

# FOIA MARKER

**This is not a textual record. This is used as an  
administrative marker by the William J. Clinton  
Presidential Library Staff.**

---

**Collection/Record Group:** Clinton Presidential Records  
**Subgroup/Office of Origin:** National AIDS Policy Office  
**Series/Staff Member:** Kristine Gebbie  
**Subseries:**

---

**OA/ID Number:** 8300  
**FolderID:**

---

**Folder Title:**  
Office of Research on Women's Health - National Institutes of Health

|               |             |                 |               |                  |
|---------------|-------------|-----------------|---------------|------------------|
| <b>Stack:</b> | <b>Row:</b> | <b>Section:</b> | <b>Shelf:</b> | <b>Position:</b> |
| <b>S</b>      | <b>66</b>   | <b>5</b>        | <b>1</b>      | <b>3</b>         |

THE WHITE HOUSE

Vivian

Nice to meet you at the  
Latin Breakfast this week.  
I also appreciate the information  
on your office. I look forward  
to collaborating with you in  
the future —  
Kristine Gebbie

THE WHITE HOUSE  
WASHINGTON

Dr. Vivian W. Pinn  
Director of Research on Women's Health  
National Institutes of Health  
Building 1, Room 201  
Bethesda, Maryland 20892

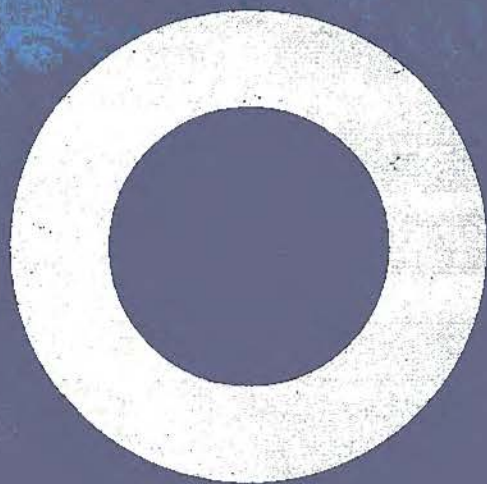
THE WHITE HOUSE

Vivian

Nice to meet you at the  
Latin Breakfast this week.  
I also appreciate the information  
on your office. I look forward  
to collaborating with you in  
the future —  
Kristine Gebbie

THE WHITE HOUSE  
WASHINGTON

Dr. Vivian W. Pinn  
Director of Research on Women's Health  
National Institutes of Health  
Building 1, Room 201  
Bethesda, Maryland 20892



# OFFICE OF RESEARCH ON WOMEN'S HEALTH

OFFICE OF THE DIRECTOR  
NATIONAL INSTITUTES OF HEALTH

PHOTOCOPY  
PRESERVATION



OFFICE OF RESEARCH ON WOMEN'S HEALTH

**Overview**  
**Office of Research on Women's Health**  
**Office of the Director**  
**National Institutes of Health**

**Director: Vivian W. Pinn, M.D.**

**Deputy Director: Judith H. LaRosa, Ph.D.**

**Background**

The Office of Research on Women's Health (ORWH) was established in September 1990 within the Office of the Director of the National Institutes of Health (NIH). The ORWH serves as a focal point for women's health research at NIH in setting and monitoring policy, promoting and directing research, and enhancing scientific career development. The ORWH works in partnership with the NIH Institutes, Centers, and Divisions (ICDs) to ensure that women's health research becomes an integral part of the scientific fabric at NIH and throughout the scientific community.

The ORWH has a threefold mandate:

- I. to strengthen and enhance research related to diseases, disorders, and conditions that affect women and to ensure that research conducted and supported by NIH adequately addresses issues regarding women's health;<sup>1</sup>*
- II. to ensure that women are appropriately represented in biomedical and behavioral research studies supported by NIH; and*
- III. to develop opportunities and support for recruitment, retention, re-entry, and advancement of women in biomedical careers.*

In addition to this threefold mandate, the ORWH collaborates on the **Women's Health Initiative**, a prevention study to examine the major causes of death, disability, and frailty — heart disease and stroke, cancers (particularly breast and colorectal), and osteoporosis — in post-menopausal women of all races and socioeconomic strata. The **Women's Health Initiative** is directed by William R. Harlan, M.D., Associate Director for Disease Prevention, NIH. Additional information on the Women's Health Initiative is available through the Women's Health Initiative Fact Sheet, the ORWH, or from the Women's Health Initiative Office, 7550 Wisconsin Avenue, Federal Building, Room 6A09, Bethesda, Maryland 20892.

---

<sup>1</sup> Women's health includes the normal biologic processes, as well as all diseases, disorders, or conditions, which affect women across the life span, and that are that are unique to, more prevalent among, or more serious in women, or for which there are different risk factors or interventions for women than for men.

Using the threefold mandate as a basis for action, the ORWH is focusing its 1993 efforts in the following major areas:

- Implementation of a Research Agenda for Women's Health at NIH — in collaboration with the NIH Institutes, Centers, and Divisions
- Tracking System and Activities to Monitor the Inclusion of Women in NIH-Supported Biomedical and Behavioral Research
- Recruitment and Retention of Women in Clinical Studies
- Policy Development Activities:
  - Legal and Ethical Issues Associated with the Inclusion of Women in Clinical Studies — with the Institute of Medicine
  - Women's Health Curriculum in Academic and Clinical Training — with the Bureau of Health Manpower, Health Resources and Services Administration
- Collaboration on the NIH Women's Health Initiative

The following descriptions highlight some of the ORWH's key activities.

### ***1. Implementation of the NIH Research Agenda on Women's Health Research***

The ORWH does not fund studies directly. Rather, the ORWH provides research funding through the NIH Institutes and Centers to support basic and clinical studies addressing women's health issues, particularly gaps in knowledge identified in the workshop, *Opportunities for Research on Women's Health*. During the first two years, efforts have been devoted to designing and implementing the **ORWH Research Agenda on Women's Health** — the ORWH's plan of research action for the next several years.

**1991.** In its first year of operation, the ORWH designed the **ORWH Research Agenda on Women's Health**. This agenda is science-driven and based on the recommendations contained in the ORWH-sponsored workshop, *Opportunities for Research on Women's Health*, from deliberations with the NIH ICDs, and those that emerged from Congressional directives,<sup>2</sup> Congressional hearings, and discussions with women's health experts and advocates. During this period, the ORWH provided funds to multidisciplinary Principle Investigators through the NIH Institutes and Centers. In addition, the ORWH provided funds to ICDs to support career development activities for students throughout the educational process from high school to graduate programs.

**1992.** In the second year of operation, the ORWH implemented the **ORWH Research Agenda on Women's Health**, awarding funding through three mechanisms: 1) supplemental funds to ongoing grants, 2) co-funding of new initiatives, and 3) special research projects. Additionally, the ORWH provided funding for research development through co-sponsorship of workshops and conferences. Career development opportunities for women scientists were a special focus for action with funding awards for women wishing to re-enter as well as advance in scientific careers.

**1993.** In the third year of operation, the ORWH refined its research agenda by providing 78 administrative supplements to on-going research grants, including five awards for AIDS research. These supplements enable currently funded investigators to address some aspects of the diseases, disorders, or conditions specified in the *Opportunities for Research on Women's Health* with special emphasis on 14 areas of interest representing gaps in knowledge. These include:

- Depression and its Interaction with Other Health Problems
- Alcohol Use and Responsiveness to Interventions for Women
- Problems of Abuse/Violence (including Post Traumatic Stress Syndrome)

---

<sup>2</sup> Congressional recommendations for additional research in women's health include such areas as endometriosis, pelvic inflammatory disease, AIDS, DES effects in DES-affected mothers and their off-spring, and the relationship of oral contraceptive use to breast cancer.

- Behavioral Factors for Women and Disease Risk
- Lung Cancer in Women
- Improved Recognition/Treatment of Coronary Artery and Thrombotic Disease
- Congenital Heart Disease and Genetic Defects
- Immunologic Factors and Autoimmune Diseases
- Inborn Errors of Metabolism
- Antiprogestins and Reproductive Health, Cancer or Meningioma
- Gender Differences Related to Disease Manifestation and Treatment
- Prevalence of Risk Factors for Disease in Women of Different Racial/Ethnic/Economic Groups
- Occupation and Disease/Disability
- Sexual Behavior and Health

Special consideration was also given to those grants that would enhance the recruitment of women research subjects, particularly minority women, within an ongoing study, and/or, demonstrate the feasibility of innovative techniques for recruiting or retaining women as subjects/respondents in research studies.

The ORWH also supports special research initiatives such as investigation into the Biology and Pathophysiology of Endometriosis and Leiomyomata Uteri (Myomas) and the Diethylstilbestrol (DES) Education Program. In addition, the ORWH is co-sponsoring scientific conferences to direct and refine future research priorities. Those conferences include: Conference on Women's Urological Health; Workshop on Autoimmune Thyroid Disease; Surgeon General's National Hispanic/Latino Health Initiative Regional Meetings; Aging & Bone Quality Workshop; Workshop on Directions for Menopause Research; NIDDK Workshop on Development of Topical Microbicides; International Chronic Fatigue Syndrome/Myalgic Encephalomyelitis Research; HIV in Women Technology Transfer Conferences: State of the Art Diagnosis & Treatment; and International Conference on Behavioral Research & AIDS Prevention in Africa.

## ***II. Tracking the Inclusion of Women in NIH Research Studies***

A revised NIH policy on the inclusion of women and minorities in study populations has been in place at NIH since 1991. These guidelines state that ***applicants and offerors for NIH... clinical research grants, cooperative agreements, and contracts will be required to include minorities and women in study population so that research findings can be of benefit to all persons at risk of the disease, disorder, or condition under study.*** The guidelines further state that: ***The NIH... funding components will not fund/award grants, cooperative agreements, or contracts that do not comply with this policy***<sup>3</sup>.

The responsibility for monitoring this process and tracking the inclusion of women in NIH-supported research now rests with the ORWH. The strengthened guidelines have been monitored closely in the first years of operation. A report on the status of the inclusion for the first years is being prepared for release in fall 1993. The ORWH has two major initiatives in progress in support of this action.

- **Legal and ethical issues surrounding the inclusion of women in clinical studies.** Myriad issues surround the inclusion (or exclusion) of women in biomedical and behavioral research. As such, the ORWH awarded a contract to the Institute of Medicine (IOM) of the National Academy of Sciences to assist the ORWH in addressing the legal and ethical barriers to inclusion of women in clinical research. The co-chairs of this IOM committee are Ruth Faden, Ph.D., Professor and Director, Program in Law, Ethics, and Health, The Johns Hopkins University, and Daniel Federman, M.D., Dean for Medical Education, Harvard University School of Medicine. The report of these deliberations will be available in the fall of 1993.

■ **Recruitment and retention of women in research studies.** The ORWH seeks to identify those issues that serve as barriers to women's participation in clinical studies and to define strategies for addressing them. A Planning Task Force was formed to advise the ORWH/NIH on these issues and to prepare recommendations including those gained from a Public Hearing and scientific workshop. This Task Force is co-chaired by Lewis H. Kuller, M.D., Dr.P.H., Professor and Chairperson, Department of Epidemiology, University of Pittsburgh, and Shiriki Kumanyika, Ph.D., M.P.H., R.D., Professor and Associate Director for Epidemiology, Center for Biostatistics and Epidemiology, Pennsylvania State University College of Medicine. Issues surrounding the inclusion of women in clinical studies were delineated and addressed during a Public Hearing held March 29-30, 1993 in Bethesda, Maryland. The recommendations from the hearing formed the basis for the scientific workshop, which was held July 12-13, 1993 in Bethesda, Maryland. The recommendations from both are to be used by multidisciplinary scientists, clinicians, health professionals, women's health advocates, and industry leaders in the appropriate and sensitive recruitment and retention of women, particularly minority women, in clinical studies.

In addition to monitoring the progress of the tracking system, the ORWH, the Office of Research on Minority Health (ORMH), and the Office of Extramural Research and Training (OERT) will be designing and implementing the new guidelines on the inclusion of women and minorities as specified in the recently enacted legislation: *NIH Revitalization Act of 1993*. This new legislation, which must be implemented in 1995, requires that: *In conducting or supporting clinical research for purposes of this title, the Director of NIH shall ... ensure that women and minorities are included as subjects in each project of such research. In the case of any clinical trial in which women or members of minority groups will be included as subjects, the Director of NIH shall ensure that the trial is designed and carried out in a manner sufficient to provide for a valid analysis of whether the variables being studied in the trial affect women or members of minority groups, as the case may be, differently than other subjects in the trial.* Efforts to modify current NIH guidelines to meet the mandates of this new legislation are underway, and will be published by March 1, 1994 in the *Federal Register* for public comment. When the guidelines are completed, they will be appropriately introduced into the NIH and extramural scientific community.

### **III. Design/Implementation of Opportunities for Women in Biomedical Careers**

The ORWH is aware of the need not only to increase numbers of women in science, but to increase opportunities for their advancement. To that end, the ORWH has several major initiatives under way.

■ **Public Hearing and Workshop.** The ORWH convened a Task Force<sup>4</sup> to gather relevant information on the issues and to hold a Public Hearing and a workshop on the recruitment, retention, re-entry, and advancement of women in biomedical and health science careers. The Task Force is co-chaired by Carola Eisenberg, M.D., Director, International Programs for Medical Students, The Harvard Medical School, and Shirley Malcolm, Ph.D., Directorate, Education and Human Resources Program, American Association for the Advancement of Science. The Public Hearing was held March 2-3, 1992, for which nearly 70 individuals and organizations provided testimony. A synopsis of the public hearing is available from the ORWH. The workshop, *Women in Biomedical Careers: Dynamics of Change — Strategies for the 21st Century*, was held June 11-12, 1992 in Bethesda, Maryland. The recommendations and deliberations generated from this workshop provide an agenda for action to enhance recruitment, retention, re-entry, and promotion of women in science. These proceedings will be available in fall 1993.

<sup>4</sup> The Task Force is co-chaired by both an African-American and an Hispanic woman scientist. The twenty-six member Task Force is composed of 50 percent ethnic and racial minorities (representing African-Americans, Native Americans, Asians, Pacific Islanders, and Hispanics) as well as 20 percent men.

- **Career Development Awards.** Based on the recommendations from the Public Hearing and the workshop, the ORWH is supporting ongoing projects and has initiated specific training projects that include: *National Science Enrichment Program of the National Cancer Institute; NIH Academy for Summer Students and Teachers; ORWH of Research on Women's Health and Office of Extramural Affairs Re-entry Program for Scientists; and the Office of Research on Women's Health and Office of Intramural Affairs Re-entry Program for Scientists.* A fact sheet is available from the ORWH that describes these efforts in more detail.
- **Academic and Clinical Training for Physicians in Women's Health.** In 1993, at the suggestion of Congress, the ORWH, in cooperation with the Bureau of Health Manpower, Health Resources and Services Administration, will support two activities directed toward a women's health curriculum: a survey of medical schools on current women's health curriculum and the development of a model women's health curriculum for academic and clinical training. While initial efforts will be directed toward medical education and women's health research, recommendations are expected to include the eventual guidance, through appropriate agencies and organizations, for other health professional disciplines, academic and clinical training, post-graduate training, and continuing education courses.

### ***ORWH/ACWHI Seminar Series***

The ORWH, through the Advisory Committee on Women's Health Issues (ACWHI), sponsored a Women's Health Seminar Series in FY 1993. This four-part series focused on Gender Differences in the following areas: stress and cardiovascular disease; addictive behaviors: alcohol, smoking, and other drugs; stress: immunologic aspects; and medical decisionmaking. The seminars were structured so that the speakers presented the most current research available and the impact on women's health.

### ***Future Plans and Action by the ORWH***

The ORWH will continue to build on its activities and programs. The scientific research agenda will become increasingly focused, concentrating on scientific areas and diseases not adequately addressed, or that require enhancement. Cooperative research efforts with NIH ICs and the ORWH will continue.

The inclusion of women in clinical studies will be enhanced, not only by the recently enacted legislation, but by recommendations from two major efforts: the ORWH/Institute of Medicine study on the Legal and Ethical Issues Surrounding the Inclusion of Women in Clinical Studies, and the ORWH scientific meeting on the Recruitment and Retention of Women in Clinical Studies.

The career development agenda will advance with a series of initiatives aimed at implementing recommendations emerging from the **Women in Biomedical Careers: Dynamics of Change** workshop, as well as evaluation of the 1992 and 1993 career development awards.

For additional information, contact:

Office of Research on Women's Health  
National Institutes of Health  
Building 1, Room 201  
Bethesda, Maryland 20892



---

OFFICE OF RESEARCH ON WOMEN'S HEALTH

## ***ORWH Research Initiatives***

The Office of Research on Women's Health (ORWH) has a threefold mandate for action. The first part of that mandate addresses the research agenda at the National Institutes of Health (NIH):

***to strengthen and enhance research related to diseases, disorders, and conditions that affect women and to ensure that research conducted and supported by NIH adequately addresses issues regarding women's health.***

This research agenda has been implemented vigorously by the ORWH through the NIH Institutes and Centers (ICs). The ORWH does not, however, have granting authority. Rather, the ORWH provides funds for research on women's health through the NIH ICs to Principal Investigators. Thus, the ORWH works in partnership with all of the NIH ICs to assure that women's health research becomes an integral part of the scientific fabric at the NIH and throughout the scientific community. Funds are awarded for ongoing research or new initiatives through three mechanisms: administrative supplements, cofunding, and special initiatives.

### **Fiscal Year 1991**

The ORWH received 41 nominations for supplemental grants and awarded 20 administrative supplements through eight Institutes and Centers to ongoing NIH-supported studies to initiate the ORWH research agenda. The awards addressed issues such as: sleep apnea in adult women, hypertension and hyperinsulinemia, women as carriers of Fragile X, human papilloma virus and its relationship to cervical cancer, and incontinence in elderly women. Fifty percent of the Principal Investigators receiving awards were women.

### **Fiscal Year 1992**

The ORWH received more than 170 applications for administrative supplements and cofunds from 15 NIH Institutes and Centers.<sup>1</sup> As a component of its research funding, the ORWH provided administrative supplemental and cofunding awards to 95 studies, including seven basic research awards and 88 clinical research awards. Thirty-six percent of the Principle Investigators receiving awards were women.

These awards addressed diverse diseases and disease conditions across the life span of women, including gestational diabetes in Hispanics, cervical cancer in Native Americans, cell calcium and hypertension in Blacks, mentoring and stress resistance among pregnant adolescents, women at high risk of HIV, women's assessment of estrogen replacement therapy, an animal model for Sjögren's Syndrome, a method to predict osteoporotic fractures, and breast cancer management in older women.

Special research initiatives, which involved six NIH Institutes, focused on endometriosis and uterine leiomyomata, cancer in women of color, and ovarian cancer in older women. To implement and update its research agenda and to plan future research activities, the ORWH also cosponsored conferences and workshops, including Long-Term Health Effects of DES Exposure; Osteoporosis and Oral Bone Loss; The Athlete's Triad: Amenorrhea, Eating Disorders, and Osteoporosis; Hispanic Cancer Control Network Meeting; and Women & Health: 11th Annual Scientific Meeting of the American College of Epidemiology.

---

<sup>1</sup> Please note that the three Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) research institutes were not yet part of NIH.

## **Fiscal Year 1993**

As part of the long range plan to focus attention on areas of women's health that require heightened attention, ORWH directed research attention to 14 areas of special interest, including:

- Depression and its Interaction with Other Health Problems
- Alcohol Use and Responsiveness to Interventions for Women
- Problems of Abuse/Violence (including Post Traumatic Stress Syndrome)
- Behavioral Factors for Women and Disease Risk
- Lung Cancer in Women
- Improved Recognition/Treatment of Coronary Artery and Thrombotic Disease
- Congenital Heart Disease and Genetic Defects
- Immunologic Factors and Autoimmune Diseases
- Inborn Errors of Metabolism
- Antiprogestins and Reproductive Health, Cancer or Meningioma
- Gender Differences Related to Disease Manifestation and Treatment
- Prevalence of Risk Factors for Disease in Women of Different Racial/Ethnic/Economic Groups
- Occupation and Disease/Disability
- Sexual Behavior and Health

The ORWH received approximately 260 applications for supplemental funding and cofunding from 16 NIH Institutes and Centers and recently awarded 78 administrative supplements, including five for AIDS research. Approximately 40 percent of the Principal Investigators receiving awards are women.

The awards addressed such issues as: Southeast Asian women: their smoking and passive smoking; children at high and low risk for depression; validation of biomarkers for bone diseases in racially/ethnically diverse populations; osteoarthritis; pregnancy outcomes in lupus patients; work injury and disability; cognitive processing of traumatic sexual victimization; and risk factors for unhealthy weight regulation. Special consideration was also given to those grants that enhanced the recruitment of women research subjects, particularly minority women, within an ongoing study and/or demonstrated the feasibility of innovative techniques for recruiting or retaining women as subjects/respondents in research studies.

Special research initiatives include the continuing support of the six research centers examining endometriosis and uterine leiomyomata; education campaign of DES mothers and offspring; HIV technology transfer conferences; computerization of the Carnegie collection of human embryos slides; prevention of maternal-fetal transmission of SIV and HIV; and vaginal cleansing to reduce perinatal transmission of HIV-1.

### **Research Conferences**

To provide guidance and impetus for future research action, the ORWH has provided 1993 support to the NIH ICs for conferences or workshops on:

- |                                     |                                                               |
|-------------------------------------|---------------------------------------------------------------|
| ■ Women's Urological Health         | ■ Behavioral Research & AIDS Prevention                       |
| ■ Aging & Bone Quality              | ■ Development of Topical Microbicides for STDs                |
| ■ Autoimmune Thyroid Disease        | ■ Chronic Fatigue Syndrome/Myalgic Encephalomyelitis Research |
| ■ Directions for Menopause Research | ■ Surgeon General's Regional Meetings on Hispanic Health      |
| ■ Older Women, Health, & Retirement | ■ Environmental Risk Factors for Osteoporosis                 |
| ■ Extramural Associates Program     | ■ Technology Transfer: Diagnosis and Treatment of AIDS        |

For more information, contact:

Office of Research on Women's Health  
National Institutes of Health  
Building 1, Room 201  
Bethesda, Maryland 20892



OFFICE OF RESEARCH ON WOMEN'S HEALTH

## ***Recruitment and Re-Entry Programs for Women in Science***

### **Introduction**

Recruitment of women into science careers has increased steadily, with women well-represented in graduate degree programs, such as medical school and doctoral studies. Women, and especially minority women, are not, however, equally represented in advanced scientific and academic leadership positions.

Commitments to children and assumption of other family responsibilities, such as caring for aging parents, often interrupt a woman scientist's career. In addition, a woman scientist who chooses to re-enter a scientific career track after an extended hiatus often has a particularly difficult time. Opportunities for retraining may be limited. Without retraining, the opportunities for resuming a scientific career are often significantly reduced. Tenure tracks typically demand the fulfillment of obligations within specified time periods, with few alternatives for substitution.

One of the major objectives of the Office of Research on Women's Health (ORWH), which was established in September 1990 within the Office of the Director of the National Institutes of Health (NIH), is to develop opportunities and support for recruitment, retention, re-entry, and advancement of women in biomedical careers.

### **Initiatives**

In June 1992, the ORWH sponsored a public hearing and a workshop—***Women in Biomedical Careers: Dynamics of Change—Strategies for the 21st Century***—to consider issues and to develop strategies for action to recruit, retain, and advance women in scientific careers. In the first two months following the workshop, the ORWH, based on recommendations from this workshop and from consultations with multidisciplinary experts from across the country, has funded four initiatives to promote women and minorities in biomedical careers at different points along the educational spectrum. Based upon experience with these first efforts, other training initiatives will follow.

#### **■ National Science Enrichment Program of the National Cancer Institute**

This program encourages high school students from underrepresented minorities and underserved groups to pursue careers in science by providing them with a comprehensive, five-week educational and cultural enrichment experience under the auspices of NIH mentors. In FY 1992, the ORWH allocated \$61,000 to the National Science Enrichment Program, and is continuing to support this program in FY 1993. *For further information contact: Office of Associate Director, Cancer Control Science Program, National Cancer Institute, National Institutes of Health, Executive Plaza North, Room 243, Bethesda, MD 20892: 301/496-8594.*

■ **NIH Academy for Summer Students and Teachers**

In FY 1992, the ORWH allocated \$100,000 to the Office of Education to provide high school students the opportunity to learn about science from NIH scientists through lectures and laboratories at the NIH campus. The academy also provides opportunities for middle and high school teachers to participate in a seven-week summer program, which includes a laboratory course, research experience, and seminar series. Both of these efforts are directed toward women and underrepresented minorities. In FY 1993, the ORWH has sponsored nine undergraduate students, seven teachers, and 13 high school students through this program. *For further information contact: Office of Intramural Affairs, Office of Education, National Institutes of Health, Building 10, Room 1C129, Bethesda, MD 20892: Michael Fordis, M.D., Director: 301/496-2427.*

■ **Office of Research on Women's Health and Office of Extramural Affairs Re-entry Program for Scientists**

The goal of this cooperative pilot program is to encourage fully trained women and men to re-enter an active research career after taking time off to attend to family needs. In FY 1992, the ORWH awarded close to \$1 million in administrative supplements to existing NIH research grants to encourage and enable the Principal Investigators to support and mentor re-entering women scientists for full- or part-time research experience. The ORWH received 15 applications through this program for FY 1993, and anticipates making six or seven awards by September 1, 1993. *For further information on training and special programs, contact: Research Training and Special Programs, Office of Extramural Research, National Institutes of Health, Building 31, Room 5B44, Bethesda, MD 20892: Walter T. Schaffer, Ph.D., Program Officer: 301/496-9743.*

■ **Office of Research on Women's Health and Office of Intramural Affairs Re-entry Program for Scientists**

The goal of this cooperative pilot program is to develop a self-perpetuating core of researchers, professors, and teachers who will serve as role models and mentors in attracting and guiding women and minorities into scientific careers. The ORWH allocated \$300,000 to the NIH Office of Education to fund the development of this program in FY 1992, which served as a pilot on the NIH campus. The ORWH will support three re-entry candidates in FY 1993. *For further information, contact: Office of Intramural Affairs, Office of Education, National Institutes of Health, Building 10, Room 1C129, Bethesda, MD 20892—Michael Fordis, M.D., Director: 301/496-2427.*

For additional information, contact:

Ellyn J. Pollack, M.A., APR  
Information Officer  
Office of Research on Women's Health  
National Institutes of Health  
Building 1, Room 201  
Bethesda, Maryland 20892  
Telephone: (301) 402-1770  
Fax: (301) 401-1798

## OVERVIEW STATEMENT ON THE WOMEN'S HEALTH INITIATIVE

Cardiovascular disease, cancer, and osteoporosis--the most common causes of death, disability, and impaired quality of life in postmenopausal women--can potentially be prevented or forestalled by dietary, behavioral, and drug interventions. These interventions require testing through clinical trials before confident recommendations can be made about the full range of benefits and risks. Shortly after being named Director of the National Institutes of Health (NIH), Dr. Bernadine Healy announced the Women's Health Initiative which addresses some of these important health issues. There are three major components to the Women's Health Initiative: a randomized controlled trial of promising but unproven approaches to prevention; an observational study to identify predictors of disease; and a trial of community approaches to develop healthful behaviors.

The randomized controlled clinical trial component of the Women's Health Initiative will enroll 55,000 to 60,000 postmenopausal women 50 to 79 years of age. This trial has three interventions, and women can enroll in one or more of the components. One will evaluate the effect of low-fat dietary pattern on prevention of breast and colon cancer and coronary heart disease. Another will examine the effect of hormonal replacement therapy on prevention of coronary heart disease, osteoporosis, and/or increased risk of breast cancer. The last will evaluate the effect of calcium and vitamin D supplementation on prevention of osteoporosis and colon cancer. The trial will require 4 years for protocol development and recruitment and 9 years of followup to achieve the goals. Women who are ineligible or unwilling to participate in the trial will be enrolled in a long-term observational study that will delineate new risk factors and biological markers for diseases in women. We expect about 100,000 women will join this part of the study. Thus, a total of 150,000 to 160,000 women will be studied.

The studies will be performed at 45 clinical centers located throughout the United States, and one coordinating center will manage data collection and analysis. Following solicitation of proposals and review by outside scientists, a contract was awarded on September 30, 1992, to the Fred Hutchinson Cancer Research Center in Seattle, Washington, to act as the Clinical Coordinating Center. Proposals for the clinical centers were reviewed by scientific peers, and contracts were awarded on March 30, 1993 to 16 Vanguard Clinical Centers. These Vanguard Centers, together with the Clinical Coordinating Center, will develop the final protocol and materials for recruitment and intervention. The study protocol and manual of operations are under development and will be completed in May 1993. After review of the protocol and training of clinic personnel, the first participants will be enrolled in September 1993.

Each of the 45 Vanguard Clinical Centers will recruit 3,490 postmenopausal women over a three year period for the Clinical Trial and Observational Study. The broad geographic distribution of the Vanguard Clinical Centers allows for recruitment efforts in medically underserved areas and targets minority populations across the country, in order to obtain a representative cross-section of the United States population. Four of the initial 16 clinical centers\* will recruit primarily minority populations-- African-Americans, Hispanics, and Native Americans. Women from all racial/ethnic groups are encouraged to participate in the study.

The design for implementation of the community studies of strategies to enhance adoption of healthful behaviors is under review. There are many behaviors of proven value to women's health, but these behaviors have not been widely adopted. These studies will mobilize community resources to enhance adoption of these behaviors by education, removing barriers, and improving social support. The behaviors to be targeted are derived from the national goals described in Healthy People 2000. Special emphasis will be focused on minorities and the medically underserved in these communities, as these groups have received too little attention and lagged in adoption of preventive behaviors. Request for grants or contracts are anticipated to be released in late 1993.

A Program Advisory Committee of the WHI has been appointed to oversee the conduct and progress of these studies. This committee will advise the NIH Director on the comprehensive plan of prevention studies to be conducted in the three components of the Women's Health Initiative. The first meeting of this committee was held on April 28, 1993, in Bethesda, Maryland.

At the request of Congress, the Institute of Medicine (IOM) will review the costs and scientific rationale of the Women's Health Initiative and report their findings to Congress in September 1993.

In total, the Women's Health Initiative will provide important, scientifically valid information for women, their health care providers, and their communities. This information will indicate the benefits and risks of preventive approaches and the means of achieving successful adoption of these behaviors. The studies will require 14 years and the investment of over \$600 million.

Vanguard Centers awarded the initial contracts are as follows:

Robert Wallace, M.D.  
University of Iowa  
Iowa City, Iowa  
(319) 335-6628  
OR 1-800-348-4692

Thomas Moon, Ph.D.\*  
University of Arizona  
Tucson, Arizona  
(602) 626-4010

Maureen Henderson, M.D.  
Fred Hutchinson Cancer Research Center  
Seattle, Washington  
(206) 667-6550

John Robbins, M.D.  
University of California, Davis  
School of Medicine  
Davis, California  
(916) 734-5497

Robert Langer, M.D.\*  
University of California, San Diego  
La Jolla, California  
(619) 622-5770  
(619) 594-7710 (Hispanic)

Richard Grimm, M.D.  
University of Minnesota Medical School  
Minneapolis, Minnesota  
(612) 336-5743

Lewis Kuller, M.D.  
University of Pittsburgh  
Pittsburgh, Pennsylvania  
(412) 624-3137

Albert Oberman, M.D.\*  
University of Alabama, Birmingham  
Birmingham, Alabama  
(205) 375-7575

Philip Greenland, M.D.  
Northwestern University Medical School  
Chicago, Illinois  
(312) 908-0895

JoAnn Manson, M.D.  
Brigham & Women's Hospital  
Boston, Massachusetts  
(617) 278-0782

Maurizio Trevisan, M.D.  
State University of New York, Buffalo  
Buffalo, New York  
(716) 829-2975

William Applegate, M.D.  
University of Tennessee, Memphis  
Memphis, Tennessee  
(901) 767-4200

Gregory Burke, M.D.  
Bowman Gray School of Medicine  
Winston-Salem, North Carolina  
(919) 716-7056

Annlouise Assaf, Ph.D.  
The Memorial Hospital  
Pawtucket, Rhode Island  
(401) 1-800-742-3446 (Rhode Island Only)  
(401) 729-2865

W. Dallas Hall, M.D.\*  
Emory University School of Medicine  
Atlanta, Georgia  
(404) 473-8600

Norman Lasser, M.D.  
University of Medicine and Dentistry of New Jersey  
Newark, New Jersey  
(201) 982-4001

WHI/NOM  
05/03/93

## NIH INFORMATION OFFICES

|                                                                                                                                           |                |
|-------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| Clinical Center<br>Building 10, Room 1C255                                                                                                | (301) 496-2563 |
| National Institute on Aging (NIA)<br>Building 31, Room 5C27                                                                               | (301) 496-1752 |
| National Institute of Alcohol Abuse<br>and Alcoholism (NIAA)<br>5600 Fishers Lane<br>Parklawn Building, Room 16C14<br>Rockville, MD 20857 | (301) 443-3860 |
| National Institute of Allergy and Infectious<br>Disease (NIAID)<br>Building 31, Room 7A50                                                 | (301) 496-5717 |
| National Institute of Arthritis and<br>Musculoskeletal and Skin Diseases (NIAMS)<br>Building 31, 4C05                                     | (301) 496-8188 |
| National Cancer Institute (NCI)<br>Building 31, Room 10A16                                                                                | (301) 496-6631 |
| National Institute of Child Health and Human<br>Development (NICHD)<br>Building 31, Room 2A32                                             | (301) 496-5133 |
| National Institute of Deafness and<br>Communicative Disorders (NIDCD)<br>Building 31, Room 3C35                                           | (301) 496-7243 |
| National Institute of Dental Research (NIDR)<br>Building 31, Room 2C35                                                                    | (301) 496-4261 |
| National Institute of Diabetes and<br>Digestive and Kidney Diseases (NIDDK)<br>Building 31, Room 9A04                                     | (301) 496-3583 |
| National Institute of Drug Abuse (NIDA)<br>11426-28 Rockville Pike<br>Rockville, MD 20847                                                 | (301) 468-2600 |
| National Institute on Environmental Health<br>Sciences (NIEHS)<br>P.O. Box 12233<br>Research Triangle Park, North Carolina 27709          | (919) 541-3345 |

|                                                                                                                          |                                                                           |
|--------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|
| National Eye Institute ( <b>NEI</b> )<br>Building 31, Room 6A32                                                          | (301) 496-5248                                                            |
| National Institute of General Medical<br>Sciences ( <b>NIGMS</b> )<br>Building 31, Room 4A52                             | (301) 496-7301                                                            |
| National Heart, Lung, and Blood Institute<br>( <b>NHLBI</b> )<br>Building 31, Room 4A21                                  | (301) 496-4236                                                            |
| National Center for Human Genome Research<br>( <b>NCHGR</b> )<br>Building 38A, Room 617                                  | (301) 402-0911                                                            |
| National Library of Medicine ( <b>NLM</b> )<br>Building 38, Room 2S10<br>8600 Rockville Pike<br>Bethesda, Maryland 20894 | 1-(800) 272-4787<br>(24 hr. - information)<br>Outside U.S. (301) 496-6095 |
| National Institute of Mental Health ( <b>NIMH</b> )<br>5600 Fishers Lane<br>Parklawn Building, Room 15C-05               | (301) 443-4515                                                            |
| National Institute of Neurological Disorders<br>and Stroke ( <b>NINDS</b> )<br>Building 31, Room 8A06                    | (301) 496-5924                                                            |
| National Center for Nursing Research ( <b>NCNR</b> )<br>Building 31, Room 5B13                                           | (301) 496-0207                                                            |
| National Center for Research Resources ( <b>NCRR</b> )<br>Building 12A, Room 4007                                        | (301) 496-5795                                                            |
| Office of AIDS Research ( <b>OAR</b> )<br>Building 1, Room 201                                                           | (301) 496-0357                                                            |
| Office of Minority Programs ( <b>OMP</b> )<br>Building 1, Room 260                                                       | (301) 402-1366                                                            |
| Office of Research on Women's Health ( <b>ORWH</b> )<br>Building 1, Room 201                                             | (301) 402-1770                                                            |

All letters to the above offices (excluding NIAA, NIDA, NIEHS, NIMH, and NLM) should include the following additional address:

The National Institutes of Health  
9000 Rockville Pike  
Bethesda, MD 20892

# Women's Health Research

## Prescribing Change and Addressing the Issues

In 1588, Michel Eyquem de Montaigne wrote: "Women are not entirely wrong when they reject the rules of life prescribed for the world, for they were established by men only, without their consent."<sup>1</sup> Montaigne's comment stretches across four centuries; a similar comment could be made about the recent status of women's health.

Today, women are becoming more aware of their unique health concerns and are not only asking that prescriptions for their well-being be determined on the basis of gender-specific research, but that anxieties about their physical and mental health be addressed with sensitive and enlightened wisdom.<sup>2-7</sup>

From prehistoric times until this century, women had a shorter life span than men, predominately resulting from complications of childbirth and chronic malnutrition.<sup>8</sup> Life expectancy for American women now exceeds that of men by an average of 7.5 years.<sup>9</sup> Yet, this longer life expectancy does not necessarily imply a better quality of life.<sup>10</sup> An even longer life expectancy may not only be desirable but possible, if health of mind and body can be preserved.

The leading causes of death for both men and women in the United States are the same: heart disease, cancer, and stroke.<sup>9</sup> However, except for malignancies of the female reproductive system and breast, many biomedical studies have used men as models for the prototypical study population, with subsequent results applied to women as though such diseases or conditions would have the same natural history or response.

Only recently have there been successful efforts to include women in such study populations or to devote entire scientific investigations to diseases, such as cardiovascular disease, in women.<sup>11-15</sup> The Women's Health Initiative is an example of such a study.<sup>16,17</sup> This multidisciplinary research study should provide answers to many of the questions that currently exist about the effects of menopause on women as well as the consequences of interventions, such as hormone replacement therapy, dietary modifications, and nutritional supplements.<sup>18,19</sup> The publication of a *JAMA* theme issue on women's health illustrates the growing awareness of this issue and sharpens our desire for more information based on biomedical and biobehavioral inquiries directed to women.

The Office of Research on Women's Health (ORWH) was established at the National Institutes of Health (NIH) in September 1990 to address the inequities in women's health research and to ensure that women are included in clinical studies.<sup>20</sup> The ORWH functions as a focal point for women's health research through the NIH institutes, centers, and divisions. Such a dynamic consolidated effort is evidence that intentions and actions are changing. Bernadine Healy, MD, through her commitment to women's health research, provides the leadership, as the first woman to be director of the NIH, to ensure that the ORWH can, and will, successfully achieve its objectives.<sup>21,22</sup>

The ORWH conducted a workshop, Opportunities for Research on Women's Health, to identify the gaps in knowledge about women's health, to establish a comprehensive research agenda for women's health for the coming decade, and to assist in establishing funding priorities.<sup>17</sup> The report, which contains recommendations that will form the basis of a women's health research agenda, was recently released.<sup>23</sup>

This agenda represents a collaborative effort of scientific and community expertise of NIH scientists, the extramural community, advocacy groups, and the health care industry. It recognizes that we must enhance and facilitate biomedical knowledge about the causes, expression, and treatment of diseases and conditions of women, including those that affect both men and women, to alleviate health problems that are depriving women of their vitality and their lives.

This inclusive concept addresses the health of women through the four stages of life: birth to young adulthood, young adulthood to perimenopausal years, perimenopausal to mature years, and mature years. A second approach consists of integrating basic science, clinical trials, and new technologies through six broad scientific areas: reproductive biology, early developmental biology, cardiovascular diseases, malignancies, immune and infectious diseases, and the aging process.

Importantly, the agenda encourages the full recognition of variables that can influence women's health, such as socioeconomic status, racial and ethnic background, and biobehavioral factors. It is imperative to define a normal physiology, reproductive system and aging in women. But, in addition, those conditions and disorders that occur in both men and women must be studied, with clarification of the effects of gender on their presentation, course, and response to interventions, and appropriate application to women's health care provision.

From the Office of Research on Women's Health, National Institutes of Health, Bethesda, Md.

Reprint requests to Office of Research on Women's Health, National Institutes of Health, Bldg 1, Rm 201, Bethesda, MD 20892 (Dr Pinn).

The article by Clancy and Massion<sup>24</sup> in this issue suggests the consideration of the development of a comprehensive women's health specialty to complement existing specialties in defining the medical profession's responsibility to eliminate the discrepancies in women's health care. The fragmentation of women's health care throughout the range of primary care and specialty providers has resulted in omission of an integrated approach to women's social, mental, and physical health.<sup>25</sup> This can be mitigated by providing a concerted educational focus on comprehensive, sensitive, and gender-specific acumen across health care disciplines. However, even if a women's health specialty is developed, we cannot allow it to be segregated from mainstream science. Nor can we allow women's health care to be neglected by other providers or assigned solely to such a specialty.

The increased participation of women in conducting gender-specific biomedical research and in participating in policy decisions related to both research and health care provision, another objective of the ORWH, can also positively affect the future of women's health.<sup>26</sup> Current efforts by the NIH to facilitate the reentry of women into biomedical careers is discussed elsewhere in this issue.<sup>27</sup>

By the year 2000, women's health should be an integral part of the scientific mainstream, with gender disparities in research programs relegated to historical interest. Hormonal differences between men and women must continue to be of interest, but must no longer serve as barriers to understanding health or treating disease. The scientific community is responding to these mandates for change. With continued concerted efforts, priorities for women's health in the 1990s can become the realities of the next century.

Vivian W. Pinn, MD

1. de Montaigne ME. *Essays, Book III*. 1588.
2. Rodriguez-Trias H. Women's health, women's lives, women's rights. *Am J Public Health*. 1992;82:664-665.
3. Schroeder P. Women's health: a focus for the 1990's. *Women's Health Issues*. 1992;2:1-2.
4. Dresser R. Wanted: single, white male for medical research. *Hastings Cent Rep*. January-February 1992;22:24-29.
5. Cotton P. Is there still too much extrapolation from data on middle-aged white men? *JAMA*. 1990;263:1049-1050.
6. Council on Ethical and Judicial Affairs, American Medical Association. Gender disparities in clinical decision making. *JAMA*. 1991;266:559-562.
7. Anastos K, Charney P, Charon RA, et al. Hypertension in women: what is really known? *Ann Intern Med*. 1991;115:287-293.
8. Lyons AS, Petrucelli RJ. *Medicine: An Illustrated History*. New York, NY: Harry N Abrams Inc; 1987.
9. National Center on Health Statistics. *Health United States, 1991*. Hyattsville, Md: US Public Health Service; 1992.
10. Verbrugge LM. Pathways of health and death. In: Apple RD, ed. *Women, Health, and Medicine in America*. London, England: Garland Publishing Co; 1990.
11. Colditz GA, Willett WC, Stampfer MJ, Rosner B, Speizer FE, Hennekens CH. A prospective study of age at menarche, parity, age at first birth, and coronary heart disease in women. *Am J Epidemiol*. 1987;126:861-870.
12. Manson JE, Colditz GA, Stampfer MJ, et al. A prospective study of obesity and risk of coronary heart disease in women. *N Engl J Med*. 1990;322:882-889.
13. Stampfer MJ, Willett WC, Colditz GA, Speizer FE, Hennekens CH. Past use of oral contraceptives and cardiovascular disease: a meta-analysis in the context of the Nurses' Health Study. *Am J Obstet Gynecol*. 1990;163:285-291.
14. Healy B. Preventing heart disease in women: another role for aspirin? *JAMA*. 1991;265:565-568.
15. Stampfer MJ, Colditz GA, Willett WC, et al. Postmenopausal estrogen therapy and cardiovascular disease. *N Engl J Med*. 1991;325:756-762.
16. Cotton P. Women's health initiative leads way as research begins to fill gender gaps. *JAMA*. 1992;267:469-470.
17. Pinn VW. Women, research, and the National Institutes of Health. *Am J Prev Med*. 1992;8:324-327.
18. Barrett-Connor E. Postmenopausal estrogen and prevention bias. *Ann Intern Med*. 1991;115:455-456.
19. Henrich JB. The postmenopausal estrogen/breast cancer controversy. *JAMA*. 1992;268:1900-1902.
20. Kirschstein RL. Research on women's health. *Am J Public Health*. 1991;81:291-294.
21. Healy B. Women's health, public welfare. *JAMA*. 1991;266:566-567.
22. Healy B. The Yentl syndrome. *N Engl J Med*. 1991;325:274-276.
23. National Institutes of Health. *Opportunities for Research on Women's Health*. Bethesda, Md: National Institutes of Health; 1992.
24. Clancy CM, Massion CT. American women's health care: a patchwork quilt with gaps. *JAMA*. 1992;268:1918-1920.
25. Johnson HT, Massion CT. Do we need a women's health specialty? *Ms*. November-December 1991:68-69.
26. Pinn VW. *Women's Health: Priority to Reality*. Boston, Mass: Wellbeing/Spring Beth Israel; 1992:58-63.
27. Marwick C. NIH researchers get retraining assistance. *JAMA*. 1992;268:1824.

# Commentary: Women, Research, and the National Institutes of Health

Vivian W. Pinn, MD

Women's physiologic and pathologic processes are capturing the national consciousness in what Dr. Bernadine Healy, the first woman director of the National Institutes of Health (NIH), has called a "new awakening." As she has pointed out, women have unique medical problems, but research focused on women's diseases has been inadequate. Our knowledge of too many common diseases is based almost entirely on studies of men. Unfortunately, most biomedical research has assumed women are just like men.

Now, we witness a dramatic shift in perspective. Not just professional and scientific journals, but newspapers, television and radio productions, community and religious organizations, and even social conversations convey the urgency of women's health concerns. You have probably seen newspaper headlines and titles of journal articles like these: "Women's Reproductive Health: A Chronic Crisis," "The Gender Gap in Drug Tests," "Reproductive Problems Are a Major Killer of Women," "The Gender Gap in Heart Disease; Women Die Far More Frequently Than Men Who Undergo Artery-opening Procedures," "Rumble in the Ranks: Sexism May Be Fact of Medical Life, But Women Physicians Are Fighting Back," "Women's Health, Public Welfare," "Preventing Heart Disease in Women; Another Role For Aspirin," "America's Neglected Weapon: Its Educated Women." In fact, women's community, academic, and other advocacy groups have placed women's health at center stage.

Moreover, the federal government is now also emphasizing women's health. The 1985 report of the Public Health Service Task Force on Women's Health Issues stated: "Biomedical and behavioral research should be expanded to ensure emphasis on conditions and diseases unique to, or more prevalent in, women in all age groups."<sup>1</sup> Full implementation of this directive has only recently, however, become a priority of the medical and scientific communities.

## Office of Research on Women's Health

In September 1990, the NIH established an Office of Research on Women's Health within the office of the NIH Director to

centralize focus on women's health issues within NIH and to establish a science base that will permit reliable diagnoses, effective treatment, and prevention strategies for women.

The major mandates of our office are (1) to develop an integrated strategy for increased research into diseases, disorders, and conditions unique to, more prevalent among, or more serious in women, or for which there are different risk factors or interventions for women than for men; (2) to ensure that women are appropriately represented in biomedical and behavioral research studies, especially clinical trials, supported by NIH; and (3) to direct initiatives to increase the numbers of female biomedical researchers.

**Integrated research strategy.** Our first objective is to increase the level of attention focused on women's health research in the NIH portfolio. In a year-long project, our office defined an NIH research agenda for women's health for the coming decade. We sought advice not only from the scientists and experts within and supported by the NIH, but also from women's organizations, advocacy groups, and consumer organizations. This project culminated in the Hunt Valley Workshop held in September 1991. When the final report of this effort is completed, it will assist us in setting priorities for research in women's health. The recommendations will focus on scientific issues affecting women's health across a female lifespan.

In addition to the more strictly biomedical issues, the workshop considered the *whole* woman and the full range of influences on women's health. It also emphasized the need for basic information on normal growth and development in girls and women. This multidisciplinary approach to women's health will lead to recommendations for studies that mingle both biomedical and social variables, such as socioeconomic status, racial or ethnic background, and family circumstances.

The integrated research agenda we are designing emphasizes the need for broadly based scientific inquiries. For example, technology in molecular biology and genetics can be used to shed light on all the phenomena involved in the normal physiology of development, disease, reproduction, and aging in women (and men). One area where broadly based inquiry is beginning to pay off is the study of breast cancer.

Dr. Pinn is Director, Office of Research on Women's Health, and Co-director, Women's Health Initiative, National Institutes of Health.

In fact, more broad-based studies on the causes and treatment of disease in women are being published now in the scientific literature. Breast cancer, in particular, has been a focus for recent intensive research, as a deadly disfiguring disease and as a model for investigating the interplay among endogenous and exogenous factors in the development of tumors.

To view women's health in terms of their total being, as women now demand, their normal physiology and reproductive system still need to be defined. A number of studies are focusing on the mechanisms involved during stages of the menstrual cycle. Our workshop has recommended other new areas for future research funding, including gynecological disorders and infertility. And Congress itself has urged the NIH to address research efforts toward "certain diseases and conditions related to women's health," including fibroids, endometriosis, pelvic inflammatory disease, and sexually transmitted diseases.

Because human health is determined by both genetic and environmental factors over the course of a lifetime, we need to understand the nature of their interactions if we are to understand the role of the environment in the etiology or progression of human disease. Examples of health problems likely to have an environmental association include spontaneous abortion, birth defects, infant mortality, cancer, asthma, Parkinson's disease, and infertility. The National Institute of Environmental Health Sciences (NIEHS), under new leadership, has made the health consequences of environmental agents on the neuroendocrine system one of its new research priorities. For instance, preliminary data from studies supported by NIEHS show that women with frequent spontaneous abortions have a greater incidence of polymorphism in the B-region of the estrogen receptor in DNA extracts from various tissues.<sup>2</sup> This abnormality may affect the neuroendocrine physiology of the hypothalamus and pituitary and contribute to pregnancy failure. Developmental abnormalities resulting in death in utero or in birth defects exact a heavy toll on our public health resources. Such environmental issues must become a research priority for women's health concerns.

**Appropriate representation in clinical trials.** The second objective, ensuring adequate representation of women in study populations, especially in clinical trials, has been one of our highest initial priorities. Women cannot gain from new advances in therapy and interventions if they are not included in the clinical trials that assess safety and efficacy.

The most obvious research needs and advances include the design and implementation of major clinical studies involving large populations of women—the kinds of studies that have been carried out on men for decades. One very important and often quoted model study is the Nurses' Health Study analysis on the effects of hormone replacement therapy. Some important, rather surprising, data about health, disease, and aging in women is beginning to emerge from this study and other longitudinal studies, such as the Framingham Heart Study and the Baltimore Longitudinal Study on Aging.

The Office of Research on Women has implemented a strengthened and revitalized policy on the inclusion of women and minorities in study populations. The policy clearly states that adequate numbers of women shall be included in clinical studies; proposals must employ a study design with sex representation appropriate to the known incidence/prevalence of the disease or condition under study. Moreover, NIH/ADAMHA (Alcohol, Drug Abuse, and Mental Health Administration)

funding components will not fund or award grants or contracts until the applicant provides sufficient information on the study population to assure compliance with the NIH/ADAMHA policy on inclusion of women (and minorities) in study populations.

We must ask the question: Why have women often been excluded from research? Was their exclusion an act of discrimination or of protection? Here are some of the stated reasons for exclusion:

1. Women's cyclical hormonal changes would confound research results.
2. Study populations would be less homogenous.
3. Study costs would be higher if sex-specific hypotheses or subgroup analyses were anticipated.
4. Recruitment of women into studies would be more difficult.
5. Legal and ethical issues would surround potential exposure of a fetus.

But, in actual practice, many treatments and modalities will be used in pregnant women and women of childbearing age, so we need to know and understand potential effects.

NIH is working with the Institute of Medicine to address the legal and ethical implications of including more women in more clinical studies. The goal is to determine recommendations to help overcome some of the barriers investigators and administrators face in facilitating these applications through the system but simultaneously considering women's health and the health of their fetuses. These are some of the questions we will consider:

1. Is including women of childbearing age in clinical research possible, considering problems related to potential fetal damage, safety, and liability?
2. What guidelines should determine when changes in drug metabolism should be investigated in relation to phases of the menstrual cycle?
3. Can guidelines be established to determine when clinical studies should be designed to evaluate sex differences?

**Increased participation in biomedical careers.** Our third objective, nurturing women as scientists and as leaders in research, assumes top priority for our efforts this year. We want to ensure appropriate representation of women on institutional review boards, study sections, advisory committees, and throughout the research community, both within and outside NIH. We believe the new prominence of women's health issues will almost certainly fade unless a "critical mass" is reached of women in biomedical research careers who have assumed decision-making positions.

To suggest that the remedy to the shortcomings in research on women's health is to enlist more women into biomedical research would be naive. Recruiting more women researchers is not a panacea. However, many suggest a direct relationship between the quantity of research on women's health issues and the number of women in research. Dr. Healy said at our research workshop last fall: "More than ever, I am convinced that a women's health research agenda for the next decade would be enhanced—and gender disparities in medical treatment and research reduced—by increasing the number of women in research—and, more particularly—in leadership positions in teaching, research, and the practice of medicine."

Our office held a conference focusing on how to attract, promote, and maintain women in scientific careers. We

emphasized the reentry of women into biomedical research careers. A first step has been to collect sufficient data on the professional progress of women in biomedical research.

**Medical schools.** We know that women are being admitted in increasing numbers to health professional schools and into postdoctoral programs. Yet, even though women have progressed from 35% of applicants to medical school in 1985 to 41% in 1991, representing the largest number of women applicants ever (13,700), and the number admitted to medical school in 1991 was 39.7% of the total admitted, we still do not see such representation in the ranks of tenured associate and full professors.<sup>3</sup>

Actually, women constitute 21.5% of faculty members at U.S. medical schools.<sup>3</sup> However, only 29.5% of all full-time female faculty members are associate or full professors, whereas 57% of male faculty members occupy these advanced positions. In fact, 1991 Association of American Medical Colleges (AAMC) data show that only 9.8% (1,386) of female faculty are full professors, compared with 31.7% of male faculty. Only 4% of department chairs are women (87, only three of whom are members of minorities). Clearly, the increase in numbers of women entering graduate and medical programs over the past 15 years has not translated into a similar number of senior positions.

**NIH grant support.** We are currently examining the trends in numbers of women who are principal investigators on research proposals or who receive funding from NIH. An analysis of numbers of women in NIH extramural grant programs between fiscal year 1981 and fiscal year 1990 completed by the NIH Division of Research Grants shows some major gains.<sup>4</sup>

For example, women's share of competing research project grant money doubled between 1981 and 1990, from \$53 million in 1981, to more than \$128 million in 1990. The average size of a competing research project grant award to a woman increased by 104%, compared with 84% for men.

However, other data still show women lagging behind their male counterparts. Although the percentage of competing research project grant funding to women has doubled since 1981, women receive only 12% of all research grant dollars awarded. Since 1984, requests for application awards (RFAs) to men have been \$86,000 more on average than awards to women, except in 1990, when the gap shrank to \$15,000. The average size of a competing research project grant award (RPG) to a woman is still about \$30,000 less than the average grant to a man.

Interestingly, since 1988, the ratio of the size of the average research grant to a woman, compared with the average size of a grant to a man, has been considerably higher for competing grants than for noncompeting grants. Further, women are receiving grant awards in exact relation to the number of applications they submit. In 1990, for example, women submitted about 19% of the applications, and they received about 19% of the awards for competing research project grants (RPGs). The success rate for competing RPG applications by women is almost identical to the success rate for men. And since 1987, the average duration of competing grants has also been virtually identical.

Among competing RPG grant mechanisms, women's largest percentage of funding in fiscal year 1990 came from first (R29) awards. That year, men's and women's success rates (22.1% versus 22.3%) for competing traditional research projects (ROIs) were nearly equal. Women now hold about 18% of all

dollars awarded for competing traditional research projects (ROIs) and 28% of first awards (R29s). Women 46 to 55 years of age had the largest average competing RPG awards of female age groups in 1990.

The percentage of training funds women currently receive is *double* the percentage of research funds. Women held more than 42% of institutional training positions funded by NIH in 1990. The number of women trainees has increased steadily since 1981, when it was less than 33%. Women of Native American, Hispanic, and white ethnic origin received approximately 40% of their racial groups' fellowships in 1990. African-American women received about 34% of the fellowship dollars awarded to blacks, and women of Asian/Pacific Islander ethnic origin received about 31% of funds within their racial group.

### The Women's Health Initiative

We are often asked, with seeming facetiousness, why such emphasis on research on women's health? Most diseases that affect women also affect men—heart disease, cancer, diabetes,—and that is indeed true.

In many important respects, however, the health status of women differs markedly from the health status of men. On average, women live about seven years longer than men. However, throughout their longer lifespans, women are more likely than men to experience ill health.<sup>5</sup> The incidence of acute conditions is 20%–30% higher in women than in men. Further, women suffer from more nonfatal chronic conditions than men, and they show consistently higher rates of short-term disability.

**Cardiovascular disease.** Among women 65 years of age and older, cardiovascular diseases and cancer continue to be the leading causes of death, but ischemic heart disease becomes more prevalent than other types of heart disease.<sup>6</sup> Death rates from heart disease remain higher for African-American women, up to 85 years of age. Only about one woman in nine in the 45–54 age group has symptomatic cardiovascular disease, but the rate climbs to one woman in three at 65 years of age and older. Nearly half of all women who suffer infarctions die within one year, as compared with about 30% of men. Of all fatal strokes, 61% occur in women. More than 90,000 women die from strokes every year.

**Cancer.** One particularly striking statistic relates to the death rate from breast cancer. In 1961, one woman in 20 in the United States could expect to develop breast cancer. Today, the figure is one in nine. The incidence of breast cancer increased by 24% in just seven years, between 1979 and 1986.<sup>7</sup> Despite research and education on breast cancer, we still lack an absolute answer to explain its increase.

**Osteoporosis.** A major cause of morbidity in older women is osteoporosis, which receives less public attention than do conditions prominent in mortality data. One-third to one-half of all postmenopausal women and nearly half of all people older than 75 will be affected by osteoporosis.<sup>8</sup> Osteoporosis causes more than a million fractures in the United States every year, and nearly a third of women older than 65 can expect to suffer at least one vertebral fracture.

These chronic diseases cause increasing concern because the population of the United States is aging. More than 12% of the population is now 65 or older, and the fastest growing age group is that >85.<sup>9,10</sup> Nearly 75% of this age group are women.

Older women may be especially vulnerable to receiving less

than optimum health care. Many of them spend their last years chronically sick and alone. Many older women suffer from negative self-images. They may feel they've outlived their usefulness, or that nobody cares about them now that they are no longer physically attractive. The health of these swelling numbers of older women will not improve unless a concerted effort is directed towards alleviating the problems, both physical and mental, that afflict them.

Shortly after Dr. Healy assumed the directorship of NIH, she announced the Women's Health Initiative, an ambitious research endeavor that addresses many of these problems. (Many confuse the Office of Research on Women's Health with the Women's Health Initiative. These are separate but related NIH activities with separate budgets. Dr. William R. Harlan is the director of the Women's Health Initiative, and I am now the codirector.) The initiative is intended to provide guidance concerning normal and abnormal processes affecting women in the aging process and to improve the quality of health and life for the postmenopausal woman. This 10-year, interrelated NIH initiative will be the most definitive, far-reaching study of women's health ever undertaken. It will focus, in particular, on diseases that cause death, disability, and frailty in postmenopausal women.

The Women's Health Initiative has three components: randomized clinical trials, a nationally based community intervention study, and a large surveillance study. Through a large, randomized, controlled trial, the Women's Health Initiative will test specific preventive measures, such as hormone replacement therapy, calcium, vitamin D, and dietary changes, for the most frequent diseases of the older woman. In addition, a broad-based community trial is being designed to test whether community-based interventions can promote healthy lifestyles and behaviors and prevent breast and other cancers, cardiovascular disease, and osteoporotic fractures. These community-based prevention interventions will include screening for cancer, hypertension, and blood cholesterol levels; substance abuse prevention; increased physical activity; and dietary and nutritional modifications.

The Women's Health Initiative will involve more than 140,000 postmenopausal women. A request for proposals for the clinical trial centers has been issued, and the community trial component is in its final stages of review. We believe that this venture will produce results to enhance our current knowledge about the major illnesses compromising the lives of so many older women.

### The Future of Research on Women's Health

The health care system must provide medical care based upon sufficient understanding of sex differences and the influences of hormones on health and disease. Scientists, practitioners, patients, and the public, of both sexes, must be sensitized about the need, value, and benefits of such directed research.

Past sex inequalities in research can be addressed with the endeavors by the NIH described here, in concert with similar undertakings by other federal agencies, academic institutions, pharmaceutical manufacturers, and public and private sector partnerships. Research on women's health with its ultimate goal, to improve the quality of life of our nation's women of all

ages and races, deserves to be an integral part of biomedical and biobehavioral initiatives.

Scientific advances and developing biomedical technologies must then be translated to application and intervention with full knowledge of potential sex differences on effectiveness. The future of our nation's health and welfare, not just of women but of all of our peoples, depends upon a better understanding of the mechanisms of the health and disorders of male and female cells, tissues, and organisms.

Our office has existed for 16 months. Much was accomplished under the initial leadership of Dr. Ruth Kirschstein, who served as acting director before me. Our area now is a whirlwind of activity, as we pursue the full and implied mandates of our office. We are planning comprehensive, deliberate strategies for the future and also, now, implementing them. We hope soon to see the intricate collaborative mosaic of biomedical and biobehavioral research I have described here become a reality, with women fully engaged in it, as researchers and as participants.

This commentary has been adapted from Dr. Pinn's Fae Golden Kass Lecture delivered on February 26, 1992, at Harvard Medical School.

### REFERENCES

1. U.S. Department of Health and Human Services, Public Health Service. Women's Health, Report of the Public Health Service Task Force on Women's Health Issues, Volume II. DHHS publication no. 88-50206; October 1987.
2. Personal communication with Kenneth Olden, PhD, Director of the National Institutes of Environmental Sciences at the National Institutes, Bethesda, Maryland.
3. Jolly P, Hudley DM, eds. AAMC Data Book, Statistical Information Related to Medical Education. Washington, DC: Association of American Medical Colleges, January 1992.
4. Women in NIH extramural grant program. Fiscal years 1981-1990. NIH: Statistics, Analysis, and Evaluation Section, Information Systems Branch, Division of Research Grants, 1992.
5. Verbrugge LD. Pathways of Health and Death. In: Apple RM, ed. Women, health and medicine in America—a historical handbook. London: Garland Publishing Company, 1990:41-79.
6. National Center for Health Statistics. Current estimates for NHIS, 1990. Vital and health statistics.
7. Ries LAG, Hankey BF, Miller BA, Hartman AM, Edwards BK. Cancer statistics review 1973-1988. Washington, DC: National Cancer Institute; 1991; NIH publication no. 91-2789.
8. Chrischilles E. A model of lifetime osteoporosis impact. Arch Intern Med 1991;151:2026-32.
9. U.S. Bureau of the Census and the National Institute of Aging. Profiles of America's elderly, US 1990 census, growth of America's elderly in the 1980's. November 1991.
10. U.S. Special Committee on Aging, American Association of Retired Persons, FCoA and AoA. Aging trends and projections, 1991 edition. Chart 1-5, p. 11.

---

## SUMMARY

---

Public Hearing on  
Recruitment, Retention, Re-Entry,  
and Advancement of Women  
in Biomedical Careers



National Institutes of Health  
Office of Research on  
Women's Health (ORWH)

Bethesda, Maryland  
March 2-3, 1992

This document was prepared for  
the Office Research on Women's Health  
National Institutes of Health  
by Computer Management Services, Inc.  
Barbara S. Lynch, Ph.D., Writer

## FOREWORD

The Office of Research on Women's Health was established within the Office of the Director of the National Institutes of Health in September 1990. It was charged with the critical objectives of *giving a central NIH focus to women's health issues and of establishing a science base that will yield reliable diagnoses, effective treatment, and prevention strategies for women.*

Recognizing the actual and potential contribution of women to the advancement of scientific knowledge is a priority for the Office of Research on Women's Health. In addition, we are concerned about (1) providing motivation for the recruitment of women into biomedical careers, (2) the retention of women who have already chosen research careers by assisting them to progress and advance, and (3) the re-entry into the profession by many women who have dropped out of research for a variety of reasons, including the difficulties they faced in combining a research career with their many other roles and responsibilities in life.

The prominence that is currently being afforded women's health issues will, almost certainly, begin to fade unless we can bring about a "critical mass" of women at work in biomedical research. We are convinced that the best means of assuring that research related to women's health remain a visible and active priority as we enter the 21st century is to increase the number of women in policy-making positions in research institutions – including universities, the Federal Government, and the private sector.

It would be naive to suggest that *all* we need to do to remedy the shortcomings in research on women's health is to enlist more women into biomedical research. However, many *are* convinced that there is a direct relationship between the amount – and quality – of research being conducted on women's health issues and the number of women engaged in this research.

We are also concerned about mentors, inspirational support, and opportunities for both traditional and nontraditional pathways for women to be successful in research careers. Our concern extends to the participation of women of all racial and ethnic origins in these endeavors.

We recognize that the attrition rate is alarming for women who enter educational and career paths in science. Even in branches of science where women are well represented at the undergraduate level, their numbers decline at the graduate level, and similar data exist for career progression.

What can be done to bring more women into biomedical research and improve their opportunities for advancement? How can we rectify the loss of women from science education and careers? The Office of Research on Women's Health is looking to the scientific and educational communities to (a) provide us with insight into the major barriers which women face and (b) formulate innovative strategies to overcome those barriers. We seek guidance in how to convince the research establishment of the benefits of having more women participating in research. We plan to address such related issues as tenure, child care and family care, nontraditional pathways to advanced education and careers, problems in the workplace, and new

professional options. Our purpose is to define the necessary "dynamics of change," the solutions and modifications that will alleviate the under-representation of women in scientific professions, and enhance the opportunities for them to assume leadership roles in biomedical careers as we enter the 21st century.

We appreciate the participation of all who have contributed to this process. Your participation affirms that the role of women in biomedical science careers is a deserving priority.

Vivian W. Pinn, M.D.  
Director  
Office of Research on Women's Health  
National Institutes of Health

## CONTENTS

|     |                                                   |
|-----|---------------------------------------------------|
| iii | FOREWORD                                          |
|     | SUMMARY OF ISSUES AND RECOMMENDATIONS             |
| 1   | INTRODUCTION                                      |
| 3   | ISSUE 1: Recruiting Women to Biomedical Careers   |
| 3   | <i>Barriers</i>                                   |
| 4   | <i>Recommendations</i>                            |
| 7   | ISSUE 2: Visibility: Role Models and Mentors      |
| 7   | <i>Barriers</i>                                   |
| 8   | <i>Recommendations</i>                            |
| 11  | ISSUE 3: Career Paths/Rewards                     |
| 11  | <i>Barriers</i>                                   |
| 13  | <i>Recommendations</i>                            |
| 19  | ISSUE 4: Re-entry Into a Biomedical Career        |
| 19  | <i>Barriers</i>                                   |
| 19  | <i>Recommendations</i>                            |
| 20  | ISSUE 5: Family Responsibilities                  |
| 20  | <i>Barriers</i>                                   |
| 21  | <i>Recommendations</i>                            |
| 24  | ISSUE 6: Sex Discrimination and Sexual Harassment |
| 24  | <i>Barriers</i>                                   |
| 25  | <i>Recommendations</i>                            |
| 28  | ISSUE 7: Research Initiatives on Women's Health   |
| 28  | <i>Barriers</i>                                   |
| 28  | <i>Recommendations</i>                            |
| 29  | ISSUE 8: Gender Sensitivity                       |
| 29  | <i>Barriers</i>                                   |
| 29  | <i>Recommendations</i>                            |
| 30  | ISSUE 9: Minority Women in Science                |
| 30  | <i>Barriers</i>                                   |
| 31  | <i>Recommendations</i>                            |
| 32  | APPENDIX: Participants                            |

## INTRODUCTION

A Public Hearing was held on March 2 and 3, 1992, on the topic of "Recruitment, Retention, Re-entry, and Advancement of Women in Biomedical Careers." The Hearing was sponsored by the Office of Research on Women's Health (ORWH) and invitations to persons and organizations interested in presenting or submitting testimony were published to the public according to Government protocol.

The purpose of the Hearing was to develop information for planning and conducting a specific activity related to ORWH's three-fold mandate. The mandate of the Office of Research on Women's Health, established in September 1990 within the Office of the Director of the National Institutes of Health (NIH), is the following:

- (1) to strengthen and enhance research related to diseases, disorders, and conditions that affect women and to ensure that research conducted and supported by NIH adequately addresses issues regarding women's health,<sup>1</sup>
- (2) to ensure that women are appropriately represented in biomedical and biobehavioral research studies supported by the NIH, and
- (3) to develop opportunities to increase the participation and advancement of women in biomedical careers.

The activity is a workshop entitled "Women in Biomedical Careers: Dynamics of Change," to be held June 11-12, 1992, in Bethesda, Maryland. The objectives of the workshop are to:

- Generate solid and innovative recommendations for actions
- Develop strategies for enhancing career achievements
- Highlight success stories and programs that work for women
- Provide pathways for networking and collaboration.

---

<sup>1</sup>Women's health issues have been defined as diseases, disorders, and conditions that are unique to, more prevalent among, or more serious in women, or for which there are different risk factors or interventions for women than men.

Recently, efforts to attract women to graduate programs and careers in science have yielded positive results, as indicated by their increased enrollment in medical schools and doctoral programs. Yet, women continue to be under-represented in a broad range of scientific professions, especially in leadership positions.

By sponsoring the Public Hearing and workshop on women in biomedical careers, the ORWH sought to identify barriers and obtain a slate of recommendations for action. In addition to guiding the June workshop, these recommendations will enable ORWH and other agencies and organizations to foster efforts to maximize involvement of women in science.

At the Hearing, 43 individuals and organizations presented testimony, and an additional 27 submitted written testimony. This document is a summary of the major issues that emerged during the hearing. Most testimonies described multiple barriers for women pursuing biomedical careers and presented several recommendations for overcoming each barrier. Those hundreds of recommendations tended to group into nine issue areas; thus, this summary is organized according to those nine issues.

For each issue area, the summary presents a synthesis of the relevant barriers, followed by a section highlighting the relevant recommendations. **In some instances, the barriers and recommendations are paraphrased or stated almost verbatim; in other instances a synthesis statement encompasses several similar recommendations, or expands them to be more comprehensive in their application to biomedical careers. For statements in which data are presented, a reference number is printed in brackets { }.** The numbers refer to the numbers of testimony as identified in the appendix of this document. An attempt was made to state each recommendation only once in the summary.

## ISSUES AND RECOMMENDATIONS

### ISSUE 1: Recruiting Women to Biomedical Careers

#### *Barriers*

Although women now constitute the majority of college students, in recent years fewer women students have been enrolling as science majors. Two factors that contribute to this lack of pursuit of science (and math) by women are—

- Discouragement of girls to study science in early grade levels (sex-role stereotyping)
- Failure of career counseling to direct women to the sciences.

***"Girls and women still see science as for 'White Males Only.'" {40}***

The critical period for encouraging students to enter the sciences is *before* high school. Yet, at each stage in early schooling, girls are culturally and attitudinally discouraged from participating in the physical sciences and mathematics, as is evident from the following facts:

- During grade school, girls are more cognizant of science than boys, but by the time the students reach secondary school, this difference reverses. {19}
- Gender gaps in science show up as early as age 9, and double by age 13. {26}
- During secondary school, girls are not as likely as boys to be encouraged to take math and science courses. {19}
- Beginning in middle and junior high school, girls exhibit more negative attitudes, pursue fewer opportunities, and by the end of high school score considerably lower than boys on measures of mathematics and science achievement, as evidenced by National Assessment of Educational Progress and Scholastic Aptitude Test scores. {40}

- Sex-role stereotyping appears to most seriously affect minority girls, even those who are high achievers. {40}

As a consequence of the lack of exposure and interest, young women are discouraged from pursuing college degrees in science.

Even when young women demonstrate interest and aptitude for science, they are not likely to be directed to a biomedical career by career counselors.

- A questionnaire revealed that students interested in science in high school were discouraged from pursuing a career in science by parents or educators. {48}
- Women are not encouraged in their training to consider *research* careers. Women entering science are often pointed toward and recruited into clinical, administrative, and other direct service roles regardless of demonstrated interest in or aptitude for conducting empirical research. {56}
- Many women, especially ethnic minority women, have difficulty perceiving the advantages and rewards of a research career. Women with specific scientific training continue to be rewarded for their emotional and "people oriented" skills instead of their analytic abilities. {56}

### *Issue 1 Recommendations*

Early in primary and secondary education young women are both consciously and unconsciously discouraged from pursuing careers in science and math. This, in part, is due to teaching styles that are not sensitive to gender-based differential attitudes regarding capability. Any intervention strategies must increase *both* motivation of students as well as their performance levels, if results in student achievement are going to be effective and long-term. Areas which should be addressed include:

- Teacher education, both pre-service and in-service
- Early childhood education
- Textbooks and instructional material
- Alternative methods of testing and evaluation
- Issues of gender stereotyping, teachers' expectations, and students' self-esteem
- Academic course and career counseling
- Parent education. {40}

More specifically, schools can help negate the myth that girls have no aptitude for science and math by:

- Fostering teacher and student awareness of equity issues
- Creating a climate in which both girls and boys learn mathematical, scientific, and technical skills effectively
- Allocating adequate teaching time to the skill areas in which each gender has the most difficulty
- Providing concrete examples of the usefulness of these skills in future career choices. {40}

The American Association of University Women (AAUW) has recently published a document entitled *How Schools Shortchange Girls* which highlights the need for equity workshops for teachers to help them recognize and address the teaching styles that negatively affect expectations and aspirations of girls and young women. NIH should—

- Join with the AAUW and other organizations in publicizing the result of the studies that form the basis of this document {42}
- Identify and eradicate the ways in which comparable behaviors are perpetuated in educational institutions receiving NIH training grants. {42}

Aggressive programs are needed to direct women into biomedical careers, for example:

- Funding for early identification and motivation programs. Middle schools especially require these types of programs because it is at this level that students begin to consider career goals. {58}
- Local health career high schools or tracks to bring potential students into science and clinical sites to learn skills and to meet successful women scientists. {58}
- More summer programs that allow women high school and undergraduate students to serve as interns in scientific laboratories. {14}
- Mentoring programs in magnet high schools to influence the scientific preparation of women. Such programs would link high school science teachers and students with universities and thereby increase the scientific knowledge and interest of students while improving the quality of high school science programs and teachers. {4}

- Professional linkages between young women in high school and biomedical researchers. {33}
- Summer internships, laboratory tours, seminars, and other programs geared to the high school students, to develop contacts that give a realistic view of research to the students. {33}
- Increased attention and concomitant Federal funding for extramural experiences for undergraduate women students. Participation in these projects, through internships or other work opportunities would offer students another route to developing an interest in science, and would provide contact with adult role models and mentors. {54}
- Financial support to allow postbaccalaureate women to study full-time and finish their courses more quickly. {48}
- Career counseling to expand women's career goals into all areas of biomedical sciences by exposing them through panel discussions and workshops to other women who have made a variety of career choices. {48}
- Research support to allow interested students to work in research laboratories where they become acquainted with hands-on science, have access to mentoring on a one-on-one basis with a research scientist, and receive intellectual and moral support from a network of other students and personnel working in the laboratory. {48}
- Intellectual support through availability of tutors and faculty to aid their progress. {48}
- Intervention workshops for women which focus on such topics as careers in science and how to combine personal and professional lives, among others. {54}

Recruitment efforts of women also should become more aggressive:

- Departmental chairpersons should designate faculty members to coordinate the department's efforts to recruit undergraduate, graduate, and postgraduate students into research careers. {3}
- Administrators of M.D. and Ph.D. programs should identify talented women undergraduates and medical students and actively recruit them. {3}

## ISSUE 2: Visibility: Role Models and Mentors

### *Barriers*

The lack of women role models is a serious barrier to all career phases of women in science: recruitment, retention, re-entry, and advancement. The need to make women in science more visible applies to the general public as well as to specific career aspirants. Seeing predominantly men in high-ranking positions in the biomedical profession subtly reinforces the image that women do not belong in science. If women do not see women successfully balancing career and family responsibilities, they become less able to imagine themselves managing these feats. After a lifetime of negative conditioning, women need the positive one-on-one interactions that mentoring provides in order to remain and advance in science fields. {14}

*"In the 31 science courses I took during my undergraduate studies at the University of Washington, I had two female science professors—both in biology. In medical school, I had five or so female lecturers—but only two full-time professors—out of a faculty of over 100. The opportunity for female professors to serve as role models for the next generation of women is lost for lack of academic appointments."*

*- Medical Student*

In high school math and science classes, young women describe cultural and sociological barriers and, by graduate school, they report that they often *feel isolated*. There are relatively few women professors, and women students believe that they do not receive the same attention from men teachers as do men students. This is particularly true regarding foreign-born faculty, whose attitudes toward women may be even less egalitarian than that of U.S. men.

In fact, there are few role models for women because of the paucity of women in biomedical career positions, especially in senior faculty and research positions. The table below describes the gap.

*Medical Gender Gap - 1990*

|                         | MEN  | WOMEN |
|-------------------------|------|-------|
| Medical School Deans    | 100% | 0%    |
| Physicians              | 84%  | 16%   |
| Medical School Faculty  | 79%  | 21%   |
| Medical School Students | 64%  | 36%   |
| Nurses                  | 3%   | 97%   |

Source: The Feminist Majority Foundation, Washington, DC

A lack of role models implies a lack of mentors, women who can personally guide and encourage other women in their careers. Mentors form a fundamental rung in the career ladder of medicine. Senior professionals give their junior colleagues attention and feedback, and are a resource for advancement, graduate opportunities, funding projects, and credential support. {31}. Without mentoring, women are handicapped in obtaining research grants, publication opportunities, tenure-track positions, and other research and clinical opportunities. {31}

In a 1989 survey of women medical students, 94% reported that they need a mentor, 61% had a mentor, but only 11% have a woman mentor. {1} A survey of the Ruth Jackson Orthopaedic Society reports that only 53% of respondents had a mentor, of which only 16% were women. {13}

### *Issue 2 Recommendations*

A majority of persons and organizations at the hearing made recommendations for increasing the visibility of women in biomedical careers:

- Encourage women in biomedical careers to *find* mentors and network among organizations.
- Encourage men faculty members to be open to mentoring women students. {1}
- Develop and support mentoring programs at the undergraduate and graduate levels. {14}
- Develop faculty reward systems for 1:1 or 1:2 mentoring of graduate student researchers in the biomedical sciences. {3}
- Develop and publicize a model mentoring program. {31}
- Continue and increase the emphasis on mentoring interested women undergraduate science students and provide the personal contacts into research laboratories to further develop research interests. {33}
- Invite campus scientists to meet informally with women undergraduates. {33}
- Develop symposia on career development which would include discussions on marital choice, children, and family life and their impact on research careers. {33}

- Develop a mechanism for measuring the success of mentoring programs and invest money to make the successful programs more widely available. {18}
- Examine attitudes of women physicians towards their peers. Actively develop women role models in academic medicine and in private practice to help women entering medicine emulate a model different from, but as valid as, the male-dominated tradition of medicine. {64}
- Recruit women researchers into positions where they will be visible and accessible to women in biomedical training. {56}
- Involve women in school curricula, where they can serve as role models for students. {19}
- Showcase the achievements of medical and scientific women, especially women of color, through speakers' bureaus and other publicized efforts aimed at high school, college, and professional audiences. {24}
- Educate chairpersons and training directors about the importance of role models for the career development of all future academics, including women. {3}
- Provide opportunities for networking among women faculty on a national basis to allow them adequate access to role models and mentors. {3}
- Develop programs for the grade-school level that present both women and men as role models in science as well as programs that encourage participation in science through events such as science fairs. {14}

The following recommendations were specifically addressed to NIH:

- Develop mentoring programs and make them available to all principal investigators, covering such issues as how to be a more effective mentor and how to avoid subtle gender bias. {46}
- Improve visibility of women in biomedical research, fund meetings on the subject, support a visiting women lecture series, and increase the number of women on NIH panels. {46}

- Adopt mechanisms for increasing the visibility of women researchers in order to counteract the view widely held not only by girls and young women, but also by their parents, siblings, peers, teachers, and counselors, that scientific research is largely, and properly, a white male endeavor. {42}
- Identify the ways in which NIH, through publications and policies, reinforces the above attitude. {42}
- Provide career guidance to women about the types of assignments and experiences they need for entry into the Senior Executive Service. {23}

### ISSUE 3: Career Paths/Rewards

#### *Barriers*

Career paths in the biomedical sciences often do not offer women the same opportunities and rewards they offer men. The statistics verify salary discrepancies between men and women, and the existence of the "glass ceiling." The "Old Boy Network" is still strong, often in the form of male bonding. Women in biomedical careers may have unequal access to appointments, promotion, and tenure, despite their credentials, numbers, or seniority. {31}

*"Our rule of thumb is 'I have to be twice as smart and work three times as hard to get three-fourths the pay and one-half the credit.'"* {2}

Biomedical careers are structured like other fields nationally—with a glass ceiling:

- Only 2% of the Fortune 500's top executives are women.
- No women are in the position of full dean of a medical school.

The two tables below show data on the distribution of medical school faculty. The first table is 1991 data for all departments; the second is 1989 data for departments of pathology.

#### **Distribution of U.S. Medical School Faculty by Sex, Rank and Tenure Status**

| TENURE STATUS               | PROFESSOR     |              | ASSOCIATE<br>PROFESSOR |              | ASSISTANT<br>PROFESSOR |              | INSTRUCTOR   |              |
|-----------------------------|---------------|--------------|------------------------|--------------|------------------------|--------------|--------------|--------------|
|                             | MALE          | FEMALE       | MALE                   | FEMALE       | MALE                   | FEMALE       | MALE         | FEMALE       |
| Tenured                     | 12,137        | 1,002        | 5,500                  | 1,101        | 459                    | 184          | 10           | 10           |
| On Tenure Track             | 620           | 72           | 1,974                  | 428          | 6,255                  | 2,199        | 433          | 316          |
| Not On Tenure Track         | 2,251         | 233          | 4,049                  | 1,032        | 7,283                  | 3,292        | 1,985        | 1,436        |
| Tenure N/A-Clinical Faculty | 220           | 11           | 245                    | 31           | 525                    | 138          | 134          | 42           |
| Tenure N/A At Institution   | 660           | 32           | 570                    | 77           | 883                    | 259          | 278          | 115          |
| Missing                     | 497           | 36           | 722                    | 123          | 2,347                  | 979          | 601          | 419          |
| <b>TOTAL</b>                | <b>16,385</b> | <b>1,386</b> | <b>13,060</b>          | <b>2,792</b> | <b>17,752</b>          | <b>7,051</b> | <b>3,441</b> | <b>2,338</b> |

Source: Association of American Medical Colleges, *U.S. Medical School Faculty 1991*, Faculty Roster System, Washington, DC, 1991.

**DISTRIBUTION OF PHYSICIAN FACULTY OF DEPARTMENTS OF  
PATHOLOGY BY GENDER AND ACADEMIC RANK – 1989**

| <b>RANK</b>         | <b>NO. OF MEN (%)</b> | <b>NO. OF WOMEN (%)</b> | <b>TOTAL (%)</b> |
|---------------------|-----------------------|-------------------------|------------------|
| Professor           | 910 (42.6)            | 76 (14.3)               | 986 (37.9)       |
| Associate Professor | 551 (25.8)            | 148 (27.9)              | 699 (26.2)       |
| Assistant Professor | 612 (28.6)            | 267 (50.3)              | 879 (32.9)       |
| Instructor          | 57 (2.7)              | 37 (7.0)                | 94 (3.5)         |
| Other and Missing   | 8 (0.3)               | 3 (0.6)                 | 11 (0.4)         |
|                     |                       |                         |                  |
| <b>TOTAL</b>        | <b>2,138</b>          | <b>531</b>              | <b>2,669</b>     |

*Source: U.S. Medical School Faculty: "The Numbers Book" 1989. Faculty Roster System, Association of American Medical Colleges, as presented in R.E. Anderson et al., Human Pathology, 22:(no.9):894. {41}*

Furthermore, the career path for women not only may lead to a dead-end, but also may be more arduous:

- Men achieve the rank of full professor in 12 years, whereas women labor 20 years to get there. {1}
- Men are four times as likely to achieve full professor rank. {24}

Salary differences exist between men and women scientists:

- In 1986 women scientists earned about 78% of salaries earned by men. The lowest salaries were earned by women in the life and social sciences, 71% and 72%, respectively, of the salaries of men employed in those fields. {26}
- At the doctoral level in 1987, overall women earned 79% of the salaries of men. {26}
- Entry-level salaries appear to be equal, but the disparity in salaries begins around age 30, when men begin to earn more than women. {26}

Nursing scientists have been disproportionately affected by gender-driven stereotyping in their attempts to advance. A common perception is that nurses are not scientists and do not perform studies of scientific merit. Committees have difficulty evaluating proposed studies within the context of the nursing profession.

### *Issue 3 Recommendations*

Participants in the Hearing made the following recommendations:

- Collect data on the career paths of graduates from medical programs. {3}
- Develop a tracking system for the career paths of NIH intramural and extramural scientists (men and women) that monitors promotions. {3}
- Offer incentives, such as equipment or support staff salaries, to universities or departments hiring and promoting women faculty at levels equal to or better than those represented in the pool. It is important to recognize the generational issues involved in funded research today. Many senior faculty, who are predominantly men, came to their positions in a time of generous funding and allocations. It is more difficult today to secure research funding, just at the time that women are making significant inroads into the scientific establishment. {54}
- Offer workshops for departmental chairs to address the issues of (1) how to promote the careers of young faculty, with an emphasis on problems faced by women, and (2) career skills such as writing papers and grant proposals. {46}
- Develop a registry and referral service to better inform research trainees of appropriate employment opportunities and to assist schools and advanced education programs seeking qualified women and minority investigators. {4}
- Investigate, rescind, and/or revise nepotism restrictions and salary limitations in a manner that improves job opportunities for women scientists whose spouses are employed at the same institution. An increasing number of married couples have dual professional careers. {52}
- Acknowledge women without advanced degrees who contribute to successful scientific research. {52}
- Increase the number of women in influential policy positions. {33}
- Increase the number of women in allied health professions on Federal grant review committees. {49}
- Assist women who have entered biomedical careers to advance to leadership positions. {2}

- Conduct a cross-sectional survey of women scientists of all academic ranks, and of those who have left the profession, in order to identify the circumstances that promote or impede the success of women. {41}

"The success of our collective efforts to increase the opportunities and improve access to graduate study and to entry-level research positions in the biomedical sciences will be amplified when there are more women in a position to influence health care and research policy." {7}

- Expand or develop leadership forums and opportunities for women scientists; establish regional forums not only to share information but also to allow women scientists to receive training in leadership skills, business issues, and other areas that will help them develop confidence in skills outside their areas of expertise. {64}
- Offer opportunities to participate in special programs that develop leadership skills, for example:
  - Leadership training
  - Communications skills
  - Personnel management
  - Assertiveness training
  - Stress reduction
  - Wellness promotion
  - Time management
  - Interpersonal relations. {2}
- Offer workshops for professional women specifically aimed at how to effectively use the power of their positions. {25}
- Ensure that women scientists have access to structured professional experiences designed to enhance self-confidence and build independence. This can include opportunities to present and defend research results, evaluate and criticize the research of others, participate in laboratory discussions and decisions, and plan and implement research plans of increasing sophistication. {54}
- Provide a hands-on research experience as part of medical school curricula. {3}

- Provide opportunities, for residents who wish to have more extensive research training, to elect a research rotation (up to 6 months) or a supervised longitudinal research project integrated into the residency. {3}
- Create linkages with clinical care settings, community-based organizations, and other direct-service providers. As many women, including minority women with interest in research, have opted for direct service and training careers, academic institutions can tap the skills of these individuals by creating collaborative working relationships with these organizations as sources of research subjects and of clinical expertise with special populations. {56}

### *Specially Funded Programs*

- Generate adequate funding for programs that will assure availability of "bridge" research funding to newly trained women beginning their academic careers. These funds would support continued research activity between the training period and the time when new researchers become capable of successful competitive grant funding. {4}
- Make available to women research assistantships {54} and summer research fellowships through foundations, Federal agencies, and medical schools. {3}
- Expand short-term research training grants for pre-doctoral students which afford students research opportunities under faculty preceptorship while they are still in the pre-doctoral program. {4}
- Offer senior fellowships to established women scientists, perhaps made available through a cost-sharing arrangement with participating institutions. {7}
- Design research fellowships to be more flexible; for example, allow for part-time research training.
- Require that institutions demonstrate adequate recruitment and mentoring of women in order to qualify for funding of training programs. {3}
- Establish and fund programs designed to increase research activities by women. These programs could be modeled on NIH's Minority Access to Research Careers (MARC) and Minority Biomedical Research Support (MBRS) Programs, and on the NIMH-funded APA Program for Minority Research Training in Psychiatry and Minority Supplement Awards which provide support for minorities pursuing research training and extra funding to investigators who include a minority co-investigator on their projects. {3}

## ISSUE 4: Re-entry Into a Biomedical Career

### *Barriers*

Many women wish to re-enter biomedical training to continue a career in research or teaching after they have been inactive in the field. These women may have left their careers in order to have and raise a family, or because of financial or geographical reasons. Re-entry may seem to pose overwhelming obstacles and deter women from doing so.

### *Issue 4 Recommendations*

Programs and funding were recommended for women who wish to retrain or re-enter biomedical careers:

- Make available post-doctoral fellowships for women to retrain or re-enter a field.
- Redesign eligibility rules for fellowships and positions to allow flexibility for accommodating gaps in career activity, for example, regarding the maximum number of years since receiving the Ph.D. or M.D. degree or the number of publications in the prior 5 years. {46}
- Exclude maternity or child-rearing leave from the time limit for tenure decisions. {46}
- Award re-entry fellowships with no stipulation about what school the awardee must attend, thereby allowing women to remain in their homes. {14}
- Offer programs for returning women students whose undergraduate work was not in the sciences, or whose degrees were completed some years ago, who wish to enter research and technical careers. Similar programs already exist for students who wish to pursue a medical degree, but lack the appropriate undergraduate science and mathematics training. Similar programs could be established for those students interested in research-oriented areas. {54}
- Redesign curriculum requirements for individuals taking nontraditional career paths. For example, amend grants to allow time off for child-rearing. {3}

## ISSUE 5: Family Responsibilities

### *Barriers*

The U.S. workforce in 1990 was composed 57.8% of women, 68% of those having children under age 18. If these statistics hold true for women in biomedical careers, one might assume that about two-thirds of the women in biomedical careers have dependents. Unfortunately, the biomedical structure not only fails to accommodate the pregnancy and parenting responsibilities of women, but also unduly penalizes those professional women who choose to have families. Women professionals who wish to bear a child may face disadvantages in planning their career opportunities, and in how they are evaluated for career advancement once they have the child. Women who take time out for pregnancy and child-rearing can lose valuable benefits, forfeit their position on the tenure track, or be harshly judged by medical leaders over the timing and direction of their career path.

Recent surveys indicate the following:

- Nearly 50% of all U.S. medical programs still have no written maternity leave policy. {31}
- Only 37.5% of medical schools have formal maternity leaves. {1}
- 50% of all teaching hospitals have no child care facilities for physicians or staff. {31}
- Only 17% of community hospitals offer child care services. {59}
- Only 18% of medical schools provide child care. {18}

Even when institutions have maternity leave policies, they typically do not resolve scheduling issues posed by dependent care needs:

- Only 14% of residency programs offer part-time or shared residency positions. {59}
- Only 5.5% of medical schools have job-sharing, {1}

*"I wouldn't mind so much the career slowdown that has come with being a mother if that were factored into the mental timetable superiors use when deciding on promotions. A mother's 30-hour week, 10-year career should be compared to a childless scientist's 60-hour week, 5-year rather than 10-year record." {39}*

In an academic career, the time to track tenure and the pressure to be productive occur

early and tend to coincide with prime child-bearing years for women. This factor impedes women's progress into the higher ranks of academic medicine. Women physicians adapt to the needs of the institutions when, instead, the institutions should focus on and provide assistance to the special needs of women physicians.

Thus, balancing family and career is one of the most serious problems facing women who choose biomedical careers. This problem is the most difficult to address because it calls into question both the traditional roles of women in society and the unstated expectations of what it means to be a scientist. The expectation is that in order to be a good scientist, one must be completely devoted to one's work, and in order to be a good mother and partner, one must be completely devoted to one's family.

### *Issue 5 Recommendations*

A majority of persons and organizations giving testimony recommended changes in institutional approach to assessing career progress and accommodating dependent care needs. One organization pointed out that even these measures are not enough if women who take advantage of them are considered "second-rate scientists" who lack dedication. The following recommendations were made:

- The biomedical community should encourage a new definition of "successful career" paths, so that women who have taken time for family responsibilities are not viewed as less committed to their profession, or penalized in their advancement opportunities {31}

#### *Family Leave*

- Distinguish between maternity leave and parental leave and provide for both. {11}
- Formulate formal maternity leave policies for all institutions.
- Formulate maternal leave policies that offer a minimum of 12 weeks family leave. {31}
- Develop work policies which recognize that women still have the major part of child-rearing responsibilities in families. Existing child-care reform and family medical leave packages passed by Congress, could serve as models for what is needed. {36}
- Promote universal acceptance of the need for equitable family leave policies and child care assistance. {1}

#### *Work Schedules*

- Promote the acceptance of and institutionalize flexible-time, part-time positions, and job-sharing opportunities. {31}
- Establish a national clearinghouse of information on such positions in biomedicine. {31}
- Acknowledge the unique needs of women during their undergraduate and graduate medical training, and provide a more flexible schedule and variable graduation dates. {19}

#### *Child Care*

- Provide child care facilities at undergraduate, graduate, and post-doctoral institutions. {18}
- Provide child care to women employees at all institutions. {18}
- Provide child-care facilities at convention centers during professional organizational meetings. {18}
- Consider providing stipends for dependent care during training programs. {7}

#### *Tenure Track*

- Explore ways to extend or slow the "tenure clock" for those who need to temporarily take time out from their careers for family purposes. {7}
- Develop policies in all institutions to allow delays of the tenure clock to accommodate women with family responsibilities. {13}
- Shift the emphasis placed on publication record from quantity to quality by limiting the number of publications that may be included in applications for promotion or tenure. {14}
- Develop attractive benefits packages in the public and private sectors to include:
  - Health insurance and disability coverage (including pregnancy)
  - On-site child care
  - Maternity leave
  - Set aside funds (grants) structured for researchers in peak child-rearing age
  - Flexible schedules
  - Liberal leave to take care of sick children or sick parents
  - "Work-at-home" assignments
  - Loan forgiveness programs

Retirement programs  
Funding mechanisms for children's college education. {2}

## ISSUE 6: Sex Discrimination and Sexual Harassment

### *Barriers*

For discussion purposes, a distinction is made between sex discrimination and sexual harassment. The former is the exclusion of women from opportunities or unfair assessment of their work because they are women. The latter, sexual harassment, comprises sexual advances in speech or actions. Sex discrimination and sexual harassment both have the same negative impacts on women, society, and the biomedical professions. These impacts were characterized at the hearing as personal, professional, and scientific.

- **Personal:** The victim's health is affected and the following may result: depression, anxiety disorders, post traumatic stress disorder, psychosomatic illness, gastrointestinal distress, immune suppression, and exacerbated underlying medical conditions. Once such symptoms are present, they are often used by the harassers as "evidence" that the woman deserved the harassment or that she caused it. {10}
- **Professional:** Science is needlessly impeded by the intentional suppression of the contributions of women scientists by harassers who intentionally bar their victims from completing their scientific work or from gaining recognition for their work. {10}
- **Scientific:** Who conducts the science affects which questions are considered important and affects how the scientific resources are allocated. It affects which questions are asked and how the questions are framed, which data are collected and how the data are analyzed, as well as how the results are interpreted and applied. Diversity is good for science. It brings a variety of perspectives to bear on solving problems and helps to ensure that the needs of all populations will more likely be recognized and met. {10}

There have been various reports of discrimination and harassment. In a survey by the Orthopaedic Society of its members, 39% of respondents reported sex discrimination during medical school, and 22% sexual harassment; 65% reported discrimination during residency, and 46% harassment. {13} A 1989 survey in Massachusetts revealed that 54% of women physicians and medical students had experienced sex discrimination and 27% harassment in a one-year period. {31}

Last summer, *TIME* magazine reported that women medical students at Stanford University complained of unwanted sexual advances by professors and peers; one student indicated that her breasts had been fondled. {24} In May 1991, the issue received public attention when Frances Conley, neurosurgeon and Stanford professor, resigned for reasons of sexual harassment and the proposed promotion of the fellow surgeon who she felt was treating her in a sexist manner.

Other cited forms of discrimination that undermine morale and productivity are the following:

- Competent, hard-working, and intelligent women are unfairly characterized as being unfeminine and undesirable. {36}
- Women who do not fall into traditional definitions of "attractiveness," including women of color, are isolated or made to feel invisible to the powers that be. {36}
- Lesbians who are open about their orientation face isolation and harassment. {36}
- Any woman who refuses the advances of men runs the risk of being pushed to "prove" her orientation. {36}
- Women's research is sometimes plagiarized or stolen. In 1988, an AMWA member's research article was stolen by a superior; she was later fired and ostracized for protesting the plagiarism. Although a Federal appeals court supported her plagiarism claim, the male superior has been promoted to a senior position, while the woman researcher is still unemployed. {31}
- Women subordinates often do not receive credit for their contributions. Many principal investigators of research grants are men, but much of the research work is often performed by lower-level, women research assistants; these women are at a significant disadvantage in protesting inequitable treatment. {31}
- Use of forced psychotherapy and forced psychiatric examinations as tools of sexual harassment and as retaliation against women for complaining about harassment is illegal and unethical but all too widespread. {10}
- The dominating style in the scientific workplace is that of men: combative, accompanied by insults and yelling. {26}
- In interviews, women are asked about family plans three times as often as men are asked. {1}

#### *Issue 6 Recommendations*

In order to create a professional environment free of gender inequities of any kind, Issues of sex discrimination and sexual harassment must be defined, then confronted through policies at all levels. The following recommendations were made:

- Document the psychological sequelae of discrimination and its impact on employees and institutions. {31}

- Conduct national surveys to document the problem. {31}
- Identify ways in which women can cope effectively. {31}
- Increase nationwide public awareness of the problem through education. {31}
- Require author anonymity in the scientific review process as a means of countering the prejudice against women. {14}
- Develop mechanisms to assure proper credit to research, including a fair hearings appeal process. {31}
- Require medical and graduate school administrators to make clear to students and faculty alike that personal and professional sexism will not be tolerated.
- Develop and enforce sexual harassment policies with prevention and education programs on all campuses. {54}
- Incorporate attitudinal as well as substantive change in curriculum reform regarding gender sensitivity. {24}
- Sensitize faculty and research mentors to the differences in learning and communication styles between men and women. {54}
- Develop arbitration as a possible alternative to lengthy and expensive litigation for tenure appeals and sex discrimination appeals. {24}

*"... snickering, giggling, and generally rude commentary occur any and every time there is a discussion of female reproductive organs."*

*- Medical Student*

*"One woman candidate who thought that her infertility would preclude questions prying into goals regarding family life was nevertheless interrogated regarding possible plans for adoption."*

*- Medical Student*

## **ISSUE 7: Research Initiatives on Women's Health**

### ***Barriers***

The issue was presented of the lack of a medical and research specialty in women's health. Possibly, more women would be attracted to biomedical careers if a specialty focusing on women were available. Even giving more emphasis to women's health in existing programs might attract women to the career field.

### ***Issue 7 Recommendations***

- Emphasize women's health in the education of all health professionals.
- Develop programs specific to women's health in existing health training programs.
- Develop a continuing education program on women's health for physicians in all specialties.
- Offer residency and fellowship programs in women's health.
- Develop a curriculum for a medical specialty in women's health. {17}

## **ISSUE 8: Gender Sensitivity**

### ***Barriers***

Insensitivity to the differences between men and women is a major barrier to compatible working relationships. The style of men tends to be hierarchial, noncollaborative, competitive, combative, and noncommunicative.

### ***Issue 8 Recommendations***

The following recommendations were offered as approaches to creating a workplace attitude more compatible to women.

- Offer seminars to men to broaden their scope in the following:

- Team Building
- Creative Thinking
- Ethnic Diversity
- Gender Awareness
- Communication Skills {2}

- Foster collaborative and synergistic research {11}
- Promote nonhierarchial research teams. {11}

## ISSUE 9: Minority Women in Science

### *Barriers*

All the issues that apply to women in general take on a special intensity for minority women in specific. Barriers to academic achievement, access, equity, excellence in education curricula, academic services, financial assistance, and the scarcity of mentors/role models have kept Hispanics, other minorities, and women from academe. {34}

Given the widespread concern of a glass ceiling for women in biomedical research careers, the predicament for under-represented minority women is so dreary, that for the most part, such a concern is totally abstract. For the overwhelming majority of minority women, careers in biomedical research appear unrealistic and out of reach, let alone worrying about the possibility of a glass ceiling. Although the numbers of minority enrolled in medical schools have increased, and at the same rate as women overall (Association of American Medical Colleges, 1989), the number of minority women in biomedical research careers and medical faculty positions is negligible. {6}

*"For many minority women, to be in a position where a glass ceiling comes into effect would be a drastic improvement." {6}*

A key element to improved health care for minorities is inclusion of researchers who understand the culture, language, and community mores. {12} Yet opportunities for such researchers and research are diminishing. Since 1961, 57 black hospitals have closed, 14 have merged, and only 12 remain. These hospitals are needed for specialized training. {2}

In 1980, the percentage of women physicians in the United States was only 13.4%. Of the total of women physicians, only 0.6% were Hispanic women. {34} The most recent data (1991) for multiple ethnicity groups are presented in the two tables below.

### Distribution of U.S. Medical School Faculty by Sex, Ethnicity and Degree

| MALE<br>ETHNICITY | MD            |             | PhD/OHD*      |             | MD-PhD/MD-OHD* |             | OTHER        |             |
|-------------------|---------------|-------------|---------------|-------------|----------------|-------------|--------------|-------------|
|                   | NUMBER        | PERCENT     | NUMBER        | PERCENT     | NUMBER         | PERCENT     | NUMBER       | PERCENT     |
| Native American   | 37            | 0.1         | 7             | 0.0         | 2              | 0.1         | 1            | 0.0         |
| Asian             | 1,942         | 4.8         | 1,274         | 7.1         | 380            | 10.5        | 121          | 3.0         |
| Black             | 610           | 1.5         | 143           | 0.8         | 36             | 1.0         | 98           | 2.4         |
| Mexican American  | 100           | 0.2         | 31            | 0.2         | 6              | 0.2         | 2            | 0.0         |
| Puerto Rican      | 261           | 0.7         | 33            | 0.2         | 6              | 0.2         | 8            | 0.2         |
| Other Hispanic    | 603           | 1.5         | 121           | 0.7         | 64             | 1.8         | 35           | 0.9         |
| White             | 27,239        | 67.8        | 11,444        | 63.4        | 2,602          | 72.1        | 1,275        | 31.6        |
| Refused           | 985           | 2.5         | 515           | 2.9         | 100            | 2.8         | 50           | 1.2         |
| Missing           | 877           | 2.2         | 278           | 1.5         | 45             | 1.2         | 341          | 8.4         |
| <i>Subtotal</i>   | <i>32,654</i> | <i>81.3</i> | <i>13,846</i> | <i>76.7</i> | <i>3,241</i>   | <i>89.8</i> | <i>1,931</i> | <i>47.8</i> |

### Distribution of U.S. Medical School Faculty by Sex, Ethnicity and Degree

| FEMALE<br>ETHNICITY | MD            |              | PhD/OHD*      |              | MD-PhD/MD-OHD* |              | OTHER        |              |
|---------------------|---------------|--------------|---------------|--------------|----------------|--------------|--------------|--------------|
|                     | NUMBER        | PERCENT      | NUMBER        | PERCENT      | NUMBER         | PERCENT      | NUMBER       | PERCENT      |
| Native American     | 5             | 0.0          | 7             | 0.0          | 1              | 0.0          | 4            | 0.1          |
| Asian               | 803           | 2.0          | 320           | 1.8          | 68             | 1.9          | 90           | 2.2          |
| Black               | 313           | 0.8          | 62            | 0.3          | 4              | 0.1          | 108          | 2.7          |
| Mexican American    | 30            | 0.1          | 9             | 0.0          | 0              | 0.0          | 5            | 0.1          |
| Puerto Rican        | 116           | 0.3          | 22            | 0.1          | 0              | 0.0          | 15           | 0.4          |
| Other Hispanic      | 118           | 0.3          | 48            | 0.3          | 2              | 0.1          | 38           | 0.9          |
| White               | 5,545         | 13.8         | 3,478         | 19.3         | 271            | 7.5          | 1,657        | 41.0         |
| Refused             | 212           | 0.5          | 135           | 0.7          | 10             | 0.3          | 36           | 0.9          |
| Missing             | 351           | 0.9          | 122           | 0.7          | 13             | 0.4          | 153          | 3.8          |
| <i>Subtotal</i>     | <i>7,493</i>  | <i>18.7</i>  | <i>4,203</i>  | <i>23.3</i>  | <i>369</i>     | <i>10.2</i>  | <i>2,106</i> | <i>52.2</i>  |
| <b>TOTAL</b>        | <b>40,147</b> | <b>100.0</b> | <b>18,049</b> | <b>100.0</b> | <b>3,610</b>   | <b>100.0</b> | <b>4,037</b> | <b>100.0</b> |

\*OHD - Other Health Doctorate

Source: Association of American Medical Colleges, *U.S. Medical School Faculty 1991*, Faculty Roster System, Washington, DC, 1991.

Minority women and girls still face race-based stereotypical attitudes, in addition to gender stereotyping. For example, young minority women tend to be neglected or are less likely to be taken seriously in career counseling.

### *Issue 9 Recommendations*

Special attention to minority women in all programs was recommended, with the following specific suggestions:

- In conducting research, ask different questions to determine race, sex, and socio-economic factors. {36}
- Allocate resources to provide one-to-one, face-to-face recruitment, particularly of minorities, into graduate, science-related programs. {58}
- Provide incentives for schools to develop and retain very diverse student populations (disadvantaged/advantaged, rural/urban, minority/majority). {58}
- Aim research initiatives at minority women's health issues. {36}
- Prepare Asian-American nurses to assume greater responsibility in management positions in health care institutions. {16}

## APPENDIX

### PARTICIPANTS

#### Speakers

Vivian W. Pinn, M.D.  
Director, Office of Research on Women's  
Health

Ruth L. Kirschstein, M.D.  
Director, National Institute of General  
Medical Sciences

Shirley Malcom, Ph.D.  
Directorate, Education and Human  
Resources Program American Association  
for the Advancement of Science

#### Presented Testimony

1. Palma E. Formica, M.D.  
American Medical Association
2. Hazel Harper, D.D.S.  
President, The Robert T. Freeman  
Dental Society, National Dental  
Association
3. Carolyn Robinowitz, M.D.  
Senior Deputy Medical Director  
American Psychiatric Association
4. Preston A. Littleton, Jr., D.D.S., Ph.D.  
Executive Director  
American Association of Dental  
Schools
5. Brenda Hoffman, M.S.  
Associate Director, Harvard Medical  
School
6. Henry T. Frierson, Jr., Ph.D.  
Professor and Associate Dean  
University of North Carolina at Chapel  
Hill
7. Leslie A. Sunell, Ph.D.  
Assistant Dean, Graduate Studies  
University of California, Davis
8. Viola M. Young-Horvath, Ph.D.  
Executive Director  
Federation of Organizations for  
Professional Women
9. William J. Holmes, Ph.D.  
President, Simmons College
10. Margaret Jensvold, M.D.  
Director, Institute for Research on  
Women's Health
11. Sarah Berga, M.D.  
Assistant Professor of Obstetrics and  
Gynecology, Magee-Womens Hospital
12. Rudy Arredondo, Chairman  
League of United Latin American  
Citizens
13. Janet L. Walker, M.D.  
Vice President, Ruth Jackson  
Orthopaedic Society
14. Tina Settineri  
University of California-San Francisco  
Women in Life Sciences
15. Dorothy A. Starr, M.D.  
Individual

### Presented Testimony

16. Eileen DeCesare, M.S., R.N., C.N.A.A.  
President, Philippine Nurses Association  
of Metropolitan Washington, D.C., Inc.
17. Lila A. Wallis, M.D., F.A.C.P.  
Founder and Past President  
National Council on Women in  
Medicine, Inc.
18. Anne Morris-Hooke, Ph.D.  
Chairman, Committee on the Status of  
Women in Microbiology, American  
Society for Microbiology
19. Shelby Rush  
Legislative Affairs Director  
The American Medical Student  
Association/Foundation
20. Erin E. Tracy  
Medical Student, Georgetown  
University
21. M. Maureen Polsby, M.D.  
Individual
22. Linda Phillips, M.D.  
American College of Surgeons
23. Suzanne G. Haynes, Ph.D.  
Individual
24. Maria Bustillo, M.D.  
Member of the Board  
Society for the Advancement of  
Women's Health Research
25. Muriel M. Lippman, Ph.D.  
ERNACO, Inc.
26. Catherine Morrison  
President, Families and Work Institute
27. Evelyne J. Warrick  
President, Lynne Warrick Enterprises,  
Inc.
28. Sharon L. Johnson, Ph.D.  
Individual
29. Billie B. Mackey  
President, Self Help for Equal Rights  
(SHER)
30. Edward C. Connors  
Individual
31. Lillian Gonzalez-Pardo, M.D.  
President, American Medical Women's  
Association, Inc.
32. Roger J. Bulger, M.D.  
President, Association of Academic  
Health Centers
33. Donald R. Mattison, M.D.  
Dean, University of Pittsburgh Medical  
Center
34. Maria Lourdes Garcia  
Director of Medical Education  
Interamerican College of Physicians  
and Surgeons
35. René Rodriguez, M.D.  
President, National Confederation of  
Hispanic American Medical  
Associations
36. Congresswoman Maxine Waters  
(D-CA), Congressional Caucus For  
Women's Issues
37. Ruth A. Anderson, D.D.S.  
Howard University, College of  
Dentistry

38. Martha Cortés, D.D.S.  
Hispanic Dental Association
39. Rosalie A. Bright, Sc.D.  
Individual
40. Susan Morris Shaffer, M.Ed.  
Director of Sex Equity Program  
Mid-Atlantic Equity Center  
School of Education, The American  
University
41. Frances A. Pitlick, Ph.D.  
Executive Officer  
American Association of Pathologists,  
Inc.
42. Stephanie J. Bird, Ph.D.  
Past President, Association for Women  
In Science
43. Elizabeth L. Travis, Ph.D.  
Professor of Experimental  
Radiotherapy, University of Texas,  
MD Anderson Cancer Center

#### Written Testimony

- |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ol style="list-style-type: none"><li>44. Vasundara V. Varadan<br/>Alumni Distinguished Professor of<br/>Engineering Science &amp; Electrical<br/>Engineering, Pennsylvania State<br/>University Research Center for the<br/>Engineering of Electronic &amp; Acoustic<br/>Materials</li><li>45. Harold A. Kaminetzky, M.D.<br/>Director, Practice Activities<br/>The American College of Obstetricians<br/>and Gynecologists</li><li>46. Charles C. Hancock, M.S.<br/>Executive Officer, American Society for<br/>Biochemistry and Molecular Biology</li><li>47. Jennifer Tucker, M.S.<br/>Deputy Director, Center for Women<br/>Policy Studies</li><li>48. Olivia C. McKenna, Ph.D.<br/>Professor and Deputy Chair of Biology<br/>The City College of the City University<br/>of New York</li></ol> | <ol style="list-style-type: none"><li>Linda H. Mantel, Ph.D.<br/>Professor and Chair of Biology<br/>The City College of the City University<br/>of New York</li><li>49. Ann Cavazos Chen, R.N., J.D.<br/>Health Policy Analyst, NAACOG,<br/>The Organization for Obstetric,<br/>Gynecologic &amp; Neonatal Nurses</li><li>50. Kara Eberly<br/>Department of Biology, St. Mary's<br/>College</li><li>51. Deborah Powell, M.D.<br/>Professor and Chairman, Department<br/>of Pathology and Laboratory Medicine,<br/>University of Kentucky, College of<br/>Medicine</li><li>52. Mrs. Constance D. Anderson<br/>Virginia Polytechnic Institute and State<br/>University</li><li>53. Linda Saland, Ph.D.<br/>Professor, University of New<br/>Mexico</li></ol> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
- and

## Written Testimony

54. Cinda-Sue Davis, Ph.D.  
Director, The Women in Science  
Program, University of Michigan
55. Betty B. Alford, Ph.D.  
Professor, Texas Woman's University
56. Rani Eversley, Ph.D.  
University of California, San Francisco
57. James Hadley  
National Institute of Allergy and  
Infectious Diseases, NIH
58. Wealtha McGurn, Ph.D.  
Professor, University of Texas Health  
Science Center at San Antonio
59. June K. Robinson, M.D.  
President, Women's Dermatologic  
Society
60. Sarah Gómez Erlach, R.N., M.P.H.  
Individual
61. William H. McBeath, M.D., M.P.H.  
Executive Director, American Public  
Health Association
62. Eleanor Smeal  
President, The Feminist Majority  
Foundation
63. Mary Pat Moyer, Ph.D.  
Professor and Director, Center for  
Human Cell Biotechnology, University  
of Texas Health Science Center at San  
Antonio
64. Beverly Husted  
Public Relations Manager, Rose  
Medical Center
65. Cynthia Kolb  
Legislative Assistant, Department of  
Government Liaison, American  
Academy of Pediatrics
66. Gwendolyn P. Keita, Ph.D.  
Director, Office of Women's Programs  
American Psychological Association
67. Barbara Herbert, M.D.  
Fellow (Medicine and Social Policy)  
The Mary Ingram Bunting Institute  
Radcliff College
68. Cynthia M. Shewan, Ph.D.  
Director, Research Division  
American Speech-Language Hearing  
Association
69. Walter E. Bollenbacher  
Associate Professor, Director  
Office of Educational Linkages  
University of North Carolina
70. Shirley E. Poduslo, Ph.D.  
Professor of Neurology  
  
Penelope Coates, Ph.D.  
Associate Professor, Cell Biology  
and Anatomy  
  
Jean Strahlendorf, Ph.D.  
Associate Professor, Physiology  
  
Texas Tech Health Sciences  
School of Medicine  
Department of Medical and  
Surgical Neurology

THE WHITE HOUSE  
WASHINGTON

Dr. Vivian W. Pinn  
Director of Research on Women's Health  
National Institutes of Health  
Building 1, Room 201  
Bethesda, maryland

---

THE OFFICE OF RESEARCH ON WOMEN'S HEALTH  
National Institutes of Health

SCIENTIFIC MEETING  
RECRUITMENT AND RETENTION OF WOMEN IN CLINICAL STUDIES

Agenda  
July 12-13, 1993

---

*Monday, July 12*

|           |                                                                                  |                                                   |
|-----------|----------------------------------------------------------------------------------|---------------------------------------------------|
| 8:30 a.m. | Introduction of Acting Director of the<br>National Institutes of Health          | Vivian W. Pinn, M.D.<br>Director, ORWH            |
| 8:35 a.m. | Opening Remarks                                                                  | Ruth L. Kirschstein, M.D.<br>Acting Director, NIH |
| 8:50 a.m. | Overview of the Office of Research on<br>Women's Health and Conference Statement | Vivian W. Pinn, M.D.<br>Director, ORWH            |

**PLENARY SESSION**

|            |                                                                                                |                                                                                                                                        |
|------------|------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|
| 9:10 a.m.  | Overview Statement                                                                             | <u>Moderator</u><br>Shiriki R. Kumanyika, Ph.D., M.P.H.<br>Pennsylvania State University College<br>of Medicine<br>Task Force Co-Chair |
| 9:20 a.m.  | Gender Bias in Women's Health Research                                                         | Jeri A. Sechzer, M.A., Ph.D.<br>Pace University                                                                                        |
| 9:40 a.m.  | <b>Break</b>                                                                                   |                                                                                                                                        |
| 10:00 a.m. | Women's Health Research Legislative and<br>Public Policy Update                                | Congresswoman Louise M. Slaughter<br>(D-New York)                                                                                      |
| 10:30 a.m. | Advocacy and Women's Health Research                                                           | Leslie R. Wolfe, Ph.D.<br>Center for Women Policy Studies                                                                              |
| 10:45 a.m. | Ethical and Legal Issues                                                                       | Karen H. Rothenberg, J.D., M.P.A.<br>University of Maryland School of Law                                                              |
| 11:00 a.m. | Summary of ORWH Public Hearing on<br>Recruitment and Retention of Women<br>in Clinical Studies | Shiriki R. Kumanyika, Ph.D., M.P.H.<br>Pennsylvania State University College<br>of Medicine<br>Task Force Co-Chair                     |
| 11:15 a.m. | Discussion                                                                                     |                                                                                                                                        |

---

---

*Monday, July 12 (continued)*

12:00 p.m.      **Lunch**

**PANEL I:      DESIGN AND IMPLEMENTATION ISSUES IN CLINICAL STUDIES**

1:30 p.m.      Overview Statement

Moderators

Carol K. Redmond, Sc.D.  
University of Pittsburgh  
Task Force Member

Julie E. Buring, Sc.D.  
Harvard Medical School  
Task Force Member

1:45 p.m.      Getting the Job Done in Treatment and  
Prevention Clinical Trials

AIDS Treatment and Prevention Research      Melanie A. Thompson, M.D.  
AIDS Research Consortium of Atlanta

Cancer Research in Community Settings      Harry E. Hynes, M.D., M.P.H.  
Cancer Center of Kansas

2:15 p.m.      Prevention Studies

Unique Issues for Risk Factor  
Assessments in Women      John M. Flack, M.D., M.P.H.  
University of Minnesota Hospital  
and Clinic

Research Considerations Across  
Diseases and Conditions      Donna Kritz-Silverstein, Ph.D.  
University of California at San Diego

2:55 p.m.      Discussion

3:15 p.m.      **Break**

3:30 p.m.      Prevention Studies (continued)

Behavioral Modification Studies      Maureen M. Henderson, M.D., D.P.H.  
University of Washington

Cancer Screening      Dinah K. Pearson, M.H.A.  
University of Missouri - Columbia

Contributions of Observational Evidence:  
Nurses' Health Study      Charles H. Hennekens, M.D., Dr.P.H.  
Harvard Medical School

4:30 p.m.      Discussion

5:00 p.m.      Closing Remarks

Vivian W. Pinn, M.D.  
Director, ORWH

5:10 p.m.      **Recess**

---

*Tuesday, July 13*

**PANEL II: PARTICIPANT AND COMMUNITY ISSUES IN RECRUITMENT AND RETENTION  
IN CLINICAL STUDIES**

|           |                                       |                                                                                                                                                                                                                                                                                                                                                                        |
|-----------|---------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 8:00 a.m. | Remarks: Food and Drug Administration | Ruth B. Merkatz, Ph.D., R.N.<br>Food and Drug Administration                                                                                                                                                                                                                                                                                                           |
| 8:10 a.m. | Overview Statement                    | <u>Moderators</u><br>Barry D. Kaufman, D.M.D.<br>CBS Radio/Medical News Network<br>Task Force Member<br><br>Helen Rodriguez-Trias, M.D.<br>American Public Health Association<br>Task Force Member                                                                                                                                                                     |
| 8:15 a.m. | Participants' Expectations and Needs  | Dyanne D. Affonso, Ph.D., F.A.A.N.<br>University of California at San Francisco<br><br>Patricia A. Ganz, M.D.<br>University of California at Los<br>Angeles Schools of Medicine and<br>Public Health                                                                                                                                                                   |
| 8:45 a.m. | Community Partnerships in Research    | Vanella A. Crawford, M.S.W., L.C.S.W.<br>The Vanella Group<br><br>Edwin B. Fisher, Jr., Ph.D.<br>Washington University School of<br>Medicine<br><br>Diane M. Becker, Sc.D., M.P.H.<br>The Johns Hopkins Center for Health<br>Promotion<br><br>Reverend Melvin B. Tuggle<br>Heart, Body, and Soul, Inc.<br><br>Barbara V. Howard, Ph.D.<br>Medlantic Research Institute |
| 9:55 a.m. | Discussion                            |                                                                                                                                                                                                                                                                                                                                                                        |

---

*Tuesday, July 13 (continued)*

10:15 a.m.      **Break**

10:30 a.m.      Recruitment and Retention of  
Special Populations

Barbara S. Brown, M.Ed.  
Goochland Elementary School  
Goochland, Virginia

Elmer E. Huerta, M.D., M.P.H.  
National Cancer Institute, NIH

Lee Lee Doyle, M.A., Ph.D.  
University of Arkansas for Medical  
Sciences  
College of Medicine

Katherine A. O'Hanlan, M.D.  
Stanford University Medical Center

11:10 a.m.      Decisionmaking Process

John C. Fletcher, Ph.D.  
University of Virginia School  
of Medicine

11:25 a.m.      Discussion

12:00 noon      **Lunch**

**PANEL III:      INVESTIGATOR AND INSTITUTIONAL ISSUES IN RECRUITMENT AND RETENTION  
IN CLINICAL STUDIES**

1:15 p.m.      Overview Statement

Moderators

Maureen M. Henderson, M.D., D.P.H.  
University of Washington  
Task Force Member

Marion M. Lee, Ph.D., M.P.H.  
University of California at San Francisco  
Task Force Member

1:20 p.m.      Outreach Planning in Designing and  
Implementing Clinical Research

Rodger J. Winn, M.D.  
University of Texas M.D. Anderson  
Cancer Center

Annlouise R. Assaf, M.S., Ph.D.  
Memorial Hospital of Rhode Island

1:50 p.m.      Benefits and Risks to Investigators and  
Institutions in Conducting Clinical Studies

William R. Hazzard, M.D.  
Bowman Gray School of Medicine  
of Wake Forest University

---

***Tuesday, July 13 (continued)***

2:05 p.m.      Office for Protection From Research Risks      Paula Knudson  
                         (OPRR) and Institutional Review Board (IRB)      The University of Texas Health Science  
                         Issues      Center at Houston

2:20 p.m.      Discussion

**PANEL IV:      CURRENT EXPERIENCES IN WOMEN'S HEALTH RESEARCH**

2:45 p.m.      Overview Statement      Moderator  
                              Lewis H. Kuller, M.D., Dr.P.H.  
                              University of Pittsburgh  
                              Task Force Co-Chair

2:50 p.m.      Women's Health Feasibility Study      W. Dallas Hall, M.D.  
                              Emory University School of Medicine

3:05 p.m.      Postmenopausal Estrogen/Progestin      Valery T. Miller, M.D.  
                         Intervention (PEPI) Study      George Washington Medical Center

3:20 p.m.      Cardiovascular Health Study (CHS)      Linda P. Fried, M.D., M.P.H.  
                         and Women in Aging Study      The Johns Hopkins Health Institutions

3:35 p.m.      Discussion

**CLOSING SESSION**

4:00 p.m.      Concluding Remarks      Vivian W. Pinn, M.D.  
                              Director, ORWH

4:15 p.m.      **Adjourn**

PUBLIC LAW 103-43—JUNE 10, 1993

NATIONAL INSTITUTES OF HEALTH  
REVITALIZATION ACT OF 1993

ler General of the United States shall conduct an audit for the purpose of determining—

(1) whether and to what extent such research conducted or supported by the Secretary of Health and Human Services has been conducted in accordance with section 498A of the Public Health Service Act (as added by section 111 of this Act); and

(2) whether and to what extent there have been violations of section 498B of such Act (as added by section 112 of this Act).

(b) REPORT.—Not later than May 19, 1995, the Comptroller General of the United States shall complete the audit required in subsection (a) and submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the findings made pursuant to the audit.

### PART III—MISCELLANEOUS REPEALS

#### SEC. 121. REPEALS.

(a) CERTAIN BIOMEDICAL ETHICS BOARD.—Title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by striking part J.

42 USC 275

(b) OTHER REPEALS.—Part G of title IV of the Public Health Service Act (42 U.S.C. 289 et seq.) is amended—

(1) in section 498, by striking subsection (c); and

42 USC 289g

(2) by striking section 499; and

42 USC 289h

(3) by redesignating section 499A as section 499.

42 USC 290b

(c) NULLIFICATION OF CERTAIN PROVISIONS.—The provisions of Executive Order 12806 (57 Fed. Reg. 21589 (May 21, 1992)) shall not have any legal effect. The provisions of section 204(d) of part 46 of title 45 of the Code of Federal Regulations (45 CFR 46.204(d)) shall not have any legal effect.

42 USC 289g  
note.

## Subtitle B—Clinical Research Equity Regarding Women and Minorities

### PART I—WOMEN AND MINORITIES AS SUBJECTS IN CLINICAL RESEARCH

#### SEC. 131. REQUIREMENT OF INCLUSION IN RESEARCH.

Part G of title IV of the Public Health Service Act, as amended by section 101 of this Act, is amended by inserting after section 492A the following section:

#### “INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH

“SEC. 492B. (a) REQUIREMENT OF INCLUSION.—

42 USC 289a-2.

“(1) IN GENERAL.—In conducting or supporting clinical research for purposes of this title, the Director of NIH shall, subject to subsection (b), ensure that—

“(A) women are included as subjects in each project of such research; and

“(B) members of minority groups are included as subjects in such research.

“(2) OUTREACH REGARDING PARTICIPATION AS SUBJECTS.—

The Director of NIH, in consultation with the Director of the Office of Research on Women's Health and the Director of the Office of Research on Minority Health, shall conduct or support outreach programs for the recruitment of women and members of minority groups as subjects in projects of clinical research.

“(b) INAPPLICABILITY OF REQUIREMENT.—The requirement established in subsection (a) regarding women and members of minority groups shall not apply to a project of clinical research if the inclusion, as subjects in the project, of women and members of minority groups, respectively—

“(1) is inappropriate with respect to the health of the subjects;

“(2) is inappropriate with respect to the purpose of the research; or

“(3) is inappropriate under such other circumstances as the Director of NIH may designate.

“(c) DESIGN OF CLINICAL TRIALS.—In the case of any clinical trial in which women or members of minority groups will under subsection (a) be included as subjects, the Director of NIH shall ensure that the trial is designed and carried out in a manner sufficient to provide for a valid analysis of whether the variables being studied in the trial affect women or members of minority groups, as the case may be, differently than other subjects in the trial.

“(d) GUIDELINES.—

“(1) IN GENERAL.—Subject to paragraph (2), the Director of NIH, in consultation with the Director of the Office of Research on Women's Health and the Director of the Office of Research on Minority Health, shall establish guidelines regarding the requirements of this section. The guidelines shall include guidelines regarding—

“(A) the circumstances under which the inclusion of women and minorities as subjects in projects of clinical research is inappropriate for purposes of subsection (b);

“(B) the manner in which clinical trials are required to be designed and carried out for purposes of subsection (c); and

“(C) the operation of outreach programs under subsection (a).

“(2) CERTAIN PROVISIONS.—With respect to the circumstances under which the inclusion of women or members of minority groups (as the case may be) as subjects in a project of clinical research is inappropriate for purposes of subsection (b), the following applies to guidelines under paragraph (1):

“(A)(i) In the case of a clinical trial, the guidelines shall provide that the costs of such inclusion in the trial is not a permissible consideration in determining whether such inclusion is inappropriate.

“(ii) In the case of other projects of clinical research, the guidelines shall provide that the costs of such inclusion in the project is not a permissible consideration in determining whether such inclusion is inappropriate unless the data regarding women or members of minority groups, respectively, that would be obtained in such project (in the event that such inclusion were required) have been

or are being obtained through other means that provide data of comparable quality.

“(B) In the case of a clinical trial, the guidelines may provide that such inclusion in the trial is not required if there is substantial scientific data demonstrating that there is no significant difference between—

“(i) the effects that the variables to be studied in the trial have on women or members of minority groups, respectively; and

“(ii) the effects that the variables have on the individuals who would serve as subjects in the trial in the event that such inclusion were not required.

“(e) DATE CERTAIN FOR GUIDELINES; APPLICABILITY.—

“(1) DATE CERTAIN.—The guidelines required in subsection (d) shall be established and published in the Federal Register not later than 180 days after the date of the enactment of the National Institutes of Health Revitalization Act of 1993.

“(2) APPLICABILITY.—For fiscal year 1995 and subsequent fiscal years, the Director of NIH may not approve any proposal of clinical research to be conducted or supported by any agency of the National Institutes of Health unless the proposal specifies the manner in which the research will comply with this section.

“(f) REPORTS BY ADVISORY COUNCILS.—The advisory council of each national research institute shall prepare biennial reports describing the manner in which the institute has complied with this section. Each such report shall be submitted to the Director of the institute involved for inclusion in the biennial report under section 403.

“(g) DEFINITIONS.—For purposes of this section:

“(1) The term ‘project of clinical research’ includes a clinical trial.

“(2) The term ‘minority group’ includes subpopulations of minority groups. The Director of NIH shall, through the guidelines established under subsection (d), define the terms ‘minority group’ and ‘subpopulation’ for purposes of the preceding sentence.”.

#### SEC. 132. PEER REVIEW.

Section 492 of the Public Health Service Act (42 U.S.C. 289a) is amended by adding at the end the following subsection:

“(c)(1) In technical and scientific peer review under this section of proposals for clinical research, the consideration of any such proposal (including the initial consideration) shall, except as provided in paragraph (2), include an evaluation of the technical and scientific merit of the proposal regarding compliance with section 492B.

“(2) Paragraph (1) shall not apply to any proposal for clinical research that, pursuant to subsection (b) of section 492B, is not subject to the requirement of subsection (a) of such section regarding the inclusion of women and members of minority groups as subjects in clinical research.”.

#### SEC. 133. INAPPLICABILITY TO CURRENT PROJECTS.

Section 492B of the Public Health Service Act, as added by section 131 of this Act, shall not apply with respect to projects of clinical research for which initial funding was provided prior to the date of the enactment of this Act. With respect to the inclusion of women and minorities as subjects in clinical research

Federal  
Register,  
publication

42 USC 289a-2  
note

conducted or supported by the National Institutes of Health, any policies of the Secretary of Health and Human Services regarding such inclusion that are in effect on the day before the date of the enactment of this Act shall continue to apply to the projects referred to in the preceding sentence.

NIH/ADAMHA POLICY CONCERNING INCLUSION OF WOMEN IN STUDY POPULATIONS

P.T. 34, II; K.W. 1014002, 1014006

National Institutes of Health  
Alcohol, Drug Abuse, and Mental Health Administration

The National Institutes of Health (NIH) and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) recognize that most researchers adequately and appropriately consider gender representation in clinical research design. Nevertheless, the following statement is published as a reiteration and further interpretation of the existing NIH/ADAMHA policy concerning inclusion of women in study populations. Clinical research findings should be of benefit to all persons at risk of the disease, regardless of gender. This policy was previously published in the NIH Guide for Grants and Contracts on October 24, 1986; January 23, 1987; March 27, 1987; January 15, 1988; and June 16, 1989. For the purpose of this policy, clinical research includes human studies of etiology, treatment, diagnosis, prevention, and epidemiology of disease, including but not limited to clinical trials. While this policy statement refers to inclusion of women, applicants are strongly reminded that a similar policy exists regarding the inclusion of minorities (NIH Guide for Grants and Contracts - September 25, 1987; January 15, 1988; and June 16, 1989). Both policies must be considered when preparing clinical research applications/proposals for submission to the NIH/ADAMHA.

Public concern requires that clinical studies include both genders in such a way that results are applicable to the general population; exceptions would be those diseases or conditions that occur only in one gender. Therefore, applications/proposals for NIH/ADAMHA support of clinical research should employ a study design with gender representation appropriate to the known incidence/prevalence of the disease or condition being studied. If inclusion of women is impossible or inappropriate with respect to the purpose of the research, the health of the subjects, or other reasons, or if in the only study population available there is a disproportionate representation of one gender, these reasons for excluding women or men must be well explained and justified by the applicant. Similar justification is required if women will not be included in numbers appropriate to the incidence/prevalence of the disease.

In conducting peer review for scientific and technical merit, members of Initial Review Groups (IRGs)/Technical Evaluation Groups (TEGs) will be instructed to evaluate the proposed gender composition of the study population.

- 1) If there is an inadequate number of women in a study design AND this affects the potential to answer the scientific question(s) addressed, that will be considered a weakness or deficiency in the study design and should be reflected in the assigned score given to the application/proposal, and in the summary statement of the review.
- 2) If an applicant proposes that there is justification for conducting a study in men only, or in a study population in which the proportion of women does not reflect the gender prevalence of the disease or condition under study, a strong scientific rationale, an explanation of the need to protect the health of the subjects, or other well-supported justification must be provided. The IRG/TEG will be instructed to evaluate the merit of such justifications. Appropriate justification will not adversely affect the assigned score. The NIH/ADAMHA will not fund such applications/proposals unless the justification provided is compelling.
- 3) If the gender composition of the study population is not described, BUT the study otherwise has the potential to answer the scientific question(s) posed and translate the findings to all persons at risk of the disease, the omission will be documented by the Executive Secretary of the IRG/TEG in an administrative note, and will not adversely affect the scientific assessment and the assigned score. If there is inadequate information on the study population to allow evaluation of the scientific question(s), the review may be deferred. The NIH/ADAMHA funding components will not fund/award grants or contracts until the applicant provides sufficient information on the study population to assure compliance with the NIH/ADAMHA policy on inclusion of women in study populations.

Since the need to modify sample design could delay award and affect the costs of the study, applicants are strongly advised to address this issue in the initial submission. If costs or study designs are significantly affected by such modification, submission of an amended application/proposal for IRG/TEG review and/or reconsideration by the appropriate National Advisory Council or Board may be necessary.

Whenever there are scientific reasons to anticipate differences between men and women with regard to the hypothesis under investigation, applicants should consider the inclusion of an evaluation of gender differences in the proposed study. However, if men and women are enrolled in numbers that reflect the gender proportion of the disease under study, it is not an automatic requirement for the study design to include statistical power for men and women separately.

It is important to note that regardless of the program relevance of the proposed research, the NIH/ADAMHA funding components will not fund/award grants or contracts that do not comply with this policy.

#### ADAMHA/NIH POLICY CONCERNING INCLUSION OF MINORITIES IN STUDY POPULATIONS

P.T. 34, FF; K.W. 1014002, 1014006

Alcohol, Drug Abuse, and Mental Health Administration  
National Institutes of Health

There are clear scientific and public health reasons for specifically including members of minority groups in study populations. Accordingly, the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) and the National Institutes of Health (NIH) require that applications/proposals for clinical research must give appropriate attention to inclusion of minorities in study populations, unless compelling scientific or other justification for not including minorities is provided. For the purpose of this policy, minorities include U.S. racial/ethnic minority populations (specifically: American Indians or Alaskan Natives, Asian/Pacific Islanders, Blacks, and Hispanics), and clinical research includes human studies of etiology, treatment, diagnosis, prevention, and epidemiology of diseases, disorders and conditions, including but not limited to clinical trials and research on health service and its impact on disease. Grants, cooperative agreements, and contracts are covered by this policy.

This statement is published as a reiteration and further interpretation of the existing ADAMHA/NIH policy concerning inclusion of minorities in study populations. This policy was previously published in the NIH Guide for Grants and Contracts on September 25, 1987, Vol. 16, No. 32; January 15, 1988, Vol. 17, No. 2; and June 16, 1989, Vol. 18, No. 21. While the focus of this policy is on inclusion of minorities in general population studies, ADAMHA and NIH also encourage attention to gaps in knowledge about specific U.S. racial/ethnic minorities and health problems that significantly affect them. Examples of these problems include but are not limited to: cancer, substance abuse, heart disease and stroke, homicide and accidents, diabetes, infant mortality, and acquired immunodeficiency syndrome (AIDS). Addressing these gaps may be appropriate justification for focusing a particular study on a single racial/ethnic group.

While this policy statement refers to inclusion of minorities, applicants are strongly reminded that a similar policy exists regarding women (NIH Guide for Grants and Contracts - October 24, 1986, Vol. 15, No. 22; January 23, 1987, Vol. 16, No. 3; January 15, 1988, Vol. 17, No. 2; June 16, 1989, Vol. 18, No. 21; and August 24, 1990, Vol. 19, No. 31). Both policies must be considered when preparing research applicants/proposals for submission to ADAMHA/NIH.

Applicants for grants/cooperative agreements and offerors for contracts should be aware that in attempting to include minority groups in a particular study, attention must be paid to research design and sample size issues. ADAMHA and NIH recognize that it may not be feasible or appropriate in all research projects to include representation of the full array of U.S. racial/ethnic minority populations. However, applicants/offerors are urged to assess carefully the feasibility of including the broadest possible representation of minority groups.

In all applications or proposals for clinical research, applicants must describe the anticipated race/ethnic composition of the study population. In conducting peer review for scientific and technical merit, members of Initial Review Groups (IRGs)/Technical Review Groups (TEGs) will be instructed to evaluate the appropriateness of the proposed minority composition:

- 1) If there is insufficient attention to inclusion of minorities in a study design AND this affects the potential to answer the scientific question(s) addressed, that will be considered a weakness or deficiency and must be reflected in the assigned score given to the application/proposal, and in the summary statement of the review.
- 2) However, if an applicant proposes that there is justification for conducting a study where there will be limited minority participation or inclusion of only one racial/ethnic group, a strong scientific rationale or other well-supported justification must be provided. The IRG/TEG will be instructed to evaluate the merit of such justifications. Appropriate justification will not adversely affect the assigned score. The ADAMHA/NIH will not fund/award such applications unless the justification is compelling.
- 3) For grant and cooperative agreement applications, if there is inadequate information on the study population to allow evaluation of the scientific question(s), the review will be deferred or the application returned.

It is important to note that the ADAMHA/NIH funding components will not fund/award grants, cooperative agreement, or contracts that do not comply with this policy.

**DRAFT**

**WORKING DOCUMENT**

ORWH Public Hearing Summary

July 9, 1993

---

**SUMMARY**

---

**Public Hearing on  
Recruitment and Retention  
of Women in Clinical Studies**

**National Institutes of Health  
Office of Research on  
Women's Health (ORWH)**

**Bethesda, Maryland  
March 29-30, 1993**

This document was prepared for  
the Office of Research on Women's Health  
National Institutes of Health  
by Prospect Associates  
Anne Brown Rodgers, Writer

## FORWARD

The Office of Research on Women's Health was established within the Office of the Director of the National Institutes of Health in September 1990. It was charged with the critical objectives of *giving a central NIH focus to women's health issues and of establishing a science base that will yield reliable diagnoses as well as effective treatment and prevention strategies for women.*

The Office of Research on Women's Health recognizes the enormous actual and potential contributions of women to the advancement of science, not only as full members of the scientific and research communities but also as participants in the clinical research process. We applaud recent efforts to increase the inclusion of women in clinical research studies but are concerned about the continuing underrepresentation of women in these trials.

It has become increasingly clear that we cannot continue to assume that risk factors for diseases are the same for women and men, nor can we assume that treatment and prevention interventions suitable for men are also applicable to women. The exclusion of women from important studies that examine lifestyle modifications, risk factor reductions, and intervention strategies for preventing morbidity and mortality from chronic diseases leaves a gap in knowledge regarding what behavioral changes are suitable and what interventions are appropriate in diagnosing, treating, and preventing diseases in women.

What can be done to bring more women into clinical research? How can we eliminate gaps in scientific knowledge resulting from the previous exclusion of women from clinical studies? The Office of Research on Women's Health is looking to the scientific and educational communities and to women's advocates to provide us with assistance in (a) convincing the research establishment of the benefits of having more women participate in clinical research studies and (b) formulating innovating strategies for overcoming the barriers women experience in participating in studies.

We appreciate the participation of all who have contributed to this process.

Vivian W. Pinn, M.D.  
Director  
Office of Research on Women's Health  
National Institutes of Health

## CONTENTS

1 INTRODUCTION

3 OPENING REMARKS

Vivian W. Pinn, M.D., Director, Office of Research on Women's Health, National Institutes of Health

7 REMARKS

Antonia C. Novello, M.D., M.P.H., Surgeon General, Public Health Service

13 REMARKS

Dianne Murphy, M.D., Assistant Director for Medical Affairs, Division of Anti-Viral Drug Products, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

15 SUMMARY OF ISSUES AND RECOMMENDATIONS

19 ISSUES AND RECOMMENDATIONS

19 ISSUE 1: Regulatory and Legal Issues

*Barriers*  
*Recommendations*

22 ISSUE 2: Cost and Insurance Issues

*Barriers*  
*Recommendations*

24 ISSUE 3: Study Design and Research Staffing Issues

*Barriers*  
*Recommendations*

26 ISSUE 4: Perspectives of Potential Study Subjects

*Barriers*  
*Recommendations*

## INTRODUCTION

In recent years, the NIH and scientists, health care professionals, Congressional representatives, women's advocacy groups, and the public have become increasingly aware of the underrepresentation of women in clinical research. This has led to a greater interest in the inclusion of women in biobehavioral studies. Analysis of issues have contributed to enhanced efforts to recruit and retain women of diverse racial and ethnic groups and socioeconomic strata into clinical research.

To define and delineate barriers to the participation of women in clinical studies, the Office of Research on Women's Health (ORWH) held a Public Hearing on March 29-30, 1993, on the topic. In response to a *Federal Register* notice dated March 4, 1993, 39 individuals and representatives of organizations presented oral and submitted written testimony. An additional 19 submitted only written testimony. The testimonies identified barriers and offered recommendations related to the participation of women in clinical research.

Recommendations presented at the Public Hearing are being incorporated into the planning for the "Recruitment and Retention of Women in Clinical Studies" scientific meeting to be held July 12-13, 1993, in Bethesda, Maryland. The objectives of the meeting are to:

- Generate innovative recommendations for action.
- Develop strategies for enhancing the participation of women in clinical research and for improving the design of research studies.
- Highlight successful strategies for recruiting and retaining women in clinical studies.

This document summarizes testimony presented at the Public Hearing. In some instances, statements are paraphrased or synthesized to encompass several similar recommendations. This summary groups issues and recommendations into five main issues. The document represents the viewpoints of those who provided testimony and does not necessarily represent the views of the ORWH or NIH.

The emphasis in the summary on the concerns of women of diverse racial and ethnic groups and socioeconomic strata reflects the fact that one-third of the 58 testimony statements addressed issues of interest to this population. Presenters described social, economic, and health status factors of this population; the consequent need to include them in clinical studies; and the significant barriers affecting their participation in the studies.

A reference number is printed in brackets { } after those statements in which data are presented. This number refers to the number of the testimony as identified in the appendix of this document. An attempt was made to state each recommendation only once, although it should be noted that many of them were offered by multiple presenters.

**OPENING REMARKS  
PUBLIC HEARING  
RECRUITMENT AND RETENTION OF WOMEN IN CLINICAL STUDIES**

**29 March 1993**

**Vivian W. Pinn, M.D.  
Director  
Office of Research on Women's Health  
National Institutes of Health**

The Office of Research on Women's Health (ORWH) was founded in September, 1990 by Dr. William Raub, then Acting Director of the National Institutes of Health (NIH). The impetus for the establishment of this Office, within the Office of the Director of NIH, was a recognition resulting from a General Accounting Office Report in June of 1990 that NIH had not fully implemented its policy from 1986 encouraging the inclusion of women in clinical research.

Attention to the inclusion of women in clinical research has escalated into a far reaching priority not only for NIH, but also for members of Congress, the wider scientific community, and women's advocacy groups.

The 1985 Report of the Public Health Service Task Force on Women's Health Issues stated: "Biomedical and behavioral research should be expanded to ensure emphasis on conditions and diseases unique to, or more prevalent in, women in all age groups." Yet, only recently has the full implementation of this directive become a priority of the medical and scientific communities. And, this directive is central to the mandate for the Office of Research on Women's Health at NIH.

The ORWH has as its mandate to give a central NIH focus to women's health issues and to establish a science base that will permit reliable diagnoses, and effective treatment and prevention strategies for women.

The major objectives of our office are:

- 1) to develop an integrated strategy for increased research into diseases, disorders, and conditions that are unique to, more prevalent among, or more serious in women, or for which there are different risk factors of interventions for women than for men;
- 2) to ensure that women are appropriately represented in biomedical and biobehavioral research studies, especially clinical trials, that are supported by NIH;

facilitating these applications through the system while still keeping women's health, and that of any potential conceptus, at the forefront of their consideration.

But, there is a further need to address the recruitment of women into clinical studies, and to retain them throughout such research, if we are to fully address gaps in knowledge about women's health.

To assist us in this endeavor, we have formed a Planning Task Force on the Recruitment and Retention of Women in Clinical Studies. The Task Force has as its goals to:

1. Assess the experiences of clinical trials researchers, practitioners, and women participants in the recruitment, retention, adherence and compliance of women in clinical research;
2. Identify issues and barriers unique to the recruitment and retention of women of all races involved in different types of studies, with a particular emphasis on clinical trials;
3. Review models and approaches that enhance the participation of women in clinical research; and
4. Develop a summary report with recommendations for improving access, participation, and retention of women from all racial/ethnic groups and socioeconomic strata in clinical research.

This Public Hearing has been convened to provide guidance and assistance to address the inclusion of women in clinical research through proven and improved methods for the recruitment and retention of women in biomedical and biobehavioral research and to eliminate barriers to their inclusion.

Recommendations from this Planning Task Force will be submitted to the Director of the National Institutes of Health and made available to the scientific and lay communities.

We appreciate your participation in this process, and look forward to your recommendations and expertise.

**REMARKS  
PUBLIC HEARING  
RECRUITMENT AND RETENTION OF WOMEN IN CLINICAL STUDIES**

**29 March 1993**

**Antonia C. Novello, M.D., M.P.H.  
Surgeon General  
Public Health Service  
Department of Health and Human Services**

We have made progress in the past few year, thanks to all the women in biomedical careers and the activists who have insisted on equality, at least some equality for women in biomedical research. But colleagues, we haven't done *enough*.

The Women's Health Initiative is a clinical trial whose time has come. But other trials equally important aren't even on the "drawing boards," and they are needed as well.

This country is far more diverse than we can imagine and needs far more prevention and health care than what we have now. Let's not forget that this is a country of 250 million people, more than half of them women. More than 15 percent of our population are African-American, more than 9 percent Hispanic, 3 percent Asian Pacific Islander, 1 percent Native Americans, and almost one in five of our citizens is under 12 years of age; more than 1 in 10 is over 65. We have to shape our research and our thinking to meet these demographic realities; otherwise, we will be practicing and planning in a vacuum.

I think we must guard against refighting old battles. We have won the battle that women's diseases must be studied. We've whipped all the dead horses about clinical trials, about aging, aspirin, beta carotene and the like--trials well known to have excluded women. We have embarrassed some scientists and some institutions and raised consciousness of the neglect of women's health issues. Now we must polish our act and come up with some new tactics and strategies for action.

We need to be in total command of the relevant facts. And we must not be bought off by a few new clinical trials or old ones being repackaged with new "women's this or that" names. We must really "get our act together," and for that, this hearing is a welcome and well planned first step.

We not only need to *look at the diseases that ravage and shorten the lives of women, but we must find* how to get women into clinical trials and look at the subgroups most severely affected by diseases as well. We need to look at HIV, AIDS, heart attacks, stroke, cancer--especially breast, cervical, and lung cancer--osteoporosis, Alzheimer's disease. We need to

Are there other drugs or therapies being prescribed for women, still unstudied and affecting women and their children yet to be born? Are we still going to continue to study women as mothers and not *women as women*? Let's make it a point to find these answers.

At the same time, in our quest for biotechnology, let us not forget for whom studies are intended. We need to be utterly practical and realistic and never think that "women" comprise a unified group. Social issues affect women in devastating ways. The woman's role in the family, the pressures on her to maintain discretion and confidentiality, the role she plays to safeguard culture, her responsibilities for her children, her financial and emotional dependence on a man or on herself--these issues all enter into her ability to consider enrollment in clinical trials and on using health care at all.

Although there is a tremendous need for educating women, there is also a tremendous need for educating health care professionals regarding women's concerns as well. The examples that come to mind are gynecologic infections--such as candidiasis and pelvic inflammatory disease and human papillomavirus, genital ulcers, cervical dysplasias, and genital warts.

We all know that regarding HIV, women have been so underdiagnosed that many first learned of their own HIV infection when their children were diagnosed.

Let me talk to you now about clinical trials and AIDS. As Surgeon General, I have seen the devastation of AIDS. Today, most women with AIDS are either African-American (53 percent) or Latinos (21 percent). Between 30,000 to 40,000 African-American or Latino children will lose both parents to AIDS between 1995 and the year 2000. About 71 percent of the women diagnosed with AIDS have been sexual partners of intravenous drug users or have injected drugs themselves.

In the presence of such data, why is it that so many people with AIDS have either been excluded or not included in the services that do exist?

Allow me to tell you why. Women have told me that:

- Women are discriminated against because of their childbearing potential.
- Women mistrust the system--after all, clinical trials have been designed by men for men, and those men have never "walked in the shoes" of a woman.

Women and their providers have told me that:

- Clinics are not open at the times women can go. They are not found in the places women can reach. They are on floors too high for the women who are sick to climb stairs when there are no elevators. And the clinics are tended by people they can't understand.

- Women have told me that in some cultures, they must have permission from their husbands in order to participate in a clinical trial. In the absence of this approval, they are unable to comply.
- Women have told me that there are no case workers outside of the clinic to explain why the trial is important in a sensitive, simple human way early on in the recruiting process.

In addition to addressing these problems, the women have recommended that:

- Once information about clinical trials is available (and is linguistically and culturally appropriate), that information can then be widely disseminated.
- The care of children is linked to the care of women and linked to the care of the family. This reality must dictate the nature of the clinical trial and how it is administered.

Obviously, we need to know more about the biology of pregnant women with HIV and more about how the unborn child is affected by antiretroviral drugs. It may make researchers feel more comfortable to exclude pregnant women from clinical trials, but at the same time it may rob women and children of important therapeutics. We need rapid progress on tests to determine if a child is infected and vaccines to protect the baby as well as the mother.

Currently, when information about HIV-related clinical trials is needed (both federally and non-federally funded), people are instructed to call the AIDS Clinical Trials Information Service. The HIV/AIDS clinical trials are usually listed by "adult" and "children." Much searching is needed to find out how many trials enroll *women*. I think in all clinical trials, not just AIDS trials, we have to press the research community to make this information easily and readily available to all of us.

In addition, the concepts of safer sex have been predicated on partners with equality. I ask you, how many women can interrogate partners about their sexual histories or sexual patterns today, and then make purely intellectual decisions about how, when, and if sex should occur? I think we've been highly unrealistic here, and unintentionally, we have been setting women up. The woman's role in making such decisions depends on her value to her partner, their relationship, her value to her family, her value to her culture, and her value to her community, among other complex mitigating factors.

We cannot continue to ask women to make decisions that rob them of their emotional and financial security. We still have a great deal of work to do in the area of safer sexual practices.

We need to consider all the socioeconomic, legal, and ethical issues that impinge on the health status of women. But we should recognize *what a woman can do versus what we want*

**REMARKS  
PUBLIC HEARING  
RECRUITMENT AND RETENTION OF WOMEN IN CLINICAL STUDIES**

**29 March 1993**

**Dianne Murphy, M.D.  
Assistant Director for Medical Affairs  
Division of Anti-Viral Drug Products  
Center for Drug Evaluation and Research  
U.S. Food and Drug Administration**

Good morning.

I am Dr. Dianne Murphy, Assistant Director for Medical Affairs in the Division of Anti-Viral Drug Products, at the Center for Drug Evaluation and Research, U.S. Food and Drug Administration.

I am here today representing Dr. David Kessler, Commissioner of Food and Drugs, Dr. Ruth Merkatz, the Commissioner's Special Assistant for Women's Health, and the FDA Working Group on Women in Clinical Trials.

Like our colleagues at NIH, we at the FDA have been concerned about the issues surrounding the inclusion of women in clinical trials.

During the past several years, a number of events have helped to focus attention on women's health issues. To name just a few, a Public Health Service task force established in 1985 concluded that women were disadvantaged both in terms of health care and access to biomedical and behavioral research. The PHS task force recommended that steps be taken to address the overall health needs of women--from bench to bedside. In the 1980's and early 1990's, the Congressional Women's Caucus was formed on the Hill, the Women's Health Equity Act was introduced in the U.S. Congress, an increasing focus on women's health occurred at NIH, and advocacy organizations made their influence felt in promoting a national women's health research agenda.

Over the past decade at FDA there has been a great deal of internal discussion and analyses focused on the appropriate inclusion of women in clinical trials. In addition, we have sought guidance and input externally by co-sponsoring or participating in a number of scientific conferences to examine relevant issues: The Institute of Medicine's March 1991, planning meeting on the inclusion of women in clinical trials; the Institute of Medicine's Drug Forum on Women and Drug Development in June of 1992; and the Food and Drug Law Institute's Workshop on Women in Clinical Trials of FDA-Regulated Products, in October 1992.

## SUMMARY OF ISSUES AND RECOMMENDATIONS

Currently, women constitute approximately 51 percent of the U.S. population. On average, women also live 7.5 years longer than men. The elderly population--those over 65--is growing rapidly, and among those, the over-85 age group is growing the most rapidly. Women are the majority of this population, and they are more likely to spend their later years with multiple chronic health conditions. {55}

Heart disease alone exacts an enormous toll in women, equivalent in scope to the toll in men:

- More than 244,000 women die of heart attacks each year and more than 90,000 die from stroke. Coronary heart disease and stroke rank first and third as causes of death for middle-aged and older women. With each decade of life, the death rate from coronary heart disease increases threefold to fourfold. {54}

Many other diseases also place a heavy burden of death and disability on women:

- Rheumatoid arthritis affects women three times as frequently as men. {52}
- Systemic lupus erythematosus occurs nine times more often in women than in men. {52}
- It is estimated that 2.6 million women live with breast cancer--1 million who are aware of their disease; 1.6 million who are not yet diagnosed. In 1993 it is estimated that there will be 185,000 newly diagnosed cases and 46,000 deaths. {33}
- Osteoporosis affects one-third to one-half of all women after menopause. {52}
- At least 80 percent of the patients with scleroderma are women. {52}
- Genital herpes or human papilloma virus infections affect 15 to 20 million women. {56}

Perhaps not surprisingly, women rely much more heavily on the medical system than do men. Approximately two-thirds of all visits to doctors and pharmacists are made by women {44}, and studies document greater health-seeking behavior in general by women as compared with men. {33}

In the search for greater understanding of the etiology, diagnosis, treatment, and prevention of disease, numerous clinical research studies have been undertaken using human subjects. Yet, women have traditionally been underrepresented or excluded from many clinical studies.

- A growing body of evidence showing that women have been systematically underrepresented in clinical research, for example, the 1992 General Accounting Office report, and that they, in fact, do not refuse to participate in or drop out of studies in any greater numbers than men.{31,59}
- Growing appreciation by the scientific community of the need to recruit and retain women in clinical studies, particularly low-income and minority women.

Despite this changing environment, steps still need to be taken to achieve parity between men and women in clinical studies. During the Public Hearing, the issues involved in recruiting and retaining women fell into five major areas:

- Regulatory and legal issues.
- Cost and insurance issues.
- Study design and research staffing issues.
- Issues related to the perspectives of potential study subjects.
- Issues related to recruiting and retaining low-income and minority women.

Numerous recommendations were made and can also be grouped:

- Recommendations about changes to NIH policies to require inclusion of women in studies; changes in incentives for drug manufacturers were also suggested.
- Recommendations regarding changes in health insurance policies so that participation in research protocols is covered.
- Recommendations regarding the design of research protocols and materials, advancement of women and minorities in clinical research positions, and staffing of research studies with personnel who are bilingual and culturally sensitive.
- Recommendations regarding the needs, concerns, and characteristics of female study participants.

There was also a recognition that efforts to recruit and retain women in clinical research will result in greatly increased costs {40} because of the need for:

- Much larger sample sizes.
- Extended, more flexible research facility hours.

## ISSUES AND RECOMMENDATIONS

### ISSUE 1: Regulatory and Legal Issues

#### *Barriers {18}*

Key players who decide what role women are to have in any given clinical study include:

- Study's sponsors
- Research institutions
- Federal regulators
- Women's advocates
- Potential female subjects
- Public officials
- Investigators

Some groups have used specific concerns as a basis for their policies regarding exclusion of premenopausal women in clinical research. Two of these concerns focus on:

- Possible harm to a fetus caused by the experimental treatment or drug.
- Possible harm to a female subject's reproductive potential.

In 1991, NIH issued strengthened guidelines on "Inclusion of Minorities and Women in Study Populations." Although these guidelines strongly encourage applicants for research grants to include women, they list several permissible justifications for excluding them. Among these justifications is a provision stating that:

- ". . .the experimental procedures/treatments present unacceptable risks for women of child-bearing age. . ."

By not defining an "unacceptable risk," the guidelines allow a trial sponsor to cite any uncertainty about the treatment or drug's effect on fertility as meeting the exclusion justification.

Another barrier thought to be presented by drug manufacturers who, in some instances, determine that costs associated with including women in clinical trials outweigh any perceived benefits is:

- Liability for *in utero* injuries is a real possibility. The consent form a women signs waiving the right to sue for any injuries suffered applies only to herself, not to any fetus conceived during the study.

- NIH should award "bonus points" to proposals that suggest particularly effective or creative strategies for recruiting and retaining women. {39}
- Increase efforts to attract and fund research proposals of qualified women researchers. {35}

### ***Recommendations***

A number of participants at the Hearing were concerned about this issue and offered specific recommendations:

- Cover subjects' costs associated with participation in a clinical trial. {24,33,39}
- Clinical studies should meet the following criteria if expenses are to be covered {29}:
  - 1) The treatment under study is therapeutic;
  - 2) The treatment is a part of a trial approved by NIH, an NIH cooperative group, the FDA, Veterans Administration (VA), or a "qualified non-governmental entity";
  - 3) The proposed therapy is reviewed and approved by a qualified institutional review board (IRB);
  - 4) The facility and personnel are adequate and qualified;
  - 5) There is no available noninvestigational therapy that is superior to the protocol treatment; and
  - 6) Available data suggest that the treatment will be as efficacious as noninvestigational therapy.
- The President's Health Care Reform Task Force should consider this issue and include some form of coverage in the minimum health care benefits package for all Americans. {24}
- NIH institutes and professional medical associations should produce guidelines for clinicians on supporting their medical decisions to third-party payers. {24}
- NIH-sponsored clinical trials should require the designation of an individual to assist patients with insurance preapproval and appeal processes. {24}

- Determine gender representation in clinical studies based on the base rates of the illness by sex or by rates of morbidity or mortality for the illness by sex. {36}
- Encourage meta-analyses and/or pooled analyses on existing data sets of women and minorities that are too small to be analyzed individually in an economical fashion. {53}
- Include women in the process of writing of proposals, research protocols, consent forms, and materials to be used with patients. {12}
- Include groups or individuals who represent the study population in planning the study in order to ensure a mutually acceptable research design. {9}
- Include, if possible, the subject's own doctor in the study so that the bonding achieved in the regular doctor-patient relationship can be carried over to the research setting as well. {6}
- Design clinical studies to accommodate the menstrual and hormonal cycles of subjects by including the need for extra visits and flexible scheduling in the protocol. {26}
- Increase the numbers of clinical research staff--at both the junior and senior level--who are similar to the study population in demographics and ethnicity. {43}
- Ensure that the staff members who work with study populations are bilingual and bicultural, if necessary. {10,30}
- Encourage the full participation of junior research staff members, who are currently more likely to be the bilingual and bicultural staff members, in the planning and execution of clinical studies. {17}
- Ensure that staff are sensitive to the concerns, questions, and fears of female study subjects. {30,32,35,38,43}

- Encourage closer relationships between local health care providers, universities, and research centers, particularly in minority communities, so that primary patient care and clinical research can be more closely integrated (that is, the cancer care and research model) and information about clinical trials can be disseminated. {29}

The following recommendations were directed to NIH and the ORWH:

- NIH should maintain a register of ongoing clinical trials that would be accessible to practitioners and the public. {33}
- Research, including focus group studies, on barriers to participation and strategies for overcoming such barriers should be funded. {34,59}
- Methods for tracking and monitoring enrollment and retention of women in clinical trials should be funded. {14}
- The ORWH should convene a Task Force to study the adaptation for medical schools of the American Medical Women's Association's *Advanced Curriculum on Women's Health* to assist physicians in providing a more sensitive and appropriate approach to women's unique health problems. {46}

- Teenage Hispanic women have the highest fertility rate in the Nation. {17,19\*}
- They also experience very high rates of sexually transmitted diseases, HIV infection, and chronic diseases, such as diabetes and hypertension. {17,19\*}

A second distinct population of special concern is migrant farmworkers {15}:

- There are 3.5 to 5 million men, women, and children who work as migrant and seasonal farmworkers.
- The bulk of these workers--85%--are ethnic minorities. Most are Hispanic, but there are also Jamaicans, African-Americans, and Haitians.
- Many experience English literacy and fluency difficulties. A 1989 study reported that 9 out of 10 migrant workers in Wisconsin reported Spanish as their primary language, one-half spoke no English, and one out of four had not completed the fifth grade (a measure of functional literacy).
- A significant number experience stringent working conditions, inadequate housing, and poor nutrition.
- A 1989 study reported the median family income to be \$7,330, supporting an average of 5.2 persons per family.
- They live an extremely mobile lifestyle and therefore have limited access to affordable health care, comprehensive health insurance, and other social support services.
- They have the highest infectious disease rate in the United States, high rates of chronic disease, and their risk of HIV infection is 10 times the national average.
- A recent Centers for Disease Control and Prevention study indicated that as many as 44% of migrant farmworkers test positive on TB skin tests.

There are multiple barriers to recruiting and retaining poor women of color to clinical studies. The barriers are economic, cultural, social, and psychological. {32} These women:

- Lack awareness about available studies. {10}
- Often do not understand the purpose of a proposed clinical study or what benefits might result to them personally or to their community from their participation. {5}
- Mistrust researchers, and the medical establishment in general, because of the gaps in gender, ethnicity, and social and educational backgrounds. {30,32}

- Ensure that study subjects understand the purpose of the study and understand the benefit to them personally and to their community. Help them to develop a pride of ownership in the study. {10}
- Include minorities and women in both senior and junior positions on the research team. {17,43}
- Develop specific ethnic and socioeconomic status indicators to identify accurately Hispanic women, especially distinct Hispanic subpopulations. {14,19\*}
- Increase the career opportunities for female and minority scientists. {30}
- Ensure that study personnel who work with subjects are bicultural/bilingual and sensitive to subjects' concerns and fears. A mutual relationship of trust, respect, and honesty is crucial. {30,32,38,43}
- As the study is implemented, ensure that the subjects' sense of their importance to the study and their personal worth is continually reinforced. {32}
- Provide transportation, child care, and expanded, flexible scheduling of visits to research sites. {21}
- Combine elements of the study in one site so as to increase convenience for subjects. {10,21}
- Conduct aspects of the study in the community itself, for example, in the church social hall, community health care center, or migrant camp. {15}
- Provide culturally sensitive and appropriate incentives for participation. {4,30}
- Provide financial coverage for participation in the study. {24,41}
- Develop partnerships among communities, their representatives, and research centers. {22}
- Recruit the family, not just the individual, to participate.
- Build on the stronger concern that many of these subjects have for their children's health rather than for their own. If their children are enrolled in a study, they may be more likely to participate in one themselves. {21}
- Provide followup to participants and their community once the study is completed by sharing the results and benefits. {22,43}

## APPENDIX

### PARTICIPANTS

#### Speakers

Vivian W. Pinn, M.D.  
Director  
Office of Research on Women's Health

Antonia C. Novello, M.D., M.P.H.  
Surgeon General, Public Health Service

Dianne Murphy, M.D., F.A.A.P.  
Assistant Director for Medical Affairs  
Food and Drug Administration

Shiriki K. Kumanyika, Ph.D.  
Associate Professor and  
Associate Director for  
Epidemiology  
The Pennsylvania State University  
College of Medicine

#### Presented Testimony

1. Nada Logan Stotland, M.D.  
American Psychiatric Association
2. Randy E. Stevens, M.D.  
Clinical Assistant Professor  
Division of Radiation Oncology  
New York University  
Medical Center
3. Ciro V. Sumaya, M.D.,  
M.P.H.T.M.  
San Antonio Hispanic  
Health Initiative
4. Paula S. Gomez  
Executive Director  
Brownsville Community  
Health Center
5. Amelie G. Ramirez, Dr.Ph.H.  
South Texas Health  
Research Center
6. Mohammed A. Bey, M.D.  
Tulane/LSU AIDS Clinical  
Trials Unit
7. Geraldine Schechter, M.D.  
Chief of Hematology  
Washington Veterans Affairs  
Medical Center
9. Wesley Segawa  
President, Advisory Board  
Malama Na Wahine Hapai Project
10. Lee Lee Doyle, Ph.D.  
Associate Dean for Continuing  
Education and Professor of  
Obstetrics and Gynecology  
University of Arkansas for  
Medical Sciences

28. Barbara Brookmyer  
Legislative Affairs Director  
American Medical Student  
Association
29. Stacey Beckhardt  
Director  
Government Relations  
American Society of Clinical  
Oncology
30. John D. Rugh, Ph.D.  
Professor and Director  
of Research  
Dental School  
The University of Texas  
Health Science Center  
at San Antonio
31. Maria Bustillo, M.D.  
Board Member  
Society for the Advancement  
of Women's Health Research
32. Jennifer Wild, Ed.D.  
Evaluation Researcher  
NOVA Research Company
33. Kay Dickersin  
Research Task Force Co-Chair  
National Breast Cancer Coalition
34. Susan Persons, M.A.  
Associate Director of  
Governmental Relations  
Consortium of Social  
Science Associations
35. Catherine J. Didion  
Executive Director  
Association for Women in Science
36. Jean A. Hamilton, M.D.  
American Medical Women's  
Association
37. Joyce Korvick, M.D.  
Medical Officer  
National Institute of Allergy  
and Infectious Diseases  
AIDS Clinical Trials Group
38. Sandra W. Wearins  
Health Educator  
Baltimore American  
Indian Center
39. Cindy Pearson  
Program Director  
National Women's Health Network
40. Naomi K. Fukagawa, M.D., PH.D.  
The Rockefeller University  
Hospital  
NIH General Clinical  
Research Centers
41. Barbara Brown  
Virginia Breast Cancer  
Foundation
42. Palma E. Formica, M.D.  
Member, Board of Trustees  
American Medical Association
43. Aida L. Giachello, Ph.D.  
Assistant Professor  
The University of Illinois  
at Chicago  
Jane Addams College  
of Social Work

---

## **Clinton Presidential Records Digital Records Marker**

---

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a publication.

---

Publications have not been scanned in their entirety for the purpose of digitization. To see the full publication please search online or visit the Clinton Presidential Library's Research Room.

---



REPORT OF THE  
National Institutes  
of Health:  
Opportunities for  
Research on  
Women's Health

September 4-6, 1991  
Hunt Valley, Maryland

Summary Report

Office of Research on Women's Health  
Office of the Director  
National Institutes of Health

