report examining the effects of endocrine disruptors on humans as required by the FY1997 Veterans Affairs and Housing and Urban Development appropriations bill (P.L. 104-204). While the NAS report found that the lack of data on endocrine disruptors led to differences in interpretation of results among researchers, a review of the literature showed that there was evidence of a link between endocrine disruptors and developmental, reproductive, neurological, immunological, and ecological problems within animal and human populations. The report made recommendations for screening and testing endocrine disruptors that are consistent with the goals of the EPA's EDSP.[6]

On the research front, the NIEHS conducts and supports research on a wide range of women's health issues, including the relationship between environmental factors and breast, ovarian, and endometrial cancers. The NIEHS also has been involved in research on the health effects of exposure to diethylstilbestrol (DES), a drug given to approximately five million pregnant women before 1971 in the mistaken belief that it prevented miscarriages.[7]

Additionally, the Institute of Medicine issued a 1998 report, *Gender Differences in Susceptibility to Environmental Factors: A Priority Assessment*. The report was requested by the NIH Office of Research on Women's Health to review the research programs of the NIH, the CDC, and the EPA. In an effort to better coordinate research, the report recommended that an annual interagency workshop be held. The report also recommended additional research on exposure to "environmental estrogens." Basic research should include studies on environmental contributions and biological causes for gender differences; gender differences in disease outcomes; metabolic and hormonal differences; genetic markers of susceptibility; and translational research, which examines ways to apply clinical research to health care practices.[8]

Congressional Action

Committee report language accompanying the final FY2001 Labor, Health and Human Services, and Education appropriations bill (P.L. 106-554) urged the NIEHS to "enhance its research efforts to study the links between the environment and breast cancer through all available mechanisms, as appropriate, including establishing centers of excellence."

Legislation

Tampon Safety and Research Act of 1999 (H.R. 890)—Rep. Carolyn Maloney (D-NY)

H.R. 890 would direct the NIH to conduct research on the presence of dioxin, synthetic fibers, and other additives in tampons to determine what, if any, health risks their presence poses to women.

Breast Cancer and Environmental Research Act of 1999/Breast Cancer and Environment Research Act of 2000 (H.R. 3433/S. 2287)—Rep. Nita Lowey (D-NY) and Sens. Lincoln Chafee (R-RI) and Harry Reid (D-NV)

H.R. 3433 would establish up to eight Breast Cancer and Environmental Research Centers of Excellence through the NIEHS. The centers would be charged with conducting multidisciplinary research on environmental factors that may be related to the etiology of breast cancer research. The bill would authorize $30 million each year in FY2000 through FY2005.

Women's Health Environmental Research Centers Act of 2000 (H.R. 4634)—Reps. Louise Slaughter (D-NY) and Sue Kelly (R-NY)

H.R. 4634 would authorize $4 million to establish Multidisciplinary Centers for Women's Environmental Health at the NIEHS. The centers would be charged with conducting multidisciplinary research on environmental factors that may be related to the development of women's health conditions.

Notes

1 American Cancer Society, "Cancer Facts and Figures: 2000" <http://www.cancer.org> (8/1/00).

2 Theo Colburn, et al., *Our Stolen Future* (New York: Penguin Books, 1996).

3 Environmental Protection Agency (EPA), "Endocrine Disruptor Screening Program: Report to Congress" (Washington:

EPA, 2000), p. 1.

4 EPA, "Review of EPA's Proposed Environmental Endocrine Disruptor Screening Program" (Washington: EPA, 1999), p. 7 <http://www.epa.gov/sab> (6/1/00).

5 EPA, "Report to Congress," pp. 1-2.

6 National Academy of Sciences, *Hormonally Active Agents in the Environment* (Washington: National Academy Press, 1999), p. 9.

7 DES Cancer Network, "DES Frequently Asked Questions" <http://www.descancer.org> (1/14/00)

8 Institute of Medicine, *Gender Susceptibility to Environmental Factors: A Priority Assessment, National Academy Press* (Washington: National Academy Press, 1998), p. 2.

HIV/AIDS Research

HIV/AIDS is a serious health concern for women in the United States and around the world. According to the Centers for Disease Control and Prevention (CDC), an estimated 800,000 to 900,000 Americans are living with HIV and an estimated 40,000 people become infected each year. Of the number living with HIV, 120,000 to 160,000 are estimated to be women.[1]

- An estimated 2.5 million people worldwide died of AIDS in 2000 and 1.3 million were women.[2]
- Approximately 47 percent of the 36.1 million adults and children living with HIV/AIDS worldwide are women, totaling 16.4 million women.[3]
- Although the number of new AIDS cases has fallen every year since 1996, women are the fastest growing group of newly reported AIDS cases and HIV diagnoses. Women accounted for 32 percent of HIV cases reported in 1999.[4]
- The proportion of all reported AIDS cases among adult and adolescent women more than tripled from 7 percent in 1985 to 23 percent in 1999, according to the CDC.[5]

U.S. women living with HIV/AIDS are disproportionately African American and Hispanic. In 1999, African Americans and Hispanics accounted for more than 77 percent of AIDS cases in women, while they account for less than 25 percent of all women in the United States.[6] While AIDS is the fifth leading cause of death for all women aged 25-44, it is the third leading cause of death for African-American women and the fourth leading cause of death for Hispanic women.[7] Additionally, African-American women represented nearly two-thirds of all new AIDS cases in 1998.[8]

Sexual Transmission

Since 1994, heterosexual contact has been the leading source of HIV infection among women, followed by injection drug use.[9] Of U.S. AIDS cases reported in 1999, 40 percent were attributed to heterosexual contact and 27 percent to injection drug use. The source of infection in the remaining cases was listed as not reported or identified.[10] Worldwide, heterosexual transmission is responsible for about 80 percent of adult HIV infections.

Other factors associated with an increased risk of HIV infection among women include substance abuse and infection with other sexually transmitted diseases. The risk of HIV infection is increased not only by STDs like syphilis or genital herpes that cause open sores, but also by gonorrhea and chlamydia—STDs that are often asymptomatic in women and which can go years without detection (see Sexually Transmitted Diseases, p. 61). HIV and a number of other STDs are also more easily transmitted from men to women than from women to men. Individuals with STDs are three to five times more likely to become HIV-infected.[11]

Different Manifestation in Women

Because AIDS first manifested itself in the United States as a disease predominantly affecting Caucasian homosexual men, most research during the beginning of the epidemic was conducted on this population. As a result, the official definition of AIDS for many years did not reflect some of the specific manifestations in women. Largely in response to criticism from women's health advocates, the CDC expanded its definition in 1993 to include several conditions that occur frequently in women with HIV infection.[12]

Women with HIV/AIDS experience a number of chronic gynecological conditions that have been linked to HIV infection. These include pelvic inflammatory disease, vaginal yeast infections, genital warts, and a precancerous cervical cell condition associated with human papillomavirus. Although these conditions occur in uninfected women, they are more severe or persistent and more complicated to treat in women with HIV/AIDS. The failure of some health care providers to recognize these chronic conditions as early manifestations of HIV infection may account for later diagnosis and poorer prognosis for some women with HIV/AIDS.[13]

Currently, researchers are investigating gender differences in HIV/AIDS. Among the questions scientists are attempting to answer are the effects of the estrogen cycle on HIV in women and the biological basis for an initial lower level of HIV in women than in men. Several studies have shown that women, upon the initial diagnosis of HIV, as well as during the early stages of

HIV, have a lower level of the virus in their systems than men. However, the initial viral load difference disappears within four to five years.[14] Additionally, another study showed that women with the same viral load as men had a 60 percent greater chance of developing AIDS.[15] Researchers are closely examining this gender difference. Despite these results, according to the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health (NIH), women whose HIV infections are detected early and who receive appropriate treatment survive as long as infected men. However, women are less likely than men to receive early diagnosis and treatment, thereby shortening their survival rates.[16]

Ongoing Research Efforts

In response to criticism that women were being excluded from HIV/AIDS research and because women were becoming increasingly infected, a number of federal health agencies, including the NIH and the CDC, have initiated studies focusing specifically on women. The Women's Interagency HIV Study (WIHS) was initiated in 1993 to examine the natural history of the disease in women, including conditions specific to women and the role played by substance abuse and sexual behavior. WIHS enrolls both HIV-negative and HIV-positive women and participants are examined every six months. Since its inception, more than 2,600 women have been enrolled in the study, of which roughly 80 percent are minorities and 60 percent live below the poverty line. In 1998, the NIAID renewed the study for an additional five years after publishing the demographic, socioeconomic, health, and other characteristics of the women enrolled.[17]

One of the great hopes for women in HIV/AIDS research is the development of a topical microbicide—an agent that would prevent transmission of HIV and other STDs—that could be used by women before intercourse.

Much of the research on women and HIV/AIDS has been more narrowly focused on pregnant women and the risk that they will infect their newborns. The Women and Infants Transmission Study (WITS) was established in 1989 to determine risk factors for perinatal HIV transmission. Since its inception, nearly 1,800 pregnant women and more than 1,400 infants have enrolled in the study.[18] In September 1997, the NIAID announced it would renew the study for an additional four years.

In 1994, the NIAID released a study reporting that women who were treated with AZT during their pregnancies reduced the risk of perinatal transmission to their newborns by as much as two-thirds. As a result, the Public Health Service recommended offering AZT to infected pregnant women.[19] Since that recommendation, the rates of perinatal HIV transmission have decreased by 75 percent between 1992 and 1998.[20]

Results worldwide, however, have been mixed. An NIAID-sponsored study in Uganda found that a single dose of the antiretroviral drug nevirapine given to an HIV-infected woman in labor and another dose given to the baby within three days of delivery reduced the transmission rate by 50 percent.[21] However, another study, whose results were announced at the 13th International Conference on AIDS in July 2000, found that the initial benefit of treating newborns with two antiretroviral drugs at birth was lost by the age of 18 months due to breastfeeding. Under the study, only 6.7 percent of babies who received the drugs were infected at 6 weeks compared with 16.4 percent of babies who did not receive the drugs. Death rates for treated babies after 18 months were 21.3 percent compared with 26.8 percent for babies who did not receive the drugs.[22]

The number of women participating in HIV/AIDS clinical trials, including the AIDS Clinical Trials Group (ACTG), has drawn criticism from women's health advocates over the years. In 1990, women made up 10 percent of the AIDS cases reported among adolescents and adults and only 7 percent of ACTG participants, half of whom took part in an AZT experiment on preventing perinatal transmission.[23] The situation has gradually improved, however. In 1999, women—who accounted for 23 percent of all U.S. AIDS cases—were 18 percent of the ACTG.[24]

Development of Microbicides

One of the great hopes for women in HIV/AIDS research is the development of a topical microbicide—an agent that would prevent transmission of HIV and other STDs—that could be used by women before intercourse. Current HIV prevention methods, including

abstinence and condoms, are not effective for some women who are not always in control of when, with whom, and on what terms they have sexual relations.

Since 1992, Congress has encouraged the NIAID and the National Institute of Child Health and Human Development at the NIH to devote resources to developing topical microbicides. The NIH spent $26 million on microbicide research in FY1999, and was expected to spend $29.4 million in FY2000 and $31.6 million in FY2001.[25] Both institutes currently have ongoing efforts in basic research, product development, and clinical evaluation (including behavioral research). Researchers are pursuing microbicides that could serve as contraceptives, as well as microbicides to protect against STDs, while still allowing a woman to become pregnant. Scientists are currently pursuing over 50 different product leads and advocates believe that with sufficient resources a microbicide may be available in five years.[26]

In July 2000, researchers announced the results of a study to determine whether nonoxynol-9, a spermicide, would be effective in preventing the transmission of HIV. The study enrolled 1,000 HIV-negative sex workers in Africa. Half of the women received the spermicide, while the other half received a placebo. The study found that women who used nonoxynol-9 became infected with HIV at a 50 percent higher rate than women who used the placebo. Additionally, the more frequently women used the spermicide, the higher their infection risk. As a result of the study, the CDC recommended that HIV prevention messages be changed to reflect that the use of spermicides alone does not prevent HIV transmission.[27]

Researchers and advocates say that the results of the study further highlight the need to pursue expanded research for HIV/STD prevention.[28]

Congressional Action

Both the House- and Senate-passed FY2001 Labor, Health and Human Services, and Education appropriations bills (H.R. 4577/S. 2553) included committee report language pertaining to microbicides. The Senate report encouraged the NIH to develop a five-year implementation plan for microbicide research, and required that the report be submitted to Congress by April 1, 2001. The House committee report urged the NIH to enhance microbicide research.

The final FY2001 Labor, Health and Human Services, and Education appropriations bill (P.L. 106-554) concurred with the Senate language.

Legislation

Microbicides Development Act of 2000 (H.R. 3891)—Reps. Connie Morella (R-MD) and Nancy Pelosi (D-CA)

H.R. 3891 would direct the NIH to expand, intensify, and coordinate microbicide research through the establishment of a program for microbicide development. The bill would include basic research on the initial mechanisms of infection, development of appropriate animal models, development of mucosal systems, research on contraceptive and non-contraceptive microbicides, clinical trials, and behavioral research. The bill would authorize $50 million in FY2001, $75 million in FY2002, and $100 million in FY2003 for such a program. Additionally, H.R. 3891 would authorize $7 million in FY2001, $11 million in FY2002, and $15 million in FY2003 for the CDC to coordinate microbicide activities with the NIH.

Notes

1 Centers for Disease Control and Prevention (CDC), "HIV/AIDS Among U.S. Women: Minority and Young Women at Continuing Risk" <http://www.cdc.gov/hiv/pub/facts/women.htm> (5/13/00).

2 Joint United Nations Programme on HIV/AIDS, *AIDS Epidemic Update: December 2000* (New York: United Nations, 2000) <http://www.unaids.org> (11/30/00).

3 Ibid.

4 CDC, "U.S. HIV and AIDS Cases Reported Through December 1999 Year-End Edition," *HIV/AIDS Surveillance Report* 11 (1999) 2: 5.

5 Ibid.

6 National Institute of Allergy and Infectious Diseases (NIAID), "HIV Infection in Women" <http://www.niaid.nih.gov/factsheets/womenhiv.htm> (11/30/00).

7 CDC, *HIV/AIDS Surveillance Report*.

8 Ibid.

9 Ibid.

10 NIAID, "HIV Infection and Women."

11 Judy Wasserheit, M.D., Ph.D., "Epidemiological Synergy: Interrelationships Between Human Immunodeficiency Virus Infection and other Sexually Transmitted Diseases," *Sexually Transmitted Diseases* 19 (1992): 61-77.

12 CDC, "HIV/AIDS Among US Women: Minority and Young Women at Continuing Risk" <http://www.cdc.gov/hiv/pubs/facts/

women.htm> (11/27/00).
13 Brynn R. Gaberman and Leslie R. Wolfe, Ph.D., "AIDS: The Women's Epidemic" (Washington: Center for Women's Policy Studies, 1999).
14 NIAID, "Gender and HIV Viral Load Workshop" (Rockville: NIAID, 2000) <http://www.niaid.nih.gov/daids/gender_and_hiv.htm> (5/30/00).
15 Denise Grady, "Study Says H.I.V. Tests Misstate Women's Risk," *New York Times*, Nov. 6, 1998, A18.
16 NIAID, "HIV Infection in Women."
17 NIAID, "WIHS Gets Five-Year Renewal," March 1998 <http://www.niaid.nih.gov/publications/agenda/0398/page8.htm> (5/31/00).
18 NIAID, "Women and Infants Transmission Study (WITS) Renewed," Nov. 1997 <http:www.niaid.nig.gov/publications/agenda/1197/page9.htm> (5/31/00).
19 CDC, "Status of Perinatal HIV Prevention: U.S. Declines Continue" <http://www.cdc.gov/hiv/pubs/facts/perinatl.htm> (5/31/00).
20 CDC, "HIV Prevention Strategic Plan Through 2005" <http://www.cdc.gov/nchstp/od/news/draft.plan.pdf> (10/18/00).
21 NIAID, "HIV Infection in Women."
22 Lawrence Altman, "Report Dims Hope for AIDS Therapy to Protect Babies," *Washington Post*, July 8, 2000, A1.
23 Joyce A. Korvick, et al., "Women's Participation in AIDS Clinical Trial Group (ACTG) Trials in the USA: Enough or Still Too Few?" *Journal of Women's Health* 5 (1996) 2: 129-136.
24 Data provided by the NIAID Division of AIDS, email communication with Women's Policy, Inc., July 27, 2000.
25 NIH, Office of the Director, Office of Financial Management funding chart <http://www4.od.nih.gov/ofm/diseases/index.stm> (5/31/00).
26 Alliance for Microbicide Development, 2000. *Microbicides: Research and Development Status*, February 2000.
27 CDC, "Nonoxynol-9 Trial—The Implications," Aug. 4, 2000 <http://www.cdc.gov/hiv/dhap.htm> (11/14/00).
28 Susan Okie, "AIDS Study Prompts New Look at Prevention," *New York Times*, Aug. 14, 2000, A3.

Ovarian Cancer

Although ovarian cancer is a common form of cancer, the lack of a simple diagnostic test makes it particularly deadly. It ranks fifth for cancer-related deaths in women.

- Currently, 50 percent of women who are diagnosed with ovarian cancer will die within five years. Only 25 percent of ovarian cancers are diagnosed in the beginning stages.[1]
- The American Cancer Society (ACS) estimated that 23,100 new cases of ovarian cancer would be diagnosed, and 14,000 women would die of the disease in 2000.[2]
- Ovarian cancer ranks second among gynecologic cancers and causes more deaths than any other gynecologic cancer.[3]

Risk factors for ovarian cancer include family history of the disease, no childbearing, and age. According to the ACS, roughly 7 percent of ovarian cancer cases result from an inherited genetic defect (BRCA1 or BRCA2), and 90 percent of women who are diagnosed with ovarian cancer do not have any known risk factors.[4]

If ovarian cancer is caught while it is still localized, the 5-year survival rate is 95 percent, but only 24 percent of cases are diagnosed at this stage. Once the cancer has spread and the disease is diagnosed in the late stages, the survival rate falls to 28 percent. Treatment usually consists of radical hysterectomy combined with chemotherapy.[5]

Improving early detection of ovarian cancer would help reduce deaths from the disease. Transvaginal ultrasound and the CA125 blood test are currently used as diagnostic tools, but not for screening purposes. Additionally, health care providers and patients are finding that the CA125 blood test produces a high number of false positives and false negatives, leading many to question its accuracy. Some studies have shown that more than half of the participating women with Stage I ovarian cancer had normal CA125 blood levels.[6] Researchers are currently working on another blood test that would better detect ovarian cancer by measuring the level of lysophosphatidic acid (LPA) in the blood. Since LPA is believed to stimulate the growth of ovarian cancer cells, researchers believe an LPA blood test would more accurately detect the disease.[7]

A recent study published in *Cancer* found that screening for ovarian cancer using transvaginal ultrasound during routine gynecological examinations greatly improved early diagnosis of ovarian cancer.[8] The study screened 183,034 Japanese women over a 10-year period and found 22 primary tumors. According to the study, of the 22 primary tumors detected, 77.3 percent were found during Stage I, the most curable stage.[9]

In addition to improving early detection methods, another study demonstrated the need to educate doctors and women about ovarian cancer. The study examined the medical records of 1,725 U.S. and Canadian women with ovarian cancer and found that many of the women had the symptoms of ovarian cancer. However, only 20 percent of the women were told they might have ovarian cancer during their first visit to a doctor. Many of the women were diagnosed with a number of other conditions, and 21 percent of the women in the study blamed their doctor for the late diagnosis.[10]

According to the Ovarian Cancer National Alliance, one-third as many women die of ovarian cancer as die of breast cancer, but the National Cancer Institute (NCI) at the National Institutes of Health (NIH) spends one-eighth as much money for ovarian cancer as for breast cancer research.[11] Additionally, the majority of ovarian cancer research funds at the NCI are directed toward treatment rather than prevention or early detection. Researchers say a sustained effort to identify risk factors, improve early detection, and expand treatment options will be crucial to reducing deaths from this disease. In FY1999, the NIH spent $65.4 million on ovarian cancer research, with an expected increase to $73 million in FY2000 and $77.9 million in FY2001.[12]

In October 1999, the NCI announced that it would grant four academic institutions a total of $5.85 million to research ovarian cancer. The grants are part of Specialized Programs of Research Excellence (SPORE) that support innovative, multidisciplinary research. The four institutions will focus their research on chemoprevention, gene resistance, vaccine development, and prevention and treatment of the disease.

In addition to research at the NIH, the Department of Defense also has been conducting research on ovarian cancer since FY1997 when it was appropriated $7.5 million. The Ovarian Cancer Research Program received $12 million in each of FY2000 and FY2001. Eight projects were funded in FY1997-1998 that focused on chemoprevention of ovarian cancer, genetic alterations in ovarian cancer, genetic definitions, the role of angiogenesis in the etiology and prevention of ovarian cancer, and multidisciplinary strategies in the prevention and early detection of ovarian cancer.[13] In FY1999, 18 new projects were funded, focusing on mechanistic studies, psychosocial assessments, development of new vaccines, biomarkers, diagnostics, and treatment, and characterization of animal models for human ovarian cancer.[14]

Legislation

Ovarian Cancer Research and Information Amendments of 1999 (H.R. 961)—Rep. Patsy Mink (D-HI)

H.R. 961 would authorize $150 million for ovarian cancer research. The funds would be divided between basic cancer research and clinical trials. Under the bill, funding priorities would be given to developing an early detection test, to identifying precursors to ovarian cancer, and to determining the relationship between ovarian cancer and endometriosis. H.R. 961 also would provide for a public education program on the known risk factors, screening procedures, and effectiveness of various treatments for ovarian cancer.

Congressional Action

The 106th Congress enacted legislation (P.L. 106-391) to reauthorize the National Aeronautics and Space Administration. The law includes a $2 million earmark for research and early detection systems for breast and ovarian cancer and other women's health issues.

Additionally, the Senate-passed FY2001 Labor, Health and Human Services, and Education appropriations bill (S. 2553) included report language urging the NCI to "expedite current research on screening methods to detect, diagnose, and identify staging of ovarian cancer" and to fully fund four ovarian cancer SPOREs. The House-passed version of the bill (H.R. 4577) included committee report language urging the NCI to fully fund four ovarian cancer SPOREs.

Notes

1 Ovarian Cancer National Alliance, "Facts About Ovarian Cancer" <http://www.ovariancancer.org/cancer/fact_sheet_mar2000.shtml> (5/30/00).

2 American Cancer Society (ACS), "Cancer Facts and Figures 2000" <http://www.cancer.org/statistics/cff2000/selectedcancers> (8/21/00).

3 Ibid.

4 ACS, The Ovary Cancer Resource Center, "Ovarian Cancer Overview" <http://www3.cancer.org/cancerinfo/load_cont.asp?ct=33&doc=37&Language=English> (8/21/00).

5 ACS, "Cancer Facts and Figures 2000."

6 Susan Boodman, "Test for Ovarian Cancer Shows Promise," *Washington Post*, Sept. 9, 1998, Health Section, 7.

7 Ibid.

8 Haleh V. Samiei and Lexie Verdon, "Ovarian Cancer: Ultrasound Screening is Effective at Identifying Early Ovarian Cancer," *Washington Post*, Aug. 8, 2000, Health Section, 21.

9 Shigemi Sato, M.D., et al., "Usefulness of Mass Screening for Ovarian Carcinoma Using Transvaginal Ultrasonography" *Cancer* 89 (2000): 582-88.

10 Reuters News Service, "Women, doctors miss signs of ovarian cancer," Nov. 14, 2000 <http://www.4woman.gov/nwhic/news/Nov00/15Nov00.htm> (11/27/00).

11 Ovarian Cancer National Alliance, "Facts About Ovarian Cancer."

12 National Institutes of Health, Office of the Director, Office of Financial Management funding chart <http://www4.od.nih.gov/ofm/diseases/index.stm> (5/30/00).

13 Department of Defense Congressionally Directed Medical Research Programs, Ovarian Cancer Research Program <http://CDMRP.army.mil> (11/14/00).

14 Department of Defense Congressionally Directed Medical Research Programs, "Department of Defense Announces Awards Summary for FY99 Ovarian Cancer Research Program" (press release, Oct. 18, 2000) <http://CDMRP.army.mil> (11/14/00).

Treatment of Women Scientists

In recent decades, increasing numbers of women have chosen careers in the sciences. Women have continued to overcome societal attitudes about what interests and activities are "appropriate" for girls and women, a lack of encouragement in the educational system, and institutional indifference in industry, government, and academia. Still, parity has not been achieved:

- Women represent 46 percent of the U.S. workforce but only 22 percent of those employed as scientists and engineers.[1]
- Among science and engineering faculty, 24 percent of women are full professors compared to 49 percent of men. Additionally, 35 percent of full-time employed women science and engineering faculty are tenured, compared to 59 percent of men. Women are one-fourth as likely as men to achieve the rank of full professor over their careers.[2]
- In 1995, the average salary of women scientists and engineers was $42,000—about 20 percent less than the $52,000 average salary for men—according to the National Science Foundation (NSF). The disparity is partly attributed to age; women scientists and engineers are on average younger and less likely to pursue higher-paying fields, such as computer science.[3]

In the 103rd Congress, several legislative initiatives addressed the status of women scientists at the National Institutes of Health (NIH). A provision of the NIH Revitalization Act of 1993 (P.L. 103-43) instructed the NIH Office of Research on Women's Health (NIH-ORWH) to monitor and promote the status of women scientists and physicians at the NIH and NIH-funded institutions, with particular emphasis on increasing the representation of women in senior positions. Additional legislation, introduced as part of the Women's Health Equity Act of 1993, would have required the NIH to establish policies regarding women scientists (including tenure, family leave, and the recruitment of women of color), and to study and address the issue of pay differences between male and female scientists. This legislation was incorporated into the Minority Health Improvement Act, a bill that died awaiting Senate approval of the conference report in 1994.

Attention by Congress, the General Accounting Office, and the Equal Employment Opportunity Commission to the status of women at the NIH has led to improvements.

- The representation of women has increased in a variety of positions at the NIH. There were no female scientific directors in 1992; in 1995, 14 percent were women; and in 2000, 17 percent were women. In 1992, 4 percent of lab and branch chiefs were women; in 1995, 10 percent were women; and in 2000, 12 percent were women. In 1992, 13 percent of section chiefs were women; in 1995, 18 percent were women; and in 2000, 19 percent were women.
- Additionally, in 2000, women accounted for 19 percent of tenured scientists and 24 percent of tenure-tracked scientists.[4]

The NIH-ORWH has undertaken several projects aimed at encouraging women's participation in biomedical science careers. In January 2000, the NIH-ORWH announced the Transitional Career Development Award in Women's Health Research. The career development program provides women scientists with the opportunity to study and conduct research at the NIH for a two-year period. Participants also are awarded funding to continue their study and research at an academic institution of their choice for an additional two years. The program began in September 2000.[5]

Additionally, the NIH-ORWH has established a Building Interdisciplinary Research Careers in Women's Health program aimed at providing career development for junior researchers. The NIH-ORWH also participates in the Professional Opportunities for Women in Research and Education (POWRE) program established by the NSF in 1997. The program's mission is to encourage the pursuit of careers by women in science and engineering. In FY1999, POWRE provided 159 grants, totaling $11.5 million.[6]

Congressional Action

Congress also has pursued the advancement of women in science and engineering. In 1998, Congress created a commission (P.L. 105-255) to examine the barriers

keeping women, minorities, and the disabled from careers in scientific fields. In July 2000, the commission released its report, which detailed a series of recommendations aimed at advancing the participation of women, minorities, and the disabled in science, engineering, and technology.[7]

The commission recommended that states adopt and implement high-quality education standards in math and science curricula and math and science teachers' qualifications. Additionally, the commission recommended aggressive and focused interventions for women, minorities, and disabled high school students transitioning into post-secondary colleges and community colleges. Another recommendation called for an increase in federal and state financial investments in science, engineering, and technology higher education. In terms of professional life, the commission recommended that all private and public science, engineering, and technology employers be held accountable for the career development and advancement of their women, minority, and disabled employees.[8]

Additionally, during the 106th Congress, the House defeated legislation (H.R. 4271) aimed at improving science and math education. The bill included a provision, sponsored by Rep. Lynn Woolsey (D-CA), that would have provided grants to educational agencies and institutions of higher education to develop curricula encouraging girls in grades 4-12 to select careers in math and science. The bill also included a provision, sponsored by Rep. Connie Morella (R-MD), that would have created a pilot project to distribute grants to community colleges for the purpose of encouraging women, minorities, and persons with disabilities to study math, science, and engineering. H.R. 4271 was defeated because of objections to an unrelated provision in the bill.

Legislation

HHS Women Scientists Employment Opportunity Act (H.R. 269)—Rep. Louise Slaughter (D-NY)

H.R. 269 would require the Department of Health and Human Services (HHS) to take action in three areas to improve the employment opportunities, pay, and visibility of women scientists. HHS would be required to establish policies to promote the employment of women scientists and monitor compliance within each of the agencies and offices of the department. These policies would include improved recruitment of minority women scientists, family leave, and interviews of departing scientists to determine their reasons for leaving.

H.R. 269 also would require the Secretary to establish a policy for the inclusion of women scientists in greater numbers at conferences, workshops, or meetings funded or sponsored by HHS agencies. The policy would mandate the inclusion of at least one woman scientist in each such group. Finally, the bill would require the department to conduct a pay equity study to identify any pay differences, and to make recommendations for adjusting any disparities.

Notes

1 National Science Foundation (NSF), *Science and Engineering Indicators 1998* (Washington: National Academy Press, 1998), pp. 3-15.

2 NSF, *Women, Minorities, and Persons with Disabilities in Science and Engineering: 1998* (Washington: National Academy Press, 1998), p. 103.

3 Ibid., p. 105.

4 Joan P. Schwartz, Ph.D., Assistant Director, Office of Intramural Research, Office of the Director, National Institutes of Health, email communication with Women's Policy, Inc., Aug. 18, 2000.

5 National Institutes of Health, Office of Research on Women's Health, "Opportunities for Women in Biomedical Careers" <http://www4.od.nih.gov/orwh/career.html> (7/17/00).

6 NSF, "Professional Opportunities for Women in Research and Education" <http://www.nsf.gov/home/crssprgrm/powre/start.htm> (7/17/00).

7 Commission on the Advancement of Women and Minorities in Science, Engineering, and Technology, Final Report, July 2000 <http://www.nsf.gov/od/cawmset/> (7/17/00).

8 Ibid.