

# Real Social Change

## Women's Health Care Research Moves Forward While Advocates See New Needs

By Cynthia L. Cooper

Turn on a television during the evening newscast and there's a good chance of catching a drug advertisement about osteoporosis. Academy Award-winning actress Sally Field, the former Flying Nun, now 60, is the public face of a campaign promoting a new drug to prevent bone density loss, which affects four times as many women as men.

But behind the scenes is a bigger drama: a shift in the funding of women's health research during the past 15 years that is yielding concrete benefits in people's lives. Not only has a treatment for osteoporosis emerged, but better diagnoses for heart disease and ovarian cancer and a reduction in breast cancer cases also have emerged. At the same time, these advances point the direction for more strides in the future.

Women lawyers were pivotal in legal changes that altered inequities in health research, and as members of a stressful profession that places extra

strains on health, they reap particular benefits, as well. In addition, women lawyers are critical to helping others pierce tangles of confusing information about health care treatment and making well-founded decisions in their lives.

### Shifts in Research

At the epicenter of change in health care research is the Office of Research on Women's Health (ORWH), established in the early 1990s as a division within the Office of the Director of the National Institutes of Health (NIH). ORWH opened after women members of Congress and advocates demanded improvements in the dismal number of women included in clinical trials and the low level of funds devoted to women's medical concerns.

NIH is the leading funder of medical research in the nation, with a budget of \$27 billion annually. The ORWH works to strengthen research on women's health and ensure that studies supported by government funds include women as subjects, according to Lisa Begg, ORWH director of research programs. In its most recent biannual review of research, a 584-page report covering the years 2003–2004, ORWH states that an average 13.1 percent of the annual NIH research budget was spent on women's health, compared with 5.8 percent on men's health. The 2005–2006 report will be released in October, and it paints a very similar picture, according to ORWH spokesperson Marsha Love. Research falls into the "women's health" category if the condition is unique to or substantially more prevalent in women, insufficient clinical research has involved women, or the medical risks differ for women. The remaining bud-

get—approximately 80 percent—is devoted to research that benefits both women and men.

The numbers translate to \$3.5 billion each year spent specifically on women's health research at the NIH and 23 independent institutes, including the National Cancer Institute, the National Institute of Mental Health, and the National Institute on Aging. Researchers are required to include women in Phase III clinical trials, which come at the later stages of research, in sufficient numbers to allow a valid analysis of data.

"That reflects a tremendous expansion of research related to women's health and a tremendous advance in sex and gender studies," Begg says. "It's not as visible to the average man and woman, but it is evident to researchers. And it's impacting clinical care."

This shift in research is a real victory for social change, according to Cindy Pearson, executive director of the National Women's Health Network, a watchdog and advocacy group in Washington, D.C. Pearson credits the feminist health movement and women members of Congress, who first demanded a study on medical research expenditures in the late 1980s and showed substantial discrepancies. Women were missing from clinical trials and were only 5 percent of the budget. "The federal government was called on the carpet. They were asked: 'Why, why, why, why?' And it exploded. Now we are feeling the effects," Pearson says.

Concrete results are steadily appearing. For example, NIH-sponsored research determined that heart attacks in men, identified by crushing pain, present differently in women, who report fatigue and nausea. As a result, doctors are changing their

practices, Begg says. Studies showing gender differences in drug addiction have resulted in modifications in intervention programs. New research on post-menopausal hormone replacement drugs, indicating significant drawbacks, caused a 25 percent reduction in their use and a decline in new cases of breast cancer, quite likely related.

The office took testimony across the country, jumpstarted a dozen multidisciplinary research groups at universities on women's health care, contacted centers of excellence, and advocated for women to enter science.

### Complex Health Care Needs

But more needs to be done to tackle some of the most intractable problems in women's health, including breast and ovarian cancer. Many health advocates have redefined research needs and, some say, it's not just about the money. What's important, advocates say, is identifying the best approach to addressing women's health in a time when individualized health care is becoming paramount. For many, that is defined in a revised concept: studying "sex differences."

"I think it's fair to say that attention to women's needs is better than it was in that we have more information," says Usha Ranji, senior policy analyst on women's health policy for the Kaiser Family Foundation in Menlo Park, California. "We have made some progress on the clinical side. But there is still plenty of room to go."

Women's health care needs are particularly complex, Ranji says. Women have reproductive health care needs that men, quite naturally, do not encounter. Women live longer than men and suffer more chronic conditions and autoimmune diseases such as lupus. Women are also the largest users of the health care system, choosing medical care not only for themselves, but also for elderly parents and children. These facts require more understanding about women's touch points to medical care. Women even access

their health care differently, often choosing obstetrician/gynecologists as primary care physicians. Race, ethnicity, and income result in additional disparities that are poorly understood and addressed, Ranji says.

The Society for Women's Health Research, an advocacy association in Washington, D.C., has led the way in calling for a shift in thinking about research altogether, away from a focus on dollars spent on "women's health" to a focus on sex differences. "To get away from the argument it's 'us versus them' or 'women versus men' and who's winning—which is silly—we want to focus on what's different between women and men. What's different in biology and different in epidemiology? And what can we do to better tailor health research?" says Sherry A. Marts, vice president of scientific affairs at the society.

Two years ago, the society launched the Organization for the Study of Sex Differences (OSSD). In May 2007, OSSD held its first annual conference in Washington, D.C. The organization wants research data to look at variable effects of treatment on men and women, for example, in symptoms, treatments, prescription doses, and the likelihood of side effects.

Marts recalls a toxicology conference she attended where one scientist talked about a study from 1963 on animals, in which the males showed different responses than the females. "They said, 'That's too confusing, so we'll just use one sex—male. Those pesky hormones will get in the way.' Well, if you think hormone cycles are going to have an impact, don't you want to know?" Marts says. She points out that the mandate to NIH only requires that women be included in later stage trials, but that dosing studies are conducted early in the research cycle.

NIH research tends to focus on basic research and causes of conditions, says Diana Zuckerman, president of the National Research Center for Women & Families in Washington,

D.C., who has worked extensively in health care policy. But gaps occur after drug treatments are developed, especially in comparing one treatment to another.

"A lot of advertising can go into a new drug when an old drug is just as effective. Wouldn't it be better to have a comparison?" Zuckerman says. The Food and Drug Administration (FDA), which approves pharmaceuti-

## Learn more about women's health care initiatives

The Office of Research on Women's Health places reports on its Web site:  
<http://orwh.od.nih.gov>.

ORWH sponsors two public Web sites that give health care information:  
[www.forwomen.gov](http://www.forwomen.gov)  
[www.girlshealth.gov](http://www.girlshealth.gov).

cal products, does not offer comparisons, and the only agency that does—the federal government's tiny Agency for Healthcare Research and Quality—does not have the resources to manage the flow, Zuckerman says.

Translational research, applying new understandings from studies to practice, is also sorely needed to improve women's health care, Zuckerman says. "Take the area of breast cancer. A lot of women are getting mastectomies that they don't need. It's not because we don't know that lumpectomies with radiation [can be as effective as mastectomies] for a large number of women," Zuckerman says. Although 200,000 women are diagnosed with breast cancer each year, and 40,000 die of it, only outdated studies compare mastectomies to lumpectomies and when and whether women are get-

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ting appropriate care. “We need more research on treatment options and how to get the information out,” Zuckerman says.

### **Closing Other Gaps**

The American Medical Women’s Association (AMWA) sees other gaps in women’s health care. AMWA president-elect Claudia Morrissey, M.D., contends that reproductive health services are being short-changed and are in peril. Ensuring access is one of her top priorities. Other members of AMWA are pursuing formal recognition of a subspecialty in women’s health care, she says.

Morrissey is also committed to advancing women into leadership positions in medicine, which she sees as central to achieving overall gains in women’s health care. “It’s always been women who have pushed for the notion that women-centered health is important,” she says. “Women are always the ones who pushed the enve-

lope.” Yet, when it comes to major government grants, women are still not the principal investigators, she notes.

There are other worrying signs that, without active engagement, women’s progress may slow or stop.


Reports in February 2007 indicated that the Bush administration planned to withhold more than one-quarter of the already-low \$4 million budget of the FDA Office of Women’s Health. Rep. Carolyn B. Maloney (D-NY) responded with the Women’s Health Office Act (HR 1072) to make five federal women’s health offices permanent.

“While it has now been established that diseases affect men and women differently, we have been left with a dearth of information on women’s health needs,” Maloney says. “Unfortunately, this is not a problem of the past. The fact that our offices of women’s health have not been properly funded demonstrates a reluctance to make women’s health a priority.”

In June, Rep. Rosa DeLauro (D-CT) introduced the FDA Scientific Fairness for Women Act

(HR 2503) to elevate the work of women’s research at the FDA and require scientific studies on emergency contraception and silicone breast implants.

Educated women consumers will be the real linchpins in advances for women’s health during the next 15 years, according to the National Women’s Health Network. Pearson, the organization’s executive director, cites women lawyers as an example. “Lawyers are information seekers, and we need information seekers involved in the health care system who will look at information, absorb it, and share only high-quality information with friends,” she says.

“The job’s not done,” ORWH’s Begg admits. Difficult challenges remain in reducing incidents of ovarian and breast cancer, lupus, and more. Advocates for women are determined to keep watching and pushing. “It’s going to take more research and more time,” Begg says. “And we’ll keep working away.” 

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