

*Introducing the new
NIH strategic plan...*



MOVING INTO THE FUTURE
WITH NEW DIMENSIONS AND
STRATEGIES:

A VISION FOR 2020 FOR
WOMEN'S HEALTH RESEARCH

Office of Research on Women's Health

20TH ANNIVERSARY

**Moving into the Future with New Dimensions and Strategies:
A Vision for 2020 for Women's Health Research**

1990



2010

SCIENTIFIC SYMPOSIUM

MONDAY, SEPTEMBER 27, 2010

*RUTH L. KIRSCHSTEIN AUDITORIUM, NATCHER CONFERENCE CENTER
NATIONAL INSTITUTES OF HEALTH*

RESEARCH

Do studies shortchange women?

Gannett News Service
Montgomery Co. Journal

THE CHARGES

Critics cite taxpayer-funded National Institutes of Health projects that favor men:

- Study on cholesterol and heart disease; 10 years, \$150 million, 3,806 subjects, no women.

- Study on aging: 30 years, \$10 million-plus, 1,000 subjects, no women until 1978 — 20 years into the study.

- Study of moral development in children: 11 years, \$638,728, discontinued after controversy over research based on boys that found girls to be morally inferior.

- NIH budget for women-related diseases: \$496 million, or less than 10 percent of total \$5.1 billion in 1985 research budget.

April 8, 1986

N.I.H.
Neglects
Women,
Study Says

New York Times

**Gender gap
plagues
U.S. health
studies**

Cleveland Plain Dealer

June/July 1990

Patricia Schroeder, Co-Chair
 Olympia Snowe, Co-Chair
 Lady Bird Palfrey, Secretary
 Mary Kaptin, Treasurer
 Barbara Blum
 Carolyn Collins
 Nancy Johnson
 Nancy Kautzman
 Richard Kucinski
 Ted Long
 Max Lowry
 Jan Meyer
 Barbara Mikulski
 Susan Muhlman
 Constance Morella
 Mary Rabe Doherty
 Elizabeth Tammann
 Nancy Pelosi
 Patricia Sisk
 Claudia Schneider
 Louise Slaughter
 Betty Wexler

Congressional Caucus for Women's Issues Congress of the United States Washington, D.C. 20515

202/544-0240
 202/544-0241
 Lady Bird Palfrey
 Executive Director

August 22, 1990

Dr. William Raab
 Acting Director
 National Institutes of Health
 Bethesda, Maryland 20892

Dear Dr. Raab:

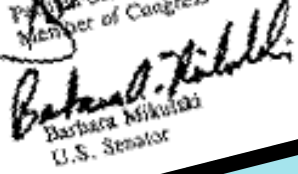
We are writing to propose a meeting between members of the Executive Committee of the Congressional Caucus for Women's Issues and key government health officials to discuss women's health research issues. We hope that this meeting can take place at the National Institutes of Health on September 10 at 10 a.m. In addition, we would like the public to be able to attend.

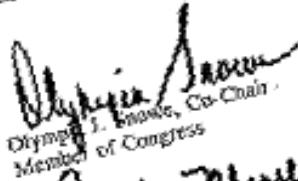
The purpose of the meeting would be to provide members of the Caucus with an opportunity to learn what steps have been taken by NIH to respond to issues raised in the GAO report and elsewhere, and to discuss with key government officials what steps may be necessary to strengthen federal research efforts on women's health issues. In addition to yourself, Dr. Ruth Kirschstein and others at NIH, we are inviting Secretary Sullivan and Surgeon General Novello to participate. Separate letters have been sent to each of them.

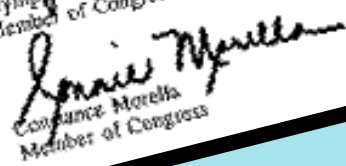
We believe that this meeting will provide an important opportunity for us to work together constructively to improve the health status of American women.

Sincerely,


 Patricia Schroeder, Co-Chair
 Member of Congress


 Barbara Mikulski
 U.S. Senator


 Olympia Snowe, Co-Chair
 Member of Congress


 Constance Morella
 Member of Congress

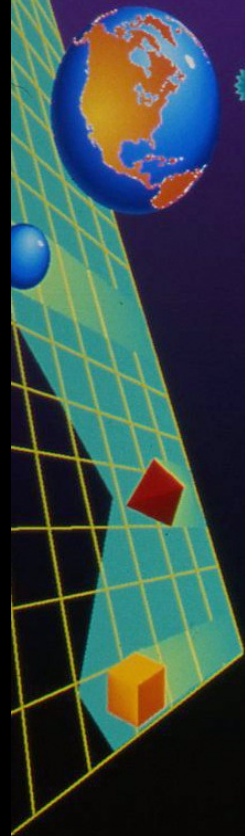
Office of Research on Women's Health

Office of the Director
National Institutes of Health

est. September 1990

From Statement by
DR. RUTH KIRSCHSTEIN

September 10, 1990



...As one of its most important activities, the Office, this fall, will convene a planning group to prepare the background for a major conference which will serve to set an agenda for NIH research on women's health...

Changing Research Design at NIH

Innovative
interdisciplinary research

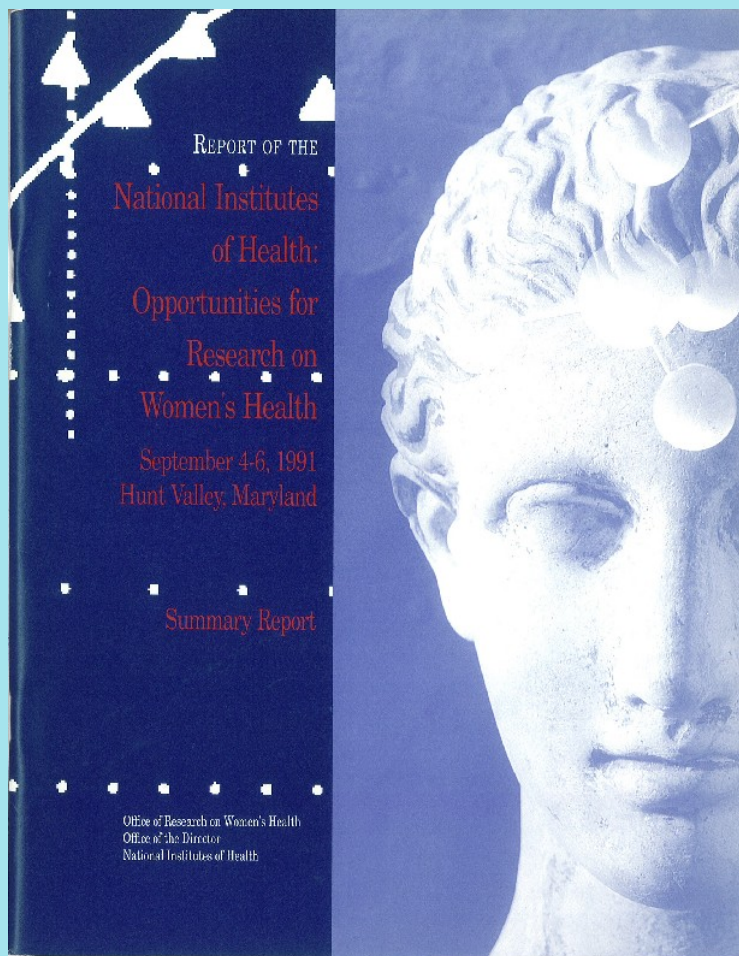
Set research agenda: Focus
on gaps and emerging areas in
women's health and
sex/gender
issues

**OFFICE OF RESEARCH
ON WOMEN'S HEALTH
OD, NIH, 2010**

Biomedical career
development for
women, & for
women's health
researchers

Inclusion of
Women & Minorities
In Clinical Research

Factors such as
race/ethnicity,
effects of poverty;
urban & rural women,
understudied populations
e.g. disabled,
immigrants, homeless,
lesbians...



‘Hunt Valley Report’ – 1991
First National Agenda on
Research on Women’s Health



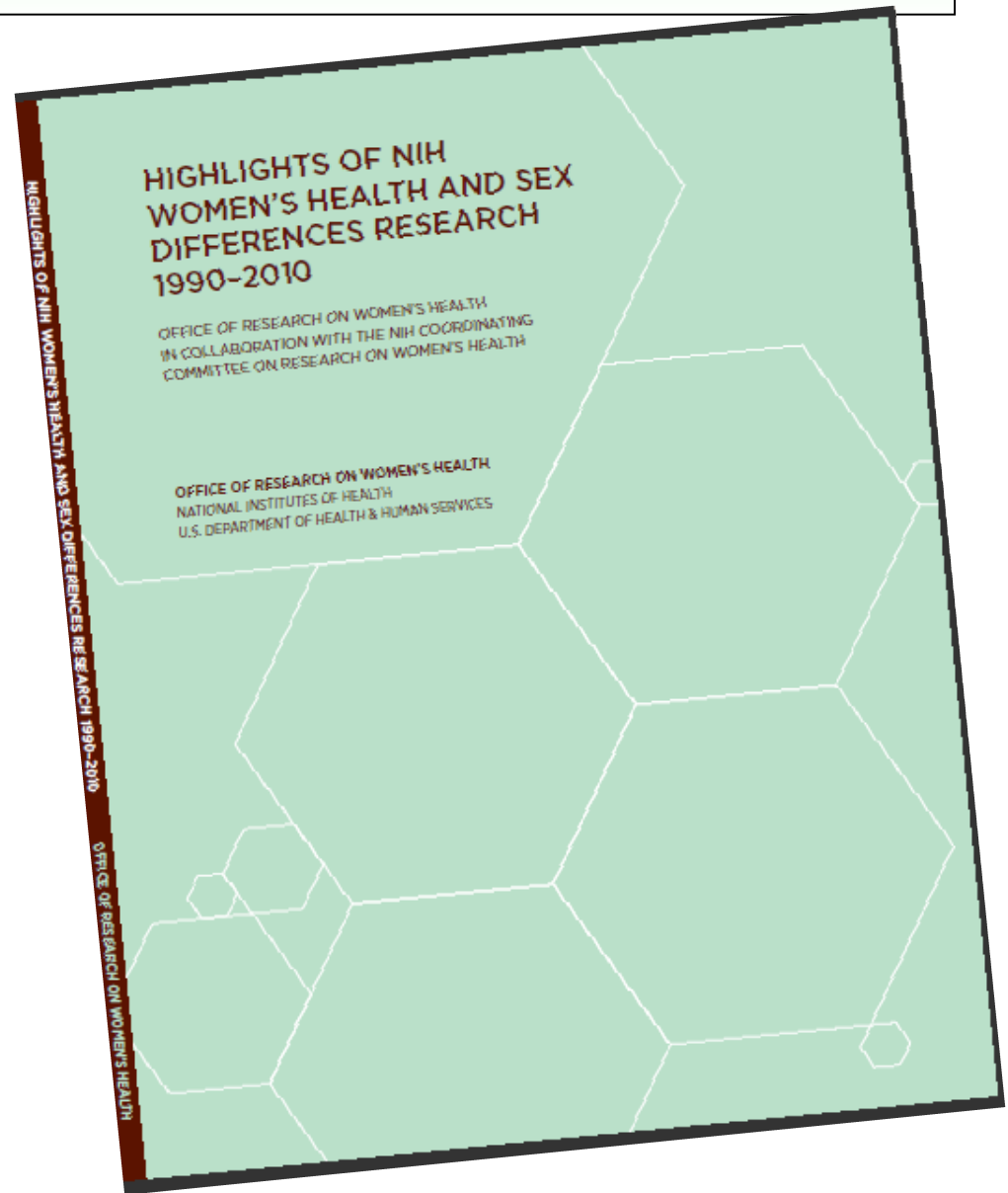
‘Hunt Valley Report Revisited’ 1997-2000 -
Second National Agenda on Research on
Women’s Health: *To address changing public health, and scientific needs and opportunities of the 21st century, this report emphasized the relevance of the full spectrum of research from basic to clinical research and trials, epidemiological and population studies, clinical applications, and health outcomes applied to women’s health.*

ORWH Strategic Planning Process for Women's Health Research & Careers

- What progress have we witnessed?
- What will be the major health concerns in the approaching years?
- What scientific issues, developing technologies, emerging diseases or conditions, or 'futuristic' strategies should ORWH advance over the next 10 years???

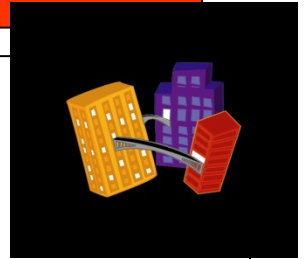
WOMEN'S HEALTH RESEARCH

Examples of
highlights
of progress
from past 20
years



Building Interdisciplinary Research Careers in Women's Health (BIRCWH): FY 2010 Update

- Total of 63 BIRCWH Programs awarded to 41 institutions since its inception
- 29 Programs currently active
- Total of **395** Scholars have participated
 - Female: 314 (79.5%)
 - Male: 81 (20.5%)
- Active scholars: 115 (many who have completed program have themselves become mentors and most have progressed up the academic pipeline)



ORWH Sponsored RFA with
NIH Institutes & FDA
(administered through NIAMS)

‘SCOR’

**SPECIALIZED CENTERS OF RESEARCH on
SEX and GENDER FACTORS AFFECTING
WOMEN’S HEALTH**

<<<>>>

The requirement that the SCOR necessarily include both basic science and clinical (**interdisciplinary**) projects, and advance translation of scientific discoveries out of the lab & into a clinical environment

ORWH Specialized Centers of Research on Sex & Gender Factors

- Fetal Antecedents to Sex Differences in Depression
- Sex & Gender Differences in Substance Abuse Relapse

- Sex and gender influences on addiction and health development

In FY 2009, the SCOR investigators report publishing 116 journal articles, 176 abstracts, and 63 other publications

- Urinary Tract Infection, Interstitial Cystitis
- Lower Urinary Tract Function in Women
- Sex steroids, sleep and metabolic dysfunction

- Risk for osteoporosis
- Molecular and epidemiologic basis of acute and recurrent UTI's in women
- Sex, stress, and substance use disorders

CERVICAL CANCER VACCINE



June 8, 2006: FDA approved use of Gardasil®

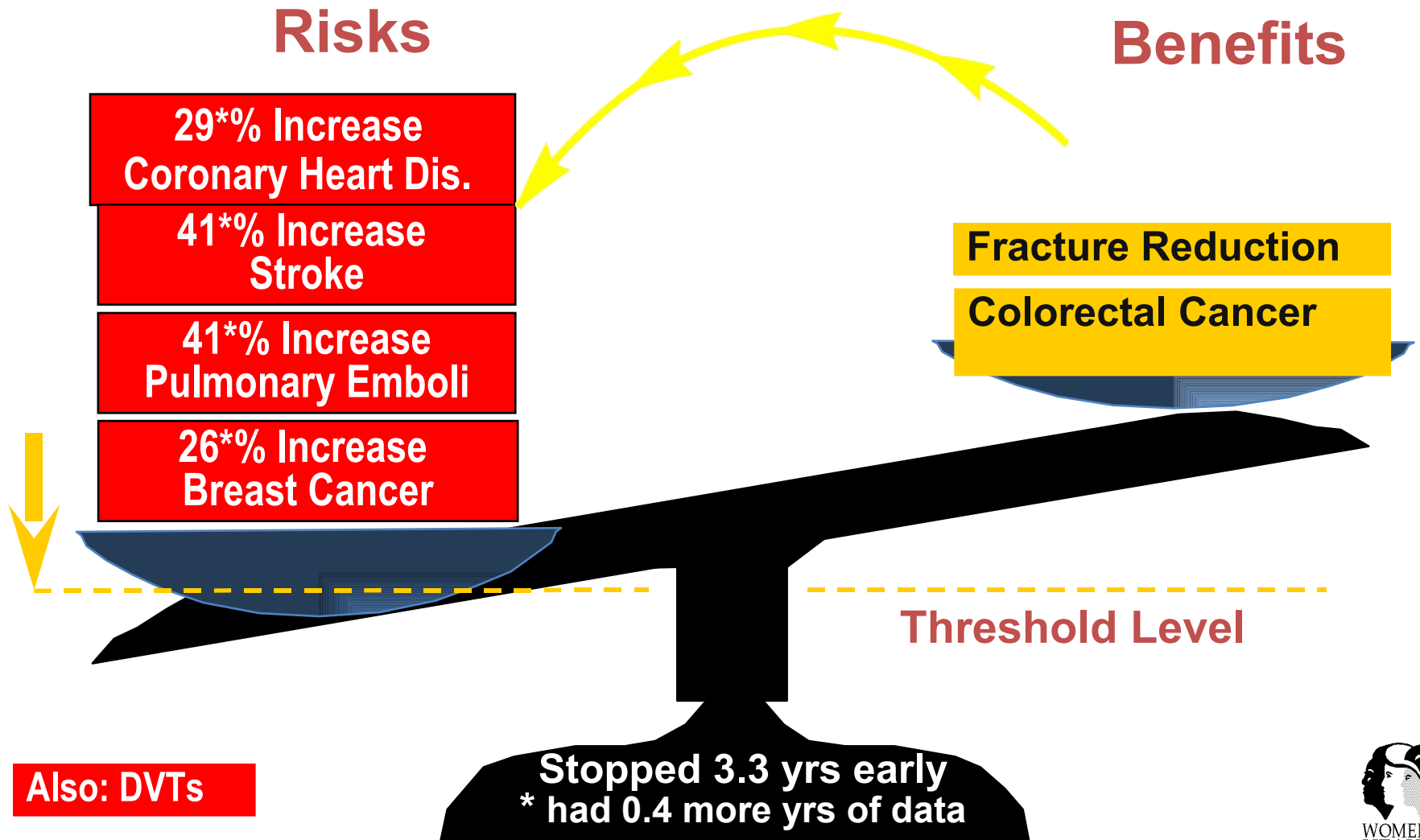
- *Based on laboratory research and technology developed at the National Cancer Institute (NCI).
- *Can potentially save more than 5,000 U.S. women's lives each year and even more globally.
 - Targets two HPV types (HPV-16 and HPV-18)
 - Responsible for approx. 70 percent of cases worldwide.
 - Two other HPV types (HPV-6 and HPV-11) cause approx. 90 percent of the cases of genital warts.



Additional ORWH funds to NCI in FY 2009 to study:

- Evaluation of vaccine efficacy at extra-cervical sites (cutaneous and mucosal sites other than cervix, such as anal, vulvar and oral cavity)
- Relevant because HPV-16 has been linked with cancer at these sites
- Expanded research continuing to address remaining questions such as time extent of effectiveness, etc.

WHI E+P Trial Findings, July 2002 (aver. 5.2 yrs)



*Adapted from: Writing Group for the Women's Health Initiative. **JAMA**. 2002;288:321-333

SPECIAL REPORT

The Decrease in Breast-Cancer Incidence in 2003 in the United States

Peter M. Ravdin, Ph.D., M.D., Kathleen A. Cronin, Ph.D., Nadia Howlader, M.S., Christine D. Berg, M.D., Rowan T. Chlebowski, M.D., Ph.D., Eric J. Feuer, Ph.D., Brenda K. Edwards, Ph.D., and Donald A. Berry, Ph.D.

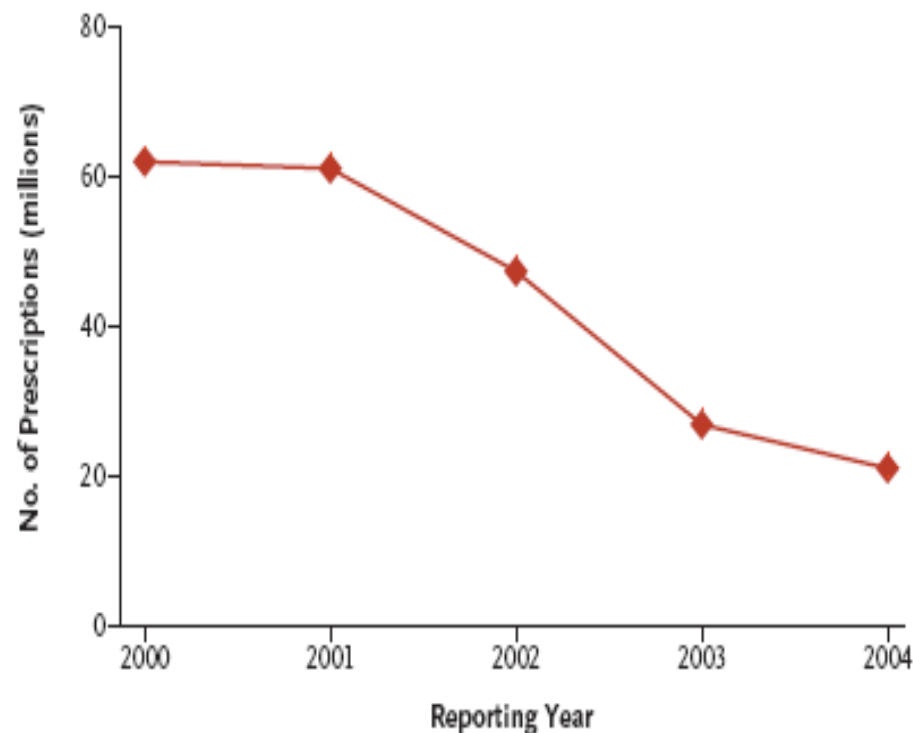
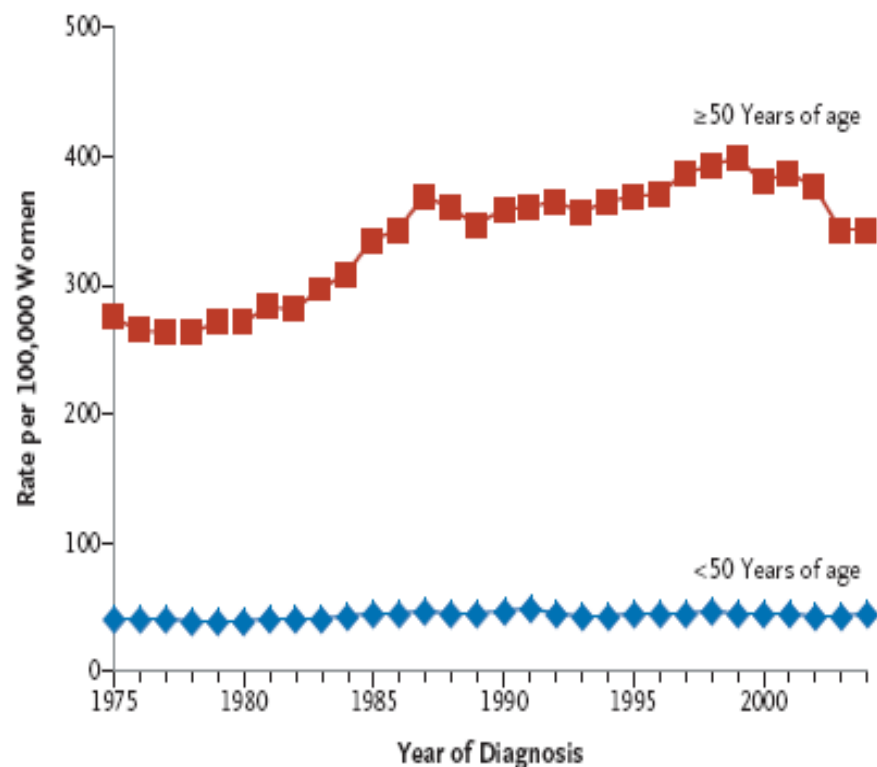


Figure 1. Annual Incidence of Female Breast Cancer (1975–2004).

Data are from nine of the NCI's SEER registries. SEER sites include San Francisco, Connecticut, Detroit (metropolitan area), Hawaii, Iowa, New Mexico, Seattle–Puget Sound, Utah, and Atlanta (metropolitan area).

Panel B shows the number of prescriptions reported in the United States for the combined estrogen–progestin preparation Prempro and the conjugated equine estrogen Premarin, according to year.

The WHI cohort is still being followed:

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Breast Cancer after Use of Estrogen plus Progestin in Postmenopausal Women

Rowan T. Chlebowski, M.D., Ph.D., Lewis H. Kuller, M.D., Dr.P.H.,
Ross L. Prentice, Ph.D., Marcia L. Stefanick, Ph.D., JoAnn E. Manson, M.D., Dr.P.H.,
Margery Gass, M.D., Aaron K. Aragaki, M.S., Judith K. Ockene, Ph.D.,
Dorothy S. Lane, M.D., Gloria E. Sarto, M.D., Aleksandar Rajkovic, M.D., Ph.D.,
Robert Schenken, M.D., Susan L. Hendrix, D.O., Peter M. Ravdin, M.D., Ph.D.,
Thomas E. Rohan, M.B.B.S., Ph.D., Shagufta Yasmeen, M.D.,
and Garnet Anderson, Ph.D., for the WHI Investigators*

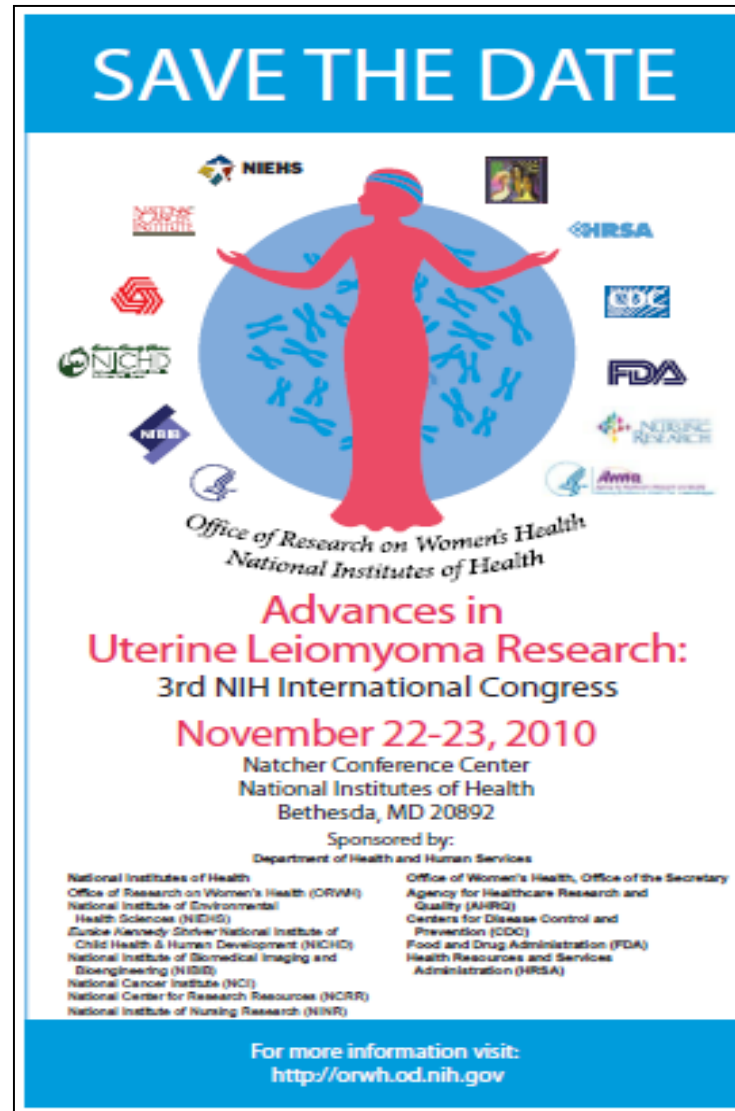
N ENGL J MED 360;6 NEJM.ORG FEBRUARY 5, 2009

- Combined E+P use after 5 yrs about doubles subsequent annual breast cancer risk
- The increased breast cancers seen with combined E+P use declines markedly after discontinuation and is unrelated to mammography utilization change
- These findings support the hypothesis that the recent reduction in breast cancer incidence is predominantly related to a decrease in combined E+P use

DIABETES MELLITUS REACHES EPIDEMIC PROPORTIONS IN THE US

- Diabetes Prevention Project (DPP) - RCT demonstrated superior efficacy of lifestyle interventions over oral hypoglycemic in delaying or preventing DM
 - Both effective in women with h/o gestational diabetes
- Economic impact, quality of life, prevention of end organ damage (blindness, amputations, CVD morbidity, oral health)

3RD NIH INTERNATIONAL CONGRESS: ADVANCES IN UTERINE LEIOMYOMA RESEARCH



CAUSES AND SYMPTOMS OF CORONARY HEART DISEASE IN WOMEN

- The Women's Ischemia Syndrome Evaluation (WISE), a multicenter study initiated in 1996, has greatly increased understanding about coronary heart disease in women and about sex-specific symptoms, risk factors, and pathology.
- The study enrolled and studied over 900 women who had symptoms of CHD (e.g., chest pain, shortness of breath) and were referred for diagnostic angiography. It found that approximately 50 percent of enrollees did not, in fact, have blockages in their large coronary arteries, yet many of them continued to experience debilitating symptoms or went on to have heart attacks.
- Microvascular dysfunction (impaired functioning of the small arteries of the heart, which is generally not detected by angiography) was often associated with the ischemia experienced by this large group of women.
- These findings indicate that CHD risk factors should be addressed aggressively in women with symptoms, even in the absence of a positive angiogram, and that better approaches to evaluate cardiac ischemia in women should be developed and used.

WOMEN'S INTERAGENCY HIV STUDY (WIHS)

- Established in 1994, this is the largest observational study (3,500) of HIV-infected women and uninfected women at high risk of HIV, the majority of whom are African American and Latina.
- With study participants at sites in six U.S. metropolitan areas, the study has yielded major discoveries about how HIV is spread, how the disease progresses, and how it can best be treated.
- WIHS has produced 440 publications dealing with women and HIV and maintains 2 million specimens to support ongoing and future research.
- The study continues to support research on:

hormonal factors

drug resistance

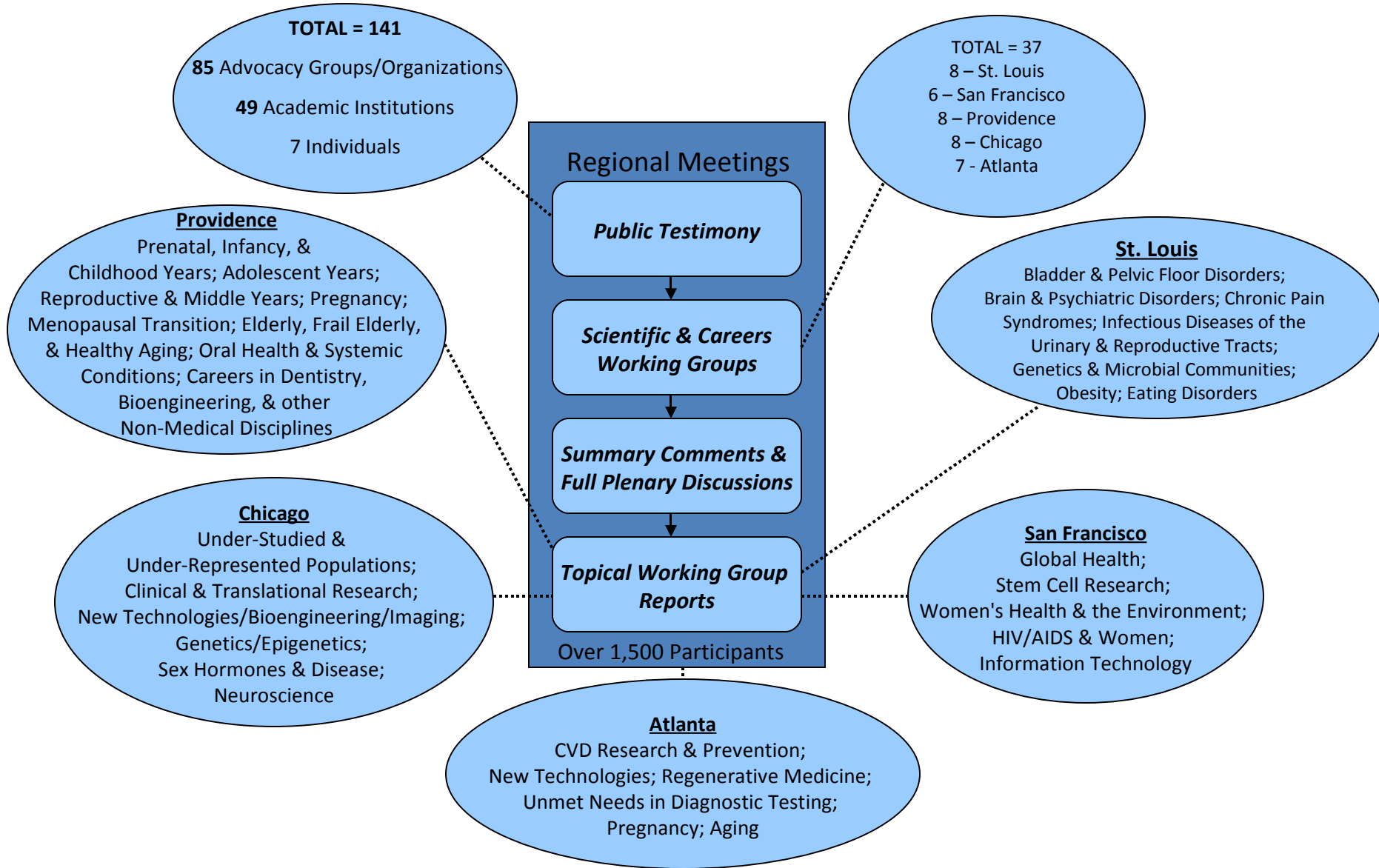
aging

coinfections

risk of cardiovascular disease

therapy use and treatment effects

THE NIH WOMEN'S HEALTH RESEARCH AGENDA SETTING PROCESS



Regional Strategic Planning Meetings Open Public Hearings & Topical Working Groups



THE NIH WOMEN'S HEALTH RESEARCH AGENDA SETTING PROCESS

➤ Public testimony: total of 141 submitted

- **85** Advocacy Groups/Organizations
- **49** Academic Institutions
- **7** Individuals

➤ Working Groups: total of 37

➤ Participants: >1500

Working Groups, St. Louis Meeting

- Bladder & Pelvic Floor Working Group
- Brain & Psychiatric Working Group
- Chronic Pain Syndromes Working Group
- Eating Disorders Working Group
- Obesity Working Group
- The Genetics and Microbial Communities Working Group
- Urinary and Reproductive Infections Working Group
- Women in Biomedical Careers Working Group



Working Groups, UCSF Meeting

- Bladder & Pelvic Floor Working Group
- Stem Cell Research Working Group
- Global Health Working Group
- The Environment and Women's Health Working Group
- HIV/AIDS Working Group
- Information Technology Working Group
- Women in Biomedical Careers Working Group



Working Groups, PROVIDENCE Meeting

- Prenatal, Infancy & Childhood Years
- Adolescent Years
- Reproductive & Middle Years
- Pregnancy
- Menopausal Transition Years
- Elderly, Frail Elderly & Healthy Aging
- Oral Health & Systemic Conditions
- Careers in Dentistry, Bioengineering, & Other Non-M.D. Disciplines



Working Groups, Chicago Meeting

- Understudied & Underrepresented Populations

(Minorities, the Poor, Disabled Women, Immigrants, Lesbian, Intersex & Transgender Women, Urban or Rural Populations, etc.)

- Clinical and Translational Research

- New Technologies, Imaging, Bioengineering

- Genetics/Epigenetics

- Sex Hormones and Disease

- Neuroscience

- Women in Science Careers



Working Groups, Atlanta Meeting

- Pregnancy and Cardiovascular Research & Ethical Considerations
- Cardiovascular Disease in Elderly & Frail Elderly
- Microvascular Disease, Biomechanics, and Application of New Technologies to Cardiovascular Research
- Stem Cells, Progenitor Cells, and the Vista of Cardiovascular Regenerative Medicine
- Unmet Needs in Diagnostic Testing for Women with Cardiovascular Disease
- Issues of Cardiovascular Prevention Across the Lifespan With an Emphasis on Gender and Underserved Populations
- Women's Careers in Biomedical Sciences



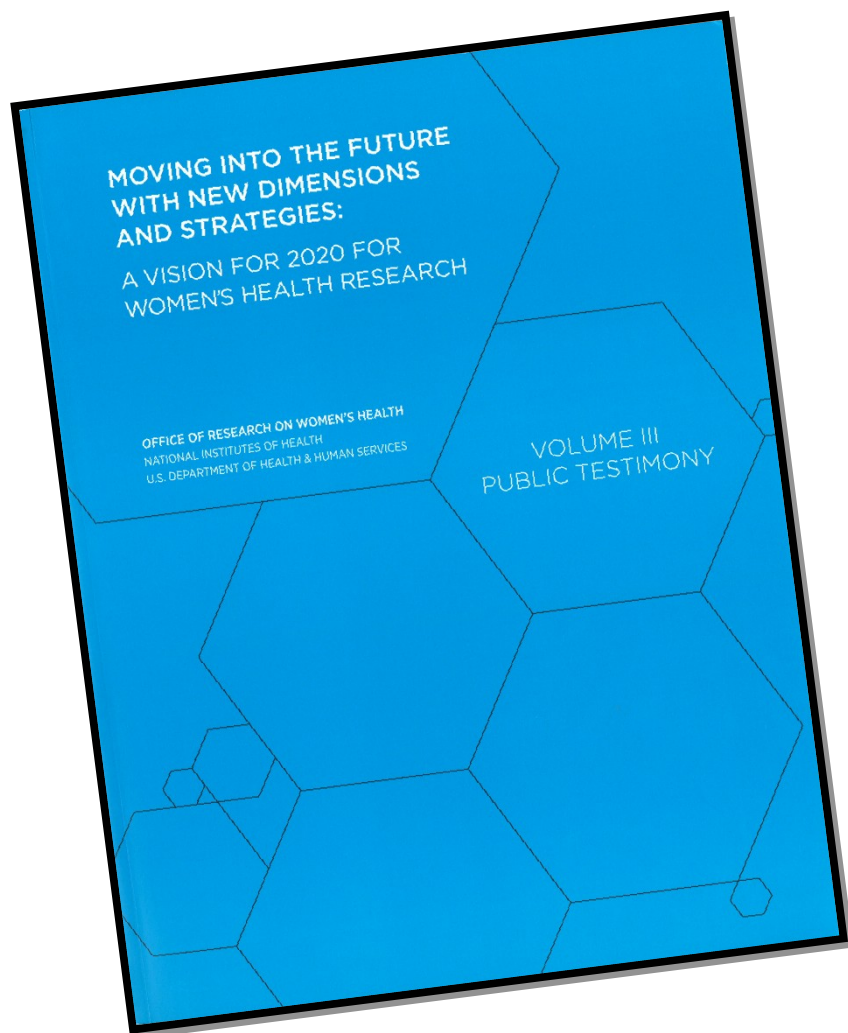
Moving into the Future with New Dimensions and Strategies: A Vision for 2020 for Women's Health Research



Volume II: Regional Scientific Working Group Reports



Moving into the Future with New Dimensions and Strategies: A Vision for 2020 for Women's Health Research



Volume III: Public Testimony



Moving into the Future with New Dimensions and Strategies: *A Vision for 2020 for Women's Health Research*

The Strategic Plan identifies six major goals to advance women's health and represents a synthesis of nearly 400 recommendations that emerged from the five regional meetings:

MOVING INTO THE FUTURE
WITH NEW DIMENSIONS
AND STRATEGIES:

A VISION FOR 2020 FOR
WOMEN'S HEALTH RESEARCH

OFFICE OF RESEARCH ON WOMEN'S HEALTH
NATIONAL INSTITUTES OF HEALTH
U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

STRATEGIC PLAN

Volume I: Executive Summary

GOAL 1 Increase the study of sex/gender differences in basic biomedical and behavioral research

GOAL 2 Incorporate findings of sex/gender differences in the design and application of new technologies, medical devices, and therapeutic drugs

GOAL 3 Actualize personalized prevention, diagnostics, and therapeutics for women and girls

GOAL 4 Create strategic alliances and partnerships to maximize the domestic and global impact of women's health research

GOAL 5 Develop and implement new communication and social networking technologies to increase understanding and appreciation of women's health and wellness research

GOAL 6 Employ innovative strategies to build a well-trained, diverse, and vigorous women's health research workforce

*Introducing the new
NIH strategic plan,
a partnership between
ORWH and the NIH ICs...*



MOVING INTO THE FUTURE
WITH NEW DIMENSIONS AND
STRATEGIES:

A VISION FOR 2020 FOR
WOMEN'S HEALTH RESEARCH