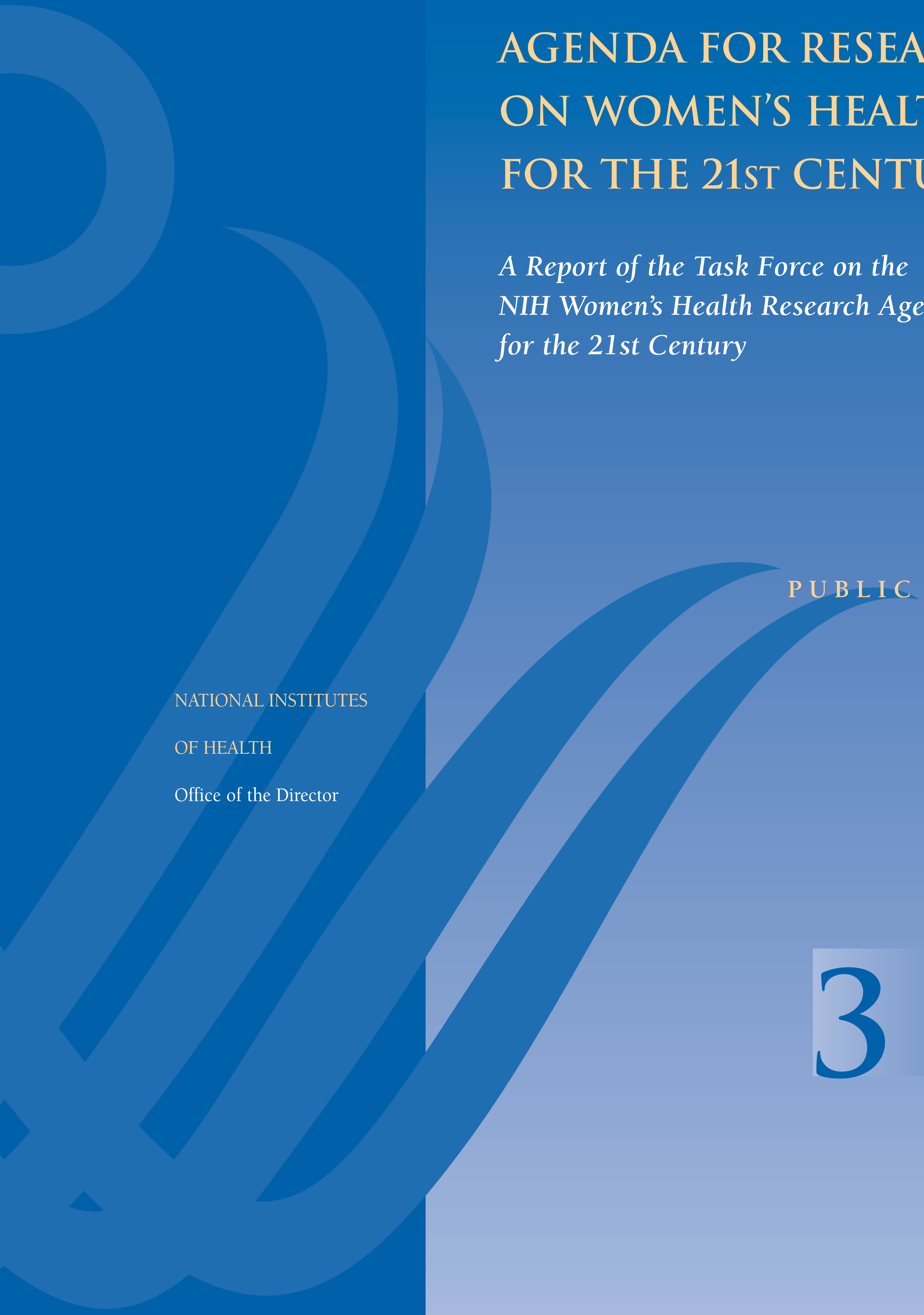

AGENDA FOR RESEARCH ON WOMEN'S HEALTH FOR THE 21ST CENTURY

A Report of the Task Force on the
NIH Women's Health Research Agenda
for the 21st Century

PUBLIC TESTIMONY

Bethesda, Maryland
November 1997

3 VOLUME

NATIONAL INSTITUTES
OF HEALTH
Office of the Director

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PREFACE

In September 1991, the Office of Research on Women's Health (ORWH) of the National Institutes of Health convened a meeting in Hunt Valley, Maryland, to assess the state of the science and to develop an agenda to guide women's health research in the coming decade. The report generated by that meeting, *Report of the National Institutes of Health: Opportunities for Research on Women's Health,* set forth the research recommendations developed by working groups focused on the major divisions of a woman's life span and on scientific issues, diseases, and conditions that affect women's health. That report has served as the broad blueprint for women's health research at the National Institutes of Health.

Now, several years later, science has continued to expand the parameters of knowledge, generating additional questions and pursuits. New public health issues and challenges emerging in the field of women's health have demonstrated a need to re-examine and update the national agenda for women's health research. To advance this concept, ORWH began a process to identify continuing or emerging gaps in knowledge and to provide research-based strategies that will result in improved health status for all women. This process included holding a series of public hearings and scientific workshops sponsored by ORWH.

The first regional conference was hosted by the University of Pennsylvania School of Medicine and Allegheny University of the Health Sciences in Philadelphia in September 1996. It focused on sex and gender issues and their impact on research in women's health; gaps in knowledge about women's health; and successful models for the recruitment, retention, re-entry, and advancement of women in biomedical careers. The second regional meeting — hosted by the Tulane University Medical Center, Xavier University of Louisiana, and Meharry Medical College — was held in New Orleans in June 1997. The New Orleans meeting focused on sex and gender perspectives for women's health. The third in the series was held in Santa Fe, New Mexico, in July 1997, and was hosted by the University of New Mexico School of Medicine and the University of Iowa College of Pharmacy. The Santa Fe meeting focused on differences among populations of women, factors that contribute to differences in their health status and health outcomes, and career issues for special populations of women. The final national meeting, convened in Bethesda, Maryland, in November 1997, and subtitled, "Putting It All Together, The Agenda for Research on Women's Health for the 21st Century," reviewed the deliberations and recommendations from the three regional public hearings and scientific workshops, and developed the recommendations and priorities for updating the women's health research agenda. All the meetings included an opportunity for public testimony as well as formal scientific sessions.

The contents of this volume represent the full text of the public testimony presented at the Bethesda national meeting. The public testimony was delivered by individuals representing themselves or organizations interested in biomedical and behavioral research on women's health. They included practitioners interested in women's health; representatives from the scientific, professional, and women's health organizations; and women's health advocates. They have all participated in the process of revising and updating the agenda for women's health research at NIH, and many continue to provide guidance and expertise to ORWH.

Additional volumes in this series consist of scientific workshop reports, presentations by distinguished scientists, and public testimony presented at the regional meetings in Philadelphia, Pennsylvania; New Orleans, Louisiana; Santa Fe, New Mexico; and Bethesda, Maryland.

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ACKNOWLEDGMENTS

The Office of Research on Women's Health wishes to acknowledge the many people who served on committees and working groups and who contributed their collective expertise to the creation of the Agenda for Research on Women's Health for the 21st Century. ORWH wishes to thank:

- *Ruth L. Kirschstein, M.D., Deputy Director, National Institutes of Health*
- *Task Force on the NIH Women's Health Research Agenda for the 21st Century*
- *Advisory Committee on Research on Women's Health*
- *Coordinating Committee on Research on Women's Health*
- *Working Group Cochairs of the Meetings of Beyond Hunt Valley: Research on Women's Health for the 21st Century*

  Philadelphia, Pennsylvania
  New Orleans, Louisiana
  Santa Fe, New Mexico
  Bethesda, Maryland

- *More than 1,500 men and women who participated in the Public Hearings and Scientific Workshops.*

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INTRODUCTION TO THE PUBLIC TESTIMONY

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BEYOND HUNT VALLEY: RESEARCH ON WOMEN'S HEALTH FOR THE 21ST CENTURY

This Public Hearing, sponsored by the Office of Research on Women's Health (ORWH), was held in conjunction with a series of landmark scientific workshops designed to provide recommendations for the National Institutes of Health (NIH) agenda for research on women's health for the 21st century.

ORWH was established within the Office of the Director of NIH in September 1990, by Dr. William Raub, then Acting Director of NIH. The Office was charged with the important role of providing a central focus for NIH-supported biomedical and behavioral research related to women's health issues, and with "...assuring that research conducted and supported by NIH appropriately addresses issues regarding women's health and that there is appropriate participation of women in clinical trials."

The major mission of ORWH is:

- To strengthen, develop, and increase research into diseases, disorders, and conditions that affect women, determining gaps in knowledge about such conditions and diseases, and then establish a national research agenda for NIH for future directions in women's health research;
- To ensure that women are appropriately represented in biomedical and biobehavioral research studies, especially clinical trials, that are supported by NIH; and,
- To direct initiatives to increase the numbers of women who are participants in biomedical research careers.

ORWH does not function in isolation. We look to the broader community of scientists, health care providers, and women's health advocates across the United States, and beyond, to ensure that the research we foster and support and our priorities for research reflect the needs and concerns of the women's health community. We rely upon members of the women's health community to provide direction for us in addressing their needs and concerns through research and in pursuing the scientific knowledge that may permit the medical community to diagnose, treat, and prevent the adverse health conditions and diseases that affect women across the life span. One of the most effective ways for us to accomplish this is through public hearings.

From the time of the establishment of ORWH and the structuring of our first NIH research agenda on women's health, we have utilized public hearings to receive testimony from public representatives, and to build upon that testimony through scientific meetings and workshops to construct priorities for women's health research. The report of our first undertaking, *National Institutes of Health: Opportunities for Research on Women's Health*, is based upon public testimony and a scientific meeting held in Hunt Valley, Maryland in 1991.

Recognizing that there has been progress in addressing women's health through research, but also recognizing that the extensive focus on women's health has brought forward new concepts and scientific questions upon which we need to focus, we began this process to reevaluate the foundation for our research agenda and to reformulate priorities as we go forward into the next century. Therefore, we began a process of revisiting our original agenda, based on the report, *National Institutes of Health: Opportunities for Research* *on Women's Health*, often referred to as the "Hunt Valley Report," through a series of public hearings and scientific meetings, of which this is the final, and which we have called "Beyond Hunt Valley: Research on Women's Health for the 21st Century."

We began by establishing a Task Force on the NIH Women's Health Research Agenda for the 21st Century to assist and guide us, and our Congressionally mandated Advisory Committee on Research on Women's Health, through this process.

At our first regional meeting, held in Philadelphia in September 1996, we began the process of reexamining our research agenda to ensure that it is relevant as we move towards the next century. We held the first Public Hearing at that time. During the New Orleans Public Hearing and Scientific Workshop, in June 1997, we invited discussion on aspects of the research agenda based upon sex and gender issues, e.g., physiological, psychosocial, and pharmacologic differences between women and men. The third regional meeting, held in Santa Fe, was designed to focus on factors that contribute to differences in health status and health outcomes among different populations of women, and career issues for special populations of women in science.

Finally, during the national meeting in Bethesda, we held our concluding public hearing of this series and brought together the results of all three regional meetings in this workshop. During the Bethesda Public Hearing, we specifically requested testimony addressing:

- State of knowledge and continuing or emerging gaps in knowledge about women's health across the life span;
- Sex/gender differences in health and disease;
- Factors that influence differences in health status and health outcomes between different populations of women;
- New priorities for research on women's health; and
- Career issues for women scientists: overcoming barriers and achieving success in biomedical careers.

NIH is the primary agency within the Department of Health and Human Services that performs, promotes, and supports biomedical and behavioral research. Therefore, the focus of the public hearings was on research that should be initiated, expanded, or enhanced to add to our existing knowledge about women's health, as well as to consider innovative programmatic and collaborative efforts appropriate for NIH, to promote career opportunities for research on women's health, and especially that of women in biomedical careers.

The testimony from all the meetings was received and reviewed by our Task Force on the NIH Women's Health Research Agenda for the 21st Century. The resulting information was used to guide the Task Force in developing recommendations for the NIH research agenda for the beginning of the 21st century. We are fortunate to have members of the NIH scientific community, as well as women's health advocates, scientists, and health professionals from across the country serving as members of this important Task Force.

On behalf of NIH, and specifically ORWH, we thank all the participants who presented public testimony for your role in reassessing our research agenda so that we can continue to make progress in women's health status as we enter the next century. We are very appreciative of your efforts to share your wisdom and concerns during our consideration of issues of importance for the NIH research agenda on women's health for the 21st century.

PUBLIC TESTIMONY
BETHESDA, MARYLAND
NOVEMBER 17, 1997

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Obstetric and Neonatal Nurses

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I am privileged to present this testimony today on behalf of the National Athletic Trainers Association (NATA). The NATA, founded in 1950, is an allied health care professional association recognized by the American Medical Association. It is made up of over 23,000 members worldwide.[1] The certified athletic trainer is the recognized professional member of this Association. The mission of NATA, and goal of the certified athletic trainer, is to provide health and injury care to physically active people of all ages through the prevention, treatment, and rehabilitation of acute and chronic activity-related injury and illness. Certified athletic trainers have a long history of demonstrating their effectiveness in providing health and injury care to elite college and professional sports athletes. They have applied these same effective skills to physically active people of all ages and, as verified by current national outcomes data, have achieved the same impressive results.[2] Simply put, certified athletic trainers are the recognized experts in effectively preventing and managing health and injury concerns of physically active people.

Historically, NATA has clearly demonstrated its commitment and attentiveness to the specific needs and concerns of the female population. Since the early 1970s, female certified athletic trainers have played a significant role in the development of NATA and the profession of athletic training, and have provided health and injury care for physically active females of all ages. Currently, over 50 percent of the membership of NATA is female. Women are represented on all major NATA committees, chair several of these committees, and are represented on the Board of Directors. The Executive Director is female, as well as is the current President of the NATA Research and Education Foundation. The NATA Research and Education Foundation has awarded over $500,000 in grants to fund research addressing issues affecting physically active people and has specifically awarded grants to female scientists serving as principle investigators pursuing research issues of critical importance to physically active females such as anterior cruciate ligament injuries and eating disorders.[3] It is with a deep personal and professional commitment for the issues before us that I represent NATA in addressing my comments to you today.

Physical Activity Participation Rates

Physically active females have been emerging as a dramatically expanding population over recent years. The influence of gender-equity legislation in the form of Title IX, and its subsequent enactment, rapidly expanded opportunities for girls and women in organized athletic experiences, demonstrated by a dramatic increase in numbers of participants.[4–6] The varied, multiple benefits of this participation in interscholastic and intercollegiate sports has been well documented.[7–9] In 1990, 91 percent of women surveyed by the Women's Sports Foundation believed that it was important for girls to participate in organized sports while growing up.[10]

Women's participation in physical activity in general has increased dramatically. Current data indicate that women are more likely than men to be frequent participants in physical activity, and a greater percentage of women participate on a more frequent basis than men.[5] Physically active women have indicated that they are willing to make the effort to be active because of the physical and mental benefits realized.[11] Research has shown that those realized benefits valued the most are cardiovascular fitness, improved muscle tone, weight maintenance, and improved self image.[12] Evidence suggests that these benefits are realized throughout the life span. The recognition of the benefits of exercise, and the motivation to continue the pattern of physical activity initiated earlier in life, has prompted a large number of women to remain, as well as become, physically active in their 40s and 50s.[13] More women over the age of 60 are physically active and a recent research study indicated that they were less stressed and happier than those who were of younger age.[11] Their physical activity was cited as a major reason for believing they were in better health than their peers.[14]

Benefits of Physical Activity

The positive effects of physical exercise in relation to the prevention and management of cardiovascular disease (a leading cause of death in women), osteoporosis, weight control, mental health, increased longevity, and an enhanced quality of life for women of all ages has been, and will continue with greater frequency to be well, documented.[15,16] Research has shown that similar patterns of physiologic and muscular adaptation to exercise occur between males and females, resulting in the realization of similar benefit.[17] The positive effects of physical activity, long emphasized and recognized by the male population, can certainly now be applied to the female population.

Physical activity throughout the life span not only demonstrates positive physical and mental outcomes and an improved quality of life but, in addition, potentially has the ability to reduce health care dollar expenditures by decreasing the need for consumer utilization of health care services. Improving the health status of our population, through physical activity, could very well demonstrate significant economic benefits.

Injury Risks

Physical activity does, however, by its inherent nature, expose participants to potential injury risks. Predominately musculoskeletal in nature, these injuries may be both acute and chronic, resulting from direct traumatic mechanisms and/or repetitive motion activities. The pre-eminent musculoskeletal scientists and practitioners testifying here today are internationally recognized for their research documenting and addressing these multi-dimensional, complex injury-related issues.[18–27] Certified athletic trainers have also made significant contributions to this body of knowledge, both as independent researchers and in collaboration with these distinguished scientists.[28–32]

Injury Documentation

Musculoskeletal concerns are indeed priority issues for physically active females. Documenting these concerns is of paramount importance in maximizing the positive effects of physical activity, increasing participation and compliance to these activities by women throughout their life span, and in controlling health care dollar expenditures directed at injury care and management among this population. Injury can be a limiting factor to exercise compliance. Many females, because of their limited exposure to movement experiences, are uneducated in relation to injury and when injury occurs, even when minor in nature, quickly become exercise “drop-outs.”

This negative experience may cause these individuals to never return to their pre-injury level of physical activity and serve to discourage them from pursuing physically active lifestyles. Information relating to injury/illness patterns, prevention, and management is essential to encouraging females to become physically active and to continue their commitment to a physically active lifestyle throughout their life span.

In order to effectively address the health care needs of physically active women, it is essential that data be obtained that scientifically and objectively documents musculoskeletal injuries that predominate in this population; and what obstacles these injuries may present to the physical activity patterns and aspirations of females. Only when injury and illness incidence is specifically identified and documented can effective programs of prevention and treatment be developed and initiated.

Today, no national system exists which can provide comprehensive information about injury and illness patterns in physically active women. Large injury surveillance databases associated with interscholastic, intercollegiate, and professional sports have been in existence for many years.[34–36] Historically, these databases have focused on male athletes participating predominantly in contact/collision sports.[34] Female athletes have recently and selectively been included in some injury surveillance databases but data collected have been limited to specific sports focusing on gender comparisons for selected injuries.[35] Data is virtually unobtainable on those injury and illness patterns among physically active females who are outside the scope of organized sports participation. This omission continues to become more evident as the numbers of physically active females, in all age groups, continues to rapidly expand.

Injury among the general population has been designated as the principle public health problem in America today.[37] Injuries have been identified as the leading cause of death and disability in children and young adults, and have been identified as the most significant cause of lost years of productive life for Americans.[38] A prerequisite for the scientific study of injury is the acquisition of data on which to base priorities and further research.

Epidemiological research methodology must be developed and applied to the injury and illness considerations of physically active females to identify problems, define their extent, and determine appropriate, effective preventative and management interventions.

Injuries have definable and correctable causes. Preventative strategies can be developed and implemented when it is known who is at risk, what types of injuries are sustained, their severity, when, where, and under what circumstances injuries occur. By comparing information over time, changing patterns of injury can be observed and strategies for intervention can be implemented. High quality epidemiologic data are essential for the planning, development, and evaluation of efforts to prevent injuries. Ensuring the safest environment, which serves to attract and encourage females to pursue and maintain a physically active lifestyle, must be our priority and our goal.

A National Injury/Illness Surveillance System

Achieving this goal requires the creation and establishment of a national injury surveillance system for monitoring injuries and illness occurring among physically active women of all ages, determining causes, and short- and long-term consequences. The establishment of this nationwide injury surveillance system would not only benefit the specific population being studied, but would allow for the inclusion of injuries not currently being followed in any system and would, therefore, make a significant contribution to the body of knowledge concerning injuries among our population in general.

Continuous, systematic data collection is essential for developing, implementing, and evaluating preventative interventions. Once injury and illness patterns are documented, objective analysis of these occurrences can occur. Specific screening protocols, designed to identify injury predisposition factors, can then be developed and implemented and serve as effective prevention strategies. The absence of a nationwide surveillance system and resulting lack of appropriate data has, at times, necessitated the use of corrective surgical interventions for injury management resulting in significant health care dollar expenditures to manage these injuries and the subsequent chronic conditions which may result.

The proposed injury surveillance system must be developed and organized to address the specific population being evaluated. Data to be collected must be specifically identified and standardized. Data collection instruments must be developed according to psychometrically proven principles, ensuring validity and reliability. Data collection methodology must be developed and specific methods for accessing representative populations must be determined. National and regional centralized data repositories need to be established and detailed systems of data retrieval and analyses must be outlined. Summaries of significant findings must be disseminated to the scientific community and to the general public on a regular basis. When specific trends are identified, a panel of scientific experts must be identified and consulted to determine methods of further study leading to the development of preventative interventions.

An effective nationwide injury surveillance system, designed to track the injury and illness patterns of physically active females, must be established now. Study groups need to be immediately identified to initiate the planning and development process for this much needed system, to ensure its timely enactment. Monies must be directed toward recognizing and establishing this priority immediately.

As health care reform continues to challenge the health care delivery system to be more effective and more economically efficient, it appears that the establishment of a system to effectively document and track injuries and illnesses occurring among a significant portion of our population would logically lead to effective interventions resulting in cost savings.

Conclusion

Realizing the documented benefits of physical activity, the current numbers of female participants, the anticipated projected increase in participation in physical activity in this population in the coming years, and the evidenced benefits of physical activity throughout the life span of women, it is our professional and moral obligation as responsive health care practitioners, researchers, scientists, and American citizens to establish a surveillance system which accurately documents activity related injury and illness patterns among females. A physically active lifestyle must be encouraged in the safest environment possible, identifying risks and developing and emphasizing appropriate prevention and management interventions. It is irresponsible to deny the importance of this issue and to ignore this problem — a problem that affects physically active females of all ages and one on which an investment in research could yield an unprecedented dramatic return.

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Amy Allina *The Reproductive Health Technologies Project*

My name is Amy Allina and I am the Project Manager for the Reproductive Health Technologies Project. The Project brings together leaders from a wide range of constituencies and disciplines for the purpose of dialogue, debate, and consensus building on issues of reproductive health and technology, especially highly charged issues where science, politics, and the interests of women converge and often clash. Where consensus develops, this strong and varied group is able to engage in effective strategic planning and serve as a catalyst for powerful public education, advocacy, and public policy advances. The mission of the Project is to advance the ability of every woman to achieve full reproductive freedom with access to the safest, most effective, and preferred methods for controlling her fertility and protecting her health.

The Project's current work is focused in four areas: (1) the potential to expand options for early abortion through education and advocacy about medical abortion (i.e., nonsurgical or noninvasive abortion); (2) the demand for regimens of emergency contraception to be medically accepted, FDA approved, and accessible to women who need or want them; (3) the need to understand, grapple with, and ultimately break the unfortunate cycle of "boom and bust" that is all too frequently the pattern for highly promoted new contraceptive methods introduced to the U.S. market; and (4) the desperate need for woman-controlled microbicides — products that protect women from sexually transmitted diseases (STDs), including the AIDS virus.

My testimony today focuses on the critically important task of making microbicide research an integral part of the women's health research agenda. Women need prevention products that are in their control to protect themselves against AIDS and other STDs. Despite the tremendous public attention that AIDS has received, and despite the commitment of both public and private funds for AIDS research, until now little attention has been given to the need for a prevention product that women can use, if necessary without their partners' knowledge or consent. Scientists are conducting research on a variety of substances which kill or inactivate the bacteria and viruses that cause STDs. Such products — known as microbicides — would allow a woman to protect herself against disease without being forced to negotiate with her partner, as she must to ensure condom use. Ideally, microbicides should be developed in spermicidal and nonspermicidal formulations to allow women the option of conception without the risk of disease.

Seventeen years into the AIDS crisis and at a time when the incidence of STDs is reaching epidemic proportions, the single public health message to women about prevention of STDs is "use condoms." For many women, this advice is inadequate or unrealistic at best. At worst, it is life threatening. There are a number of interrelated problems with relying on promotion of condoms to protect women against STDs. First, a woman cannot decide on her own to use condoms. Women don't wear condoms. In order to protect herself, a woman must negotiate with her partner and gain his cooperation. Even the female condom, while a welcome addition to women's options, requires such cooperation. Second, women often lack the power within relationships to insist on condom use. Third, women may be hesitant to insist on condom use because they feel that asking a partner to use a condom sends a message that they do not trust their partner to be faithful or that they are not being faithful themselves.

The heavy reliance on promoting condom use is often justified by the argument that condoms provide the best protection against sexually transmitted disease, but this logic fails to recognize the difference between theory and practice. While condoms may provide the best protection against transmission of STDs under controlled-testing conditions, a 1993 review of condom effectiveness in practice showed that, in their daily lives, women use woman-controlled methods (such as cervical caps or diaphragms) more consistently than condoms and therefore get more STD protection from these methods. It is only within the last few years that the need for woman-controlled prevention products has begun to receive the serious attention it deserves. There are a number of reasons why this need is only now beginning to be recognized.

First of all, microbicide development is not an appealing investment for pharmaceutical companies. Women need a low-cost product that can be used regularly, with every act of intercourse. Pharmaceutical companies are unlikely to earn large profits from such a product, as they do with HIV treatment drugs such as AZT or as they might expect with an AIDS vaccine, in part because of the difficulty of securing patent protection.

In addition, pharmaceutical companies are cautious about investing in the development of microbicides because of their concern about liability if the product does not provide complete protection. A company making the claim, even with cautionary labeling, that its product will prevent transmission of HIV/AIDS, a life-threatening disease, may attract product liability suits from people who become infected with the AIDS virus.

Another barrier to microbicide development is that sexually transmitted diseases have only recently been recognized as a widespread problem affecting large numbers of women, and AIDS has not been considered a woman's problem. Prevention and treatment of sexually transmitted diseases in women has been inadequate. Research efforts have been severely underfunded, and education and diagnostic efforts have not targeted women, who rarely go to STD clinics. In addition, many health care providers fail to take advantage of the regular contact that they have with many women during family planning visits to screen for STDs and talk about prevention. Compounding this problem is the fact that in the early years of the AIDS epidemic in the United States, much of the public information about the disease reinforced the misconception that only gay men and injected drug users were at risk of contracting HIV. Today, rates of HIV infection in this country are rising faster among women than among men, and heterosexual intercourse is recognized as a major mode of transmission.

The reality is that sexually transmitted diseases are a women's health issue. Women are at greater risk of acquiring an STD than men. Anatomical differences make these diseases more easily transmissible to, and more difficult to diagnose in, women. The prevalence of some STDs is higher among teenagers in the U.S. population than among older women. Young women have characteristics that make them particularly vulnerable to some STDs; concerns have recently been raised that young women may be susceptible to STD infections because of age-related physiological changes in the cervix.

Because many STDs are asymptomatic in women, a woman may be unaware she has an STD until the infection has been active for some time. In most cases, the consequences of contracting an STD are more serious and permanent for women than for men. Left undiagnosed and untreated, STDs such as syphilis, chlamydia, gonorrhea, and human papillomavirus (HPV) can have a severe, lifelong impact on women's health causing infertility, ectopic pregnancy, stillbirth, premature delivery, and genital cancers. In addition, all STDs — both those which create visible, open sores and those that are invisible and asymptomatic — increase a woman's risk of contracting HIV.

Heterosexual contact with an HIV-infected man is the most rapidly increasing transmission category among women. In the United States, approximately 80,000 women between the ages of 15 and 44 are currently infected with HIV. Women are the fastest-growing group with HIV/AIDS in the country, and internationally AIDS is already equally common in women and men. In 1994, AIDS became the third leading cause of death among women aged 25 to 44. African-American women and Latinas suffer from HIV/AIDS disproportionately: although they make up 21 percent of all U.S. women, they account for 77 percent of AIDS cases reported among women. According to the Centers for Disease Control and Prevention (CDC), AIDS is the leading cause of death for African-American women.

Microbicides would allow women to protect themselves against AIDS and other STDs without being forced to negotiate condom use with their partners. While the ultimate goal is to have products that are safe and effective for use to prevent the transmission of STDs, the reality is that it will take a number of years to complete the necessary research on such a product and bring it to market. Researchers working on the development of new products are pursuing some encouraging leads, and it is absolutely critical that resources be made available so that they can continue their efforts to develop microbicidal products.

Experts in the field acknowledge that while it is encouraging to see such research funded and moving forward, the resources available for microbicide development are still desperately inadequate. Federal funding is quite limited, few foundations fund in this area, few pharmaceutical companies have demonstrated an interest, and the small companies that are currently conducting research may lack the capital to market a new product successfully. Industry estimates that it takes approximately $250 million to bring a new drug to market. Because large pharmaceutical companies have expressed little interest in pursuing microbicide research, public sector collaboration is essential both for developing new product leads and for supporting the increasing numbers of small biotech companies that are entering the field of microbicide research.

The Reproductive Health Technologies Project commends the National Institutes of Health and the Administration for their commitment to funding microbicide research. A year ago in Vancouver, Secretary Donna Shalala announced that the National Institutes of Health would spend $100 million over the next 4 years on research aimed at developing a safe and effective vaginal microbicides. We believe this research is critical to preserving the health of women around the world and to stopping the spread of HIV. However, this funding — although a step in the right direction — is just a drop in the bucket of the investment that will be necessary to develop, test, and make microbicidal products available to women.

The problem is, in summary, that the need for woman-controlled methods of STD and HIV prevention has only recently been recognized as a priority, and much remains to be done to move this issue to the forefront of the women's health agenda. As microbicide advocates, we will continue to expand advocacy and public education efforts to build support for the research that is going on and to demonstrate the potential market for these products in hopes of increasing the investment in research aimed at developing microbicides. We believe that this research should be a priority of women's health research because it has the potential to save and improve millions of women's lives. Microbicidal products will give women all over the world one more tool to protect themselves against the ravage of sexually transmitted diseases, including HIV/AIDS.

Thank you for your attention.

Frankie Billinglea, M.D. *Medical Professionals/Persons With CFIDS*

I wish to extend greetings to the distinguished members of the Chronic Fatigue Syndrome Coordinating Committee, particularly to the Honorable Dr. John M. Eisenberg, Interim Assistant Secretary of Health and therefore Interim Chair of the CFSCC; to the Honorable Dr. Arthur J. Lawrence, Assistant Surgeon General and Senior Advisor to the Assistant Secretary of Health; to Dr. Karen Ezrine, Medical Officer, Office of Disability, Division of Medical and Vocational Policy; to representatives of the CFIDS Association of America; and last, but certainly not least, to patient/advocates, care givers, and patients themselves. I especially commend the persons in the last three categories, as many of them were just here in the Nation's capital, approximately 2 weeks ago for CFDDS AWARENESS WEEK. I can personally attest to the mental, physical, and financial drain caused by these two activities taking place so closely together, as I am a patient/advocate and all I had to do was take a 30-minute ride on the subway from my mother's home.

For those of you that do not know me, my name is Dr. Frankie Billingslea, a homeless physician currently disabled with CFIDS, without health insurance, and unemployed for 4 years. Although self diagnosed 6 years ago, I attempted to continue working as long as I could as there were bills to be paid — I had to go through some eight different "specialists" to get my diagnosis confirmed, as this disease was not even within my particular area of expertise or clinical experience. Of course, by this time, I was almost completely nonfunctional, and my career was just about shot to hell, at my particular place of employment. In my life prior to CFIDS, I was an Assistant Clinical Professor of Maternal-Fetal Medicine and the first black female faculty member in the College of Medicine at Pennsylvania State University, Hershey Campus. I am a new member of the American Association for Chronic Fatigue Syndrome and Medical Advisor to the Medical Professionals with Chronic Fatigue Syndrome, as well as a member of the CFIDS Association of America. Our support group (NPWCs) is approaching 600 in number and is growing rather rapidly. For reasons unknown at this time, the two physician groups with the highest incidence of CFIDS are the obstetricians/gynecologists and the family practitioners.

I would really like to lead a normal life again, i.e., be gainfully employed, with health care and disability benefits; have opportunities for retirement planning; have the energy and finances for normal socialization with family and friends; make physical and/or financial contributions to community service; and even pay homage to that special branch of our government, the Internal Revenue Service. I would especially like to assist in improving the health care of others, as is the usual fashion of persons selecting medicine as a career choice. Last year, when this group convened in April, I gave a very personal testimony to express how difficult it is for persons afflicted with this devastating ailment to get properly diagnosed and treated. As an adult, an extremely well educated physician, a person with an excellent command of the English language as well as a native citizen of this country, my point was to arouse empathy and compassion for those patients who are undereducated; the working poor who cannot afford health and disability benefits; those on public assistance, who usually do not get quality medical care in an expeditious fashion; and who now have a limited time in which to develop skills and find jobs in light of the new welfare reforms; and, most of all, the children with this devastating illness. They are dependent upon adults for every aspect of their well being. Just imagine, if you will, a CFIDS patient on public assistance, with children, who can't stay on his or her feet long enough to seek appropriate medical care, let alone secure employment, but is yet expected to be able to support his or her family within the next 5 years. Much of the homeless population are not in their predicament because of some past or present vices or "demons." Neither do they lack the desire to pursue the "American Dream" within their own capabilities and with the opportunities presented to them.

I have been turned down twice for Social Security/Disability, and actually have letters that state that "although you apparently have a diagnosis consistent with CFIDS, we do not have reason to grant your request for Social Security/Disability benefits." We need to educate the claims examiners of third-party payers and case workers in Social Security/Disability offices, as well as practicing physicians. There is talk of incorporating discussion of CFIDS in the curricula of medical schools and in the various residency programs. Although I agree with this wholeheartedly, we need to begin this pursuit with those persons already in practice and with the eligibility to bill patients and/or their third-party payers (e.g., private insurers, Social Security/Disability) for the care that is rendered. Although the logistics still need to be worked out to some practical conclusion, this effort should not have to be viewed as such a major undertaking, and therefore delayed, as every licensed physician practicing the art of medicine in the United States has to have a working knowledge of the English language.

I now await a hearing that is to take place who knows when. Since I do look forward to life after CFIDS, or a manageable and independent one with CFIDS, I am attempting to maintain continuing medical education credits for licensure and membership in the American College of Obstetricians and Gynecologists, as well as with the Society of Perinatal Obstetricians. These tasks are very difficult without an income as well as the unpredictable changes in my state of health. When asked, "Can't you find something part time?" I answer, "What part of the time?" Whether I'd be mopping the floor at some fast food establishment or exploring horizons far beyond our own, as a very highly trained aeronautical engineer/astronaut, consistency of attendance and performance would be required to maintain employment part time, full time, or even some of the time. Unfortunately, I cannot make any of these commitments at this time; however, I do look forward to the day that I can, as do the majority of patients with this incredibly awful disease.

Someone recently remarked to me that the Social Security compensation award (an award for becoming too ill and dysfunctional to even be physically independent with a disease, generally perceived as something fabricated *by* someone fortunate enough to have chosen a field that has historically provided a comfortable living, mental stimulation, as well as much needed community service) was cumulative. I then explained that my health care providers, the pharmacy, and the health food stores where I trade, expect payment as services are rendered. When my "award" is issued, it won't be millions of dollars and I will still have to go back to work, if at all possible. With God's help, hopefully I will.

During this "down time," I have conversed with many *normal* weight premenopausal women with CFIDS that admit to hyperlipidemia and abnormal lipid metabolism. As Americans are getting more and more obese and, as more and more studies are including women, the increasing morbidity and mortality of cardiovascular disease is being recognized in this patient population. It is now known to be the number one cause of death in both men and women, taking into consideration all deaths from the various cancers, AIDS, and trauma. If only lip service is still going to be paid to the CFIDS crisis, an equal opportunity affliction, I shudder at the impact of osteoporosis on the housebound and nonambulatory patients, as well as on those who have an intolerance for regular aerobic weight-bearing physical activity — the majority of CFIDS patients. (Although fair skinned, I have never lacked this much pigmentation in my life, I'm sure that the warming rays of the sun in small increments, filtered by appropriate sunblock protection, would ease my aching fibromyalgia; but my respiratory system, both upper and lower, cannot tolerate the pollen/pollution mix. My photophobia has improved, though I still prefer to wear shaded glasses, even at night.) At least we have not had to deal with blizzards and/or flooding so far this year, in the District, by the Grace of God.

Fortunately, I have a roof over my head and food on the table because I could move back home to Mama (although aging and with health problems of her own). Mama is a retired registered nurse. For this, and the fact that I already have some job skills (which I hope to retain or redirect, if it is God's will), I feel truly blessed. This has also allowed me to keep regular appointments with my health care providers and to obtain the medications and treatments that have helped me to improve to this point, e.g., civil and intelligent communication with other persons for more than a few minutes at a time, and better attendance at my chosen house of worship. Dr. Joseph A. Bellanti, an internationally renown pediatric allergist/immunologist based at the Georgetown University Medical Center, located here in Washington, has admitted to the difficulties he has had in getting grant approval and funding for clinical trials and treatment for his CFIDS patients, because of all the layers of ineffective federal bureaucracy. I mention this not only because he provides my primary care, but he is also a very sincere and compassionate man; I have the highest regard for him and his efforts. (How many adults do you know that rely on a pediatrician for medical care?)

Lastly, as there are increasing numbers of cases of CFIDS being reported in persons of color, particularly blacks and Native Americans, two groups who, unfortunately, have been and still are stigmatized as being naturally lazy, crazy, and genetically depressed, by some not yet clearly identified authority, I would think that every effort would be made to inform physicians and other health care professionals of color of this illness and its many ramifications, as many of their patients are persons of color or "non-whites." The term "minority," when used to define or describe racial and/or ethnic background, is both statistically incorrect as well as socially demeaning. A *golden* opportunity was missed last summer when the National Medical Association, the National Dental Association, the Association of Black Nurses, and even the National Bar Association, all convened during the last week of July-first week of August in Chicago, Illinois. Chicago has also been the national headquarters of the American Medical Association since 1902. The upcoming annual meeting of the NMA is scheduled for August 2-8, in Honolulu, Hawaii. Unfortunately, I am too physically and financially challenged to make such a journey. I certainly have no lack of time. The national headquarters of the above-mentioned professional organizations all are conveniently located here in Washington, D.C. Also, remember that clinicians are very busy saving lives and fighting disease and that academic physicians have the addi-tional charge of educating young doctors in training. Therefore, they need ample notification of any educational programs to schedule themselves accordingly. The sense of urgency of the CFIDS crisis needs to be repeatedly emphasized, as well. (I continue to refer to this scourge of humankind that has disrupted the quality and, in some cases the quantity of life in approximately 2 percent of the American population as CFIDS, as there is currently much debate as to what it is to be called).

I look forward to eradicating this awful burden on the health of the world family, and, on the economy as well. There was a time when I could have easily wished this horrendous fate upon my worst enemy; but now, I just can't. It would not only be inhumane and unforgivable, but would completely contradict the oath I took when I became a physician.

I would now like to ask for a moment of silence in memory of the far too many patients lost to this disease, usually at their own hand, or with physician-assisted suicide. Mrs. Judith Curran, a 42-year-old mother of two little girls, former registered nurse, and wife of a psychiatrist who personally “handled her case,” rather than referring her to a colleague, only made headlines in August 1996, as she was the 35th known case of the infamous Dr. Jack Kevorkian and not because of the devastation of her illness, which led her to make this tragic decision. I am especially saddened when I hear of suicide cases in young children and adolescents, who never even had a chance of pursuing goals and living life itself. They, like their adult counterparts, died primarily of despair and hopelessness in a country considered to have the most advanced medical facilities and highly trained personnel in the world today.

Thank you for your time and kind attention; as well as positive and timely action on this matter of utmost urgency.

Linda Burnes Bolton, Dr.P.H., R.N., F.A.A.N. *National Black Nurses Association, Inc.*

The National Black Nurses Association, Inc. is a 501(c)3 professional nursing association representing over 150,000 black nurses throughout the United States and Eastern Caribbean. The Association was founded in 1973 to investigate, define, and determine the health needs of black Americans and to conduct research, health promotion, and health policy initiatives to improve the health and well being of individuals and communities. The Association is headquartered in Washington, D.C. It's current president is Dr. Betty Smith Williams, Professor Emeritus, California State University, Long Beach, and former Dean of Colorado University, School of Nursing. The Association's *Position Statement on Women's Health,* published in 1994, advocates for increased research funding on issues disproportionately affecting black women and other women of color including: premature labor and it's sequelae of premature birth; low-birthweight infants and infant mortality; cardiovascular disease including stroke; breast and cervical cancer; physical and psychological trauma resulting from crime, battery, and other acts of violence; diabetes and kidney disease; osteoporosis and other debilitative disorders; systematic lupus and arthritis; infertility;

infectious diseases including tuberculosis and AIDS/HIV; clinical depression and other mental health disorders; barriers to preventive health care utilization and practices; and the impact of poverty, lack of access to education, and economic viability on women's health and well being.

Education and Career Issues

The Association urges the National Institutes of Health (NIH) to provide funding to increase the number of black health professional research scientists in all fields. The number of black nurses with earned doctorates represents less than 1 percent of all professional nurses in the United States. Black nurses with earned doctorates have contributed to our scientific knowledge in a variety of areas. Work supported by NIH on preventive health behavior in reducing risk of acquiring and transmitting HIV/AIDS (Loretta Sweet Jemont, Ph.D.); increasing black women's utilization of cancer screening and treatment services (Sandra Miller Underwood, Ph.D.); and multifactorial, multivariate repeated-measure analysis of premenstrual syndrome — a health issue that results in hundreds of thousands of disability days for women annually (Dr. Ora L. Strickland), are a few examples of contributions made in women's health research. Funding is necessary to support more doctoral and postdoctorate programs for women research scientists.

Obstetrical Care

Delayed entry into prenatal care continues to be a major predictor of low birthweight and poor perinatal outcome. Research on stress and social support as mediating factors affecting prenatal care utilization behavior has been funded by NIH. We require additional funding to test interventions among diverse populations which would improve prenatal care utilization; and decrease the adverse effects of stress. Research on reduction of stress and the provision of community-based social support services has been limited. NIH has funded research to identify biochemical markers of stress in pregnancy (Hobel, NICHD, 1994). As a co-investigator of this research initiative, our preliminary data indicates a correlation between behavior in pregnancy and birth outcome. Funding is required to test mediating interventions during pregnancy which will decrease the incidence of poor perinatal outcome. This research has a potential for significant cost savings if we can decrease the incidence of preterm labor.

Research Across the Life Span

NIH should maintain the Office of Research on Women's Health as a center for sponsoring a comprehensive research enterprise. Additional funding should be allocated to support research initiatives on life span phases of women. These include:

- Prenatal and perinatal,
- Childhood and preconceptual,
- Puberty,
- Reproductive adults,

- Climacteric and menopausal, and
- Postmenopausal.

A comprehensive matrix of research across the life span should consider phases of women's lives.

Research Agenda Topics

Research funding to promote women's health must include a complimentary approach including:

- Basic science research,
- Epidemiological and health outcomes research,
- Human studies and clinical trials,
- Nutritional and nonnutritional dietary research,
- Behavioral research,
- Historical and ecological research of the effects of this factor on the risk of disease occurrence (Example: ecological factor's influence on the risk of reproductive hormonal-related cancers.),
- Organ systems and disease pathophysiology, and
- Lifestyle and health-beliefs research including social isolation, disability, and chronic disease management using self-care and alternative-care intervention. (An example of the latter is the Duke University researchers findings (Manton, 1993). The research team documented decreased disability rate through education of study participants, early interventions, and aggressive chronic disease management.)

In summary, the National Black Nurses Association, Inc. urges NIH to increase it's funding for women's health research and the Office of Research of Women's Health. We urge NIH to support the following:

Women's Health Research Recommendations

- Increase funding for issues affecting women's health across the life span. These include:
    - Coronary heart disease and vascular disease,
    - Diabetes, urologic, kidney, and connective tissue diseases,
    - Breast, cervical, and ovarian cancer,
    - Osteoporosis,
    - Functional disability,

  - Preterm labor and it's sequelae,
  - Physical, psychological, and emotional abuse,
  - Alcohol and substance abuse,
  - Infectious diseases including sexually transmitted diseases, tuberculosis, and AIDS/HIV,
  - Obesity and eating disorders,
  - Depressions and mental disorders,
  - Poverty and its effects on human potentiation, and
  - Violence and crime and their effects on human potentiation.
- Establish an effective recruitment and retention strategy to increase the number of women from diverse cultures included in NIH-sponsored clinical research trials.
- Increase community availability to NIH-sponsored clinical treatment centers.
- Encourage partnerships between professional societies, community agencies, and NIH principal investigators to assure inclusion of culturally diverse human subjects.
- Increase funding for NIH training grants for master, doctorate, and postdoctoral research scientists.
- Provide funding for NIH technical assistance workshops, sponsored by the Office of Research on Women's Health, to be held at national conferences.
- Develop a public-private partnership to fund an integrated, comprehensive research agenda which addresses the breadth of social, environmental, physical, pathological, psychological, and behavioral issues which impact the health of women.

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Lori A. Boyajian, D.O. *University of Health Sciences College of Osteopathic Medicine*

The University of Health Sciences College of Osteopathic Medicine supports the advancement of women's health through research. This includes, but is not limited to, research into all aspects of women in biomedical careers, medical school curricula, establishment of postdoctoral training in women's health, and the continuing medical education of professionals about women's health. We recognize the difficulties in establishing norms for education and research, but we also understand that we can help establish changes that will affect the health of women for generations.

We believe that some basic concerns need be addressed in order for effective changes to be implemented. These are all interrelated and interdependent. The main points of the testimony are:

- The development of medical school curricula to address women's health,
- The encouragement of women to enter academic medicine,
- The establishment of postgraduate training programs in the form of residencies and fellowships,
- The continued education of practicing clinicians about women's health,
- The establishment of departments of women's health in all medical schools, and
- The establishment of a speaker's bureau to disseminate information to schools, professional societies, and associations about women's health.

Joel Osler Brende, M.D. *Mercer University School of Medicine*

We live in a violent society where the high incidence of domestic violence seems to be rising. Each year, approximately 12 million women are battered[1] and 3 million children are abused.[2] Females, in particular, report increasingly high incidences of physical or sexual abuse.[3–5] When victims are not protected and receive no help for their emotional distress, there will be long-term consequences in the form of emotional, behavioral, and physical symptoms. Members of the medical professions can potentially help many victims, both during the immediate or acute phase as well as the chronic phase of posttrauma symptom expression, if they know about their patients' trauma histories and how these may be related to their symptoms. But many physicians are not aware of the problem, particularly since victims don't generally talk openly about being abused. None the less, it has been reported that 22 to 35 percent of women who visit emergency rooms have acute physical or emotional symptoms related to an abusive relationship. The majority of these women are not asked by physicians whether or not they have been victims of trauma or abuse and most are afraid or ashamed to talk about it, as one woman described:

"When I went to the emergency room, I was terrified that they would ask me how I got my injuries and terrified that they would not."[6]

What are the symptoms reported by victims during either acute or chronic posttraumatic recovery? Shortly after a traumatic event, survivors report sleep disturbance, nightmares, irritability, disturbed interpersonal relationships, physiological hyperarousal, and intrusive memories.[7] Chronic symptoms may be similar but often victims attempt to block their traumatic experiences from memory and become emotionally detached[8] yet continue to experience periodic 'flashbacks' or dreams of dissociated[9] abusive experiences.

Survivors of acute traumas frequently have a variety of medical complaints including headaches, nausea, diarrhea, vomiting, muscle aches, chest pain, restlessness, tremors, sweating, and general fatigue.[10] In one study of disaster survivors, physical complaints were the primary symptoms in 66 percent of the cases[11] and included respiratory diseases, gastrointestinal disorders, diabetes, alcoholism, drug problems, and hypertension. Sixty percent of these survivors sought medical help within 4 months while the remaining 40 percent did not visit physicians until many months or even years later.[12]

Survivors of early life traumas often forget what happened. In one study, 38 percent of women abused during childhood did not recall their traumatic experiences 20 years later.[13] Although victims have often consciously forgotten what happened,[14–16] their bodies generally remember.[17] It has been discovered that forgotten or distorted traumatic memories may be expressed in the form of somatic symptoms.[18,19] Researchers have found that girls who have been abused have a much higher incidence of chronic pelvic pain,[20,21] gastrointestinal complaints, skin problems, headaches, asthma, and urinary problems — compared to girls who were not abused.[22] Children abused while they were very young may suffer from alexithymia (the absence of emotional awareness)[23] and develop physical symptoms and somatization disorders in an unconscious attempt to express basic emotional needs for nurturing.[24] Some researchers, studying 100 women with somatization disorders, found that more than 90 percent reported physical or sexual abuse during childhood.[19]

Other researchers have found a high correlation between functional gastrointestinal (GI) symptoms (including irritable bowel syndrome [IBS]) and histories of trauma, reported in several studies to be as high as 50 to 80 percent.[25–27] In a study of 50 women with gastroesophageal reflux disease (GERD), noncardiac chest pain (NCCP), and IBS, the incidence of prior sexual or physical abuse was 56 percent.[24] There has also been found to be a significant relationship between victims of childhood sexual experiences and adults with eating disorders. Forty to 60 percent of women suffering with bulimia, anorexia, or compulsive overeating reported having been victimized during childhood.[28]

Memories not only take the form of somatization but can be expressed physiologically in the form of sleep terrors, panic disorder with palpitations, chest tightness, shortness of breath, and other physiological manifestations of sympathetic hyperarousal[29] such as:[30]

- Hypertension,
- Stress-related ventricular fibrillation,
- Nonischemic myofibrillar degeneration,
- Stress-related coronary artery disease,
- Migraine headaches,
- Raynaud's disease,
- Muscle contraction headaches, and
- Other muscle contraction dysfunctions.

Any one of these physiological symptoms, as well as 'flashbacks' of the original trauma, can be triggered by one or more sensory reminders, such as the smell of smoke, the sight of blood, the sound of gunfire, a media report of rape, a television documentary about cancer deaths, etc.

In the most severe cases of chronic hyperarousal, patients may suffer from the effects of a toxic excitatory neurotransmitter, glutamate,[31] which causes a buildup in lactic acid and damage to neural substrates resulting in intractable aggressive behavior, diminished capacity for interpersonal bonding, alexithymia, attention deficit-related disorders,[32] and loss of memory and concentration.[33] Many of these individuals suffer from behavioral problems and become perpetrators of abuse upon others.

Victims of sexual trauma may also experience a high incidence of chronic pain,[34,35] headaches,[36] musculo-joint pains, fibromyalgia, and other functional pains. Their pain thresholds are often altered — either too high or too low. Sometimes they have lower available levels of their own internal pain killers, endogenous opioids,[37] causing recurring chronic pain. In contrast, survivors may also have increased levels of endogenous opioids, particularly when exposed to stressful circumstances. At such times they may feel physically and emotionally numb.[38] Such individuals have been known to induce stress in their lives and become self destructive in order to experience a sense of control over their internal discomfort — exemplified by those many women who were traumatized as children and later became battered spouses, seemingly attracted to abusive men like flies attracted to a bright light.[39,40]

During the past 2 years, I have been interested in the relationship between trauma and clinical symptoms and have gathered data about the incidence of trauma and the severity of posttraumatic symptoms from women in the following four settings:

- Group 1 — comprised of 48 female patients hospitalized for psychiatric reasons,

- Group 2 — comprised of 20 female patients examined in an internal medicine clinic who also reported symptoms of depression and anxiety;
- Group 3 — comprised of 47 female patients receiving treatment for emotional problems in a private psychiatric outpatient setting; and
- Group 4 — comprised of 11 females employed in a psychiatric hospital.

Using a newly validated instrument in the form of a self-report questionnaire,[41] I found that the women in these four groups reported one or more of 43 possible stressful or traumatic events, among which were eight violent stressors:

1. Violence between family members,
2. Being abused as a child,
3. Witnessing violence or murder;
4. Being a victim of sexual trauma by a family member or friend;
5. Beaten by a spouse;
6. Victim of assault;
7. Being a victim of repeated sexual abuse; and
8. Having a loved one murdered.

They were also asked to complete a 24-question assessment pertaining to possible symptoms including anxiety, depression, feelings of powerlessness, loss of concentration, distrust, memory lapses, anger, guilt, unresolved grief, suicidal thinking, purposelessness, and difficulties with interpersonal relationships.[41]

The Results

Group 1 (hospitalized women psychiatric patients) — Reported the highest numbers of stressful or traumatic events from a list of a possible 43. This group averaging 18 stressors per patient; and also reported the highest numbers of violent stressors — averaging 3.4 of the eight listed — and the most severe symptoms.

Group 2 (medical patients) — Reported the next highest number of stressful events — 12 — and the second highest numbers of violent stressors — an average of two per patient. They suffered from a variety of medical complaints. Although they had moderate levels of depression and anxiety, they had surprisingly high total symptom scores associated with their histories of trauma and abuse.

Group 3 (psychiatric outpatients) — Averaged nine stressful events with an average of 1.8 violent stressors. This group had few physical complaints but the second highest level of depression and anxiety.

Group 4 (control group of hospital employees) — Averaged ten stressful events with an average of 1.5 violent stressors per person although these individuals were symptom free.

Summary

The literature, as well as my personal experience, points to the fact that many patients, particularly medical patients who have moderate levels of anxiety and depression, suffer from unresolved traumatic experiences. These problems remain undetected and untreated, in part because physicians tend not to ask their patients questions pertaining to prior stressors, violent traumatic experiences, or related posttraumatic symptoms.[42]

Recognizing the need to integrate psychosocial and medical diagnosis and treatment, the Departments of Internal Medicine and Psychiatry at Mercer University School of Medicine, where I am a faculty member, have initiated a training program for internal medicine residents to improve their interviewing and listening skills. They are being taught that it is important to learn how to empathically ask the right questions, listen with sensitivity, and assess their patients' histories of trauma and stress so that appropriate treatment and/or referral may be forthcoming. We have now added a Behavioral Medicine Clinic wherein medical patients with depression, anxiety, and chronic pain are being evaluated more thoroughly by residents who are also learning the use of a trauma assessment.[41] The results have been very positive and patients appear to be responding with more rapid recoveries in some cases, reduced need for pain medication in other cases, and less frequent medical visits in many. As a result of this success, a collaborative research project is planned in order to evaluate this diagnostic and treatment process more thoroughly.

We are hoping that this new program and proposed research will provide information that will help to improve training programs for medical personnel and also provide data about the effectiveness of improved diagnosis and treatment of medical patients with emotional problems.

Supplemental Information and Tables

The instrument used[36] to gather this data included 43 possible stressful or traumatic events, among which were eight violent stressors (described earlier).

The women were also asked to complete 24 questions pertaining to possible symptoms including anxiety and depression.

Each of the four groups reported the following data pertaining to numbers of stressors:

- Members of Group 1 (female psychiatric inpatients) — Reported the greatest number of stressful events, averaging 17 per patient, as well as the highest numbers of violent stressors, averaging 3.4 of the eight listed.
- Members of Group 2 (female medical outpatients) — Reported the second highest number, an average of 12 different stressful events, and the second highest numbers of violent stressors, an average of two per patient.
- Members of Group 3 (female psychiatric outpatients) — Reported an average of nine stressful events and 1.8 violent stressors per person.
- Members of Group 4 (female hospital employees) — Reported ten stressful events and 1.5 violent stressors per person.

Each of the four groups were ranked according to the frequency of being affected by violent stressors, as follows:

- Living in a violent family was reported by 68 percent of Group 1, 55 percent of Group 2, 36 percent of Group 3, and 27 percent of Group 4.
- Being abused as a child was reported by 60 percent of Group 1, 20 percent of Group 2, 34 percent of Group 3, and 27 percent of Group 4.
- Witnessing violence was reported by 52 percent of Group 1, 25 percent of Group 2, 19 percent of Group 3, and 27 percent of Group 4.
- Being sexually abused by a family member or friend was reported by 52 percent of Group 1, 10 percent of Group 2, 34 percent of Group 3, and 9 percent of Group 4.
- Being beaten by a spouse was reported by 48 percent of Group 1, 40 percent of Group 2, 21 percent of Group 3, and 9 percent of Group 4.
- Being a victim of physical assault was reported by 1.40 percent of Group 1, 20 percent of Group 2, 21 percent of Group 3, and 27 percent of Group 4.
- Being a victim of repeated sexual abuse as a child was reported by 35 percent of Group 1, 15 percent of Group 2, 21 percent of Group 3, and 18 percent of Group 4.
- Having a loved one murdered was reported by 23 percent of Group 1, 25 percent of Group 2, 11 percent of Group 3, and 9 percent of Group 4.

	Total Traumas	Total Score	Anxiety	Depression	Purposelessness	Relationship Problems
Female psychiatric inpatients	17	43	4.7	3.8	3.1	3.6
Female indigent medical outpatient	12	41	5.4	1	3.5	3.3
Female psychiatric outpatients	9	36	6.1	5.2	2.6	2.9
Female hospital employees	10	12	0	1	0	0

Each of the four groups were tested for severity of posttraumatic symptoms and ranked accordingly, as follows:

- Group 1 (48 female psychiatric inpatients) — Had the highest total symptom score of 43 of a possible 96 which was in the fairly severe range.
  - The anxiety score of 4.7 out of 8 was in the moderately severe range and second highest of all groups.
  - The depression score of 3.8 out of 8 was in the moderate range and the third highest of all the groups.
- Group 2 (20 female patients with medical problems) — Scored slightly lower than Group 1 with a total score of 41, the second highest of all groups.
  - The anxiety score of 5.4 out of 8 was the highest score of all groups.
  - The depression score of 1 out of 8 was the lowest of all groups.
- Group 3 (47 female patients receiving outpatient treatment for emotional problems) — Had moderately high total symptom scores of 36, the third highest of all groups.
  - The anxiety scores of 6.1 out of 8 was the highest of all groups.
  - The depression score of 5.2 out of 8 was the second highest of all groups.
- Group 4 (11 female hospital employees) — Had a total symptom score of 12, which was a mild score and the lowest of all groups.
  - The anxiety score was 1.
  - The depression score was 1.

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Evelyn J. Bromet, Ph.D. *Sjögren's Syndrome Foundation Inc.*

The Sjögren's Syndrome Foundation is a nonprofit organization established to educate Sjögren's patients and their families, doctors, and the public about the diagnosis and treatment of Sjögren's syndrome, to develop programs and literature to help patients learn how to manage their symptoms, to publicize recent advances in the treatment of Sjögren's syndrome, and to promote and support behavioral and basic science research on the etiology and course of this disease.

Testimony

As a patient with Sjögren's syndrome, a scientist specializing in epidemiology, and Vice President-Elect of the Sjögren's Syndrome Foundation, I would like to impart a simple but pressing message, namely, that we must stop living in a state of medical and scientific ignorance about Sjögren's syndrome, a disease that is as prevalent as Alzheimer's disease and as insidious and chronic as schizophrenia. We must emerge from the Dark Ages and attack this disease on all fronts — not in the 21st century, but starting now. In the early 1980s, the National Institute of Mental Health approached the lack of knowledge about clinical depression with a large-scale, public education program called the Depression Awareness Recognition and Treatment Program, or D/ART program. I propose that we address the general ignorance about the etiology, clinical detection, and treatment of Sjögren's syndrome with the Sjögren's Medical Awareness Research and Treatment Program, or S/MART program.

Why is Sjögren's syndrome in the Dark Ages when we know that it is a common, progressive, debilitating, autoimmune disorder that afflicts 2 to 4 million patients, mostly women? At the 6th International Conference on Sjögren's Syndrome in October 1997, it was called the most prevalent autoimmune disorder. The symptoms of Sjögren's syndrome were first described one century ago, yet we still have no cure for this disease. So why is it that the general population, primary care physicians, dentists, epidemiologists, clinical researchers, most basic scientists, and probably most people in this room, give patients a blank look when we tell them we have Sjögren's syndrome? Why is the medical community so unaware of this disease that even when the signs, symptoms, and lab tests point so obviously in that direction, we are frequently misdiagnosed? Why is there so little basic science research on this disorder and almost no clinical and epidemiologic research? And why are the available treatments so limited in scope when the patient or consumer pool involves 2 to 4 million people?

I will try to answer these questions by describing the S/MART program one letter at a time. Starting with the "S," for Sjögren's syndrome, the disorder itself has characteristic features that some professionals seem to know about — dry eyes and dry mouth — but the severity, discomfort, pain, and chronicity of these symptoms are not widely appreciated. Dryness of the mouth is not just a matter of inconvenience, like an inability to eat crackers, bread, or meat. More importantly, the lack of saliva causes difficulty swallowing, rampant tooth decay, and opens our mouths to opportunistic bacterial and yeast infections that cause excruciating ulcers and sores. A dry mouth and throat are very painful, and talking and lecturing are sometimes impossible. With lack of tears, our eyes burn and itch, our eyelids sometimes stick to our eyes, we get frequent eye infections, and some patients get corneal ulcers, abrasions, and become blind. The pain in my eyes sometimes feels like someone stuck an ice pick through my eyeball.

In addition to the lack of saliva and tears, the major symptom reported by patients with Sjögren's syndrome is debilitating fatigue. In addition, depression, as well as fever, joint and muscle pain, irritable bowel, sleep problems, and weakness occur very frequently. Some patients have Sjögren's syndrome in the absence of other autoimmune diseases, or primary Sjögren's syndrome, while others have Sjögren's plus other autoimmune diseases, or secondary Sjögren's syndrome. In the worst case scenario, a sizable subgroup of Sjögren's patients develop lymphoid malignancy. For the majority of us, however, the symptoms I described are disruptive and persistent, and interfere significantly with our productivity and with the quality of our lives. Like other chronic and incurable diseases, they affect the whole family, not just the patient.

So why is this intractable, intrusive, disruptive, multisystem and multisymptom disease in the Dark Ages compared to other equally prevalent illnesses like schizophrenia and Alzheimer's disease? Why do experts refer to Sjögren's as a "rare disorder" when, even with the inadequate epidemiology we have, it is believed to affect 2 to 4 million people? Let me suggest two possible reasons why most of us had never heard of this illness until we got the diagnosis. The first is a sociological explanation — women's medical complaints are often dismissed as "stress-related." Indeed, some of us have stress-related symptoms — we lead complicated lives with multiple demands, what sociologists refer to as "job vs. non-job conflict." And we buy into this notion ourselves and are willing to assume that our symptoms probably are caused by stress. Hence, we do not investigate their origin any further.

The second is that Sjögren's syndrome is usually diagnosed at the time of menopause. Our friends and physicians tell us, erroneously, that dryness is part of normal aging. It is not true, but we believe them and try to cope with it. However, by not starting appropriate interventions, like preservative-free eye drops and nightly fluoride treatments, we turn a bad situation into a nightmare.

Thus, Sjögren's syndrome is a progressive, incurable autoimmune disease that is comorbid with a host of other serious symptoms and diseases. We know enough about how to diagnose it that there is no longer any excuse for the general ignorance about the disorder.

The "M" and "A" stand for medical awareness. It is clear that primary care physicians are very poor at detecting Sjögren's syndrome even though this disease is chronic and persistent. When it is not diagnosed, the damage it does to our eyes and mouth, and the medically unexplained pain and suffering we experience, are endless. No formal studies have documented the extent to which, and the reasons why, Sjögren's syndrome is underdetected. We also know that the correlations between subjective and objective measures of dryness are imperfect, but there are no studies designed to explicate the mechanisms underlying these low correlations.

How can we make the medical and dental community more aware of Sjögren's syndrome so that early detection and a reduction in long-term morbidity can occur? One place to start is in medical and dental school curricula, which need to cover Sjögren's syndrome in as much depth as any other major chronic illness. As more and more women enter medical and dental schools, the pathology and clinical symptoms of diseases that afflict women in particular may hit home in a personal way. Perhaps this new generation of physicians will have a deeper understanding of Sjögren's syndrome than their predecessors. A second place is with new books on women's health.

NIH and organizations like the Sjögren's Syndrome Foundation must alert authors immediately to omissions about Sjögren's syndrome. For example, I am the section editor for the mental health section of a new, comprehensive volume on women and health. When I looked at the chapter titles in the section on autoimmune diseases, there was no chapter on Sjögren's syndrome, while there were chapters on lupus and other conditions which affect fewer women. We changed that, and the book will now cover Sjögren's syndrome. Third, we also need to develop awareness programs for dentists and physicians that emphasize the symptoms and medical management of this disease so that we reduce the glaring underdetection and poor medical management that exist today.

The "R" stands for research — basic, clinical, epidemiologic, and behavioral. Sjögren's syndrome has been as underresearched by biomedical researchers as it has been underdetected by medical professionals. One reason is that we patients have not lobbied effectively enough on our own behalf. For that, we take responsibility and are trying to remedy this situation through the Sjögren's Syndrome Foundation. A second reason is that Sjögren's syndrome affects women primarily, and women's health problems, especially problems occurring to middle-aged women, have been notoriously understudied. A third, perhaps most important reason is that the disease affects multiple organ systems — the eyes, mouth, central nervous system, respiratory system, vascular system, the GI tract, etc. From a federal-funding perspective, it falls between the cracks of a number of institutes, namely, NIAMS, NIAIDS, NEI, NIDR, NHLBI, and NIA. It does not appear to be the mission of any of these institutes to promote this disease in particular. It is important to acknowledge that NIH has long been the leading source for research on Sjögren's syndrome beginning in the 1950s. Indeed, NIH has been responsible for several key discoveries on the pathogenesis of this disease. However, the magnitude of current basic science research is limited, and there is almost no clinical, epidemiologic, or behavioral research.

As an epidemiologist, I went to the medical library when I was diagnosed with Sjögren's syndrome to learn about the incidence, prevalence, risk factors, genetics, natural history, and prognostic variables for this disease. I learned close to nothing because this disease is remarkably understudied. But I became convinced that a proper epidemiologic study would discover that Sjögren's syndrome is more common than current wisdom would have it, and that it probably has two forms — the rarer early-onset form and more common mature-onset form. This in itself raises a number of important avenues for research. Then I asked myself, why haven't these studies been done? I discovered that there is a lack of agreement on diagnostic criteria, and that this is the major stumbling block. As a psychiatric epidemiologist, I am aware of much worse debates about classification of psychiatric disorders which, unlike Sjögren's syndrome, do not have biological markers. However, we have a rich body of research on mental illness. In fact, the seven existing classification systems for Sjögren's syndrome overlap significantly. The lack of a "gold standard" does not provide a sufficient explanation for the paucity of clinical research. Thus, the research aim of the S/MART program has as its fundamental goal the promotion of active interdisciplinary research aimed at understanding the etiology and course of this disease.

This brings me to the last letter, "T" for treatment. The letter "T" also stands for team, because Sjögren's syndrome requires a team approach to treatment. We need both interdisciplinary and innovative treatments for the symptoms we endure and, most of all, we desire a cure. Every month, we patients spend a significant amount of money on over-the-counter, non-reimbursable medicines, such as preservative-free eye drops, saliva substitutes (another misnomer) and other expensive dental products for dry mouth, sleep remedies, skin and vaginal lubricants, and the like. Many of us are on expensive prescription medications. We spend a lot of time each day treating our symptoms and taking care of our mouths and eyes. In spite of this, the disease progresses and evolves. Currently, we can only treat symptoms as they arise because there is no treatment for the disease.

As is obvious from the results of the effort, time, and money that NIH has allocated to other chronic diseases like AIDS and cancer, a cure will not be discovered overnight. Such effort will require a long-term commitment. We urge NIH to be at the forefront of research aimed at finding the cure for Sjögren's syndrome. This can be accomplished by bringing attention to the disease through NIH-sponsored conferences, requests for grant applications, adding experts on Sjögren's syndrome to study sections, and working with pharmaceutical companies to develop the treatment component of the S/MART program.

To conclude, an estimated 2 to 4 million Americans are diagnosed with Sjögren's syndrome, and 90 percent of them are women. It may well be that the true number of people with this progressive, debilitating disease is more than twice as high since it often takes years of seeking help before this diagnosis is made — even as a "rule-out" diagnosis. And, of course, the baby-boomer generation is now entering the at-risk age which will further increase the number of Sjögren's patients. It is unacceptable that Sjögren's syndrome is unrecognized and untreated. We emphatically urge NIH to develop a large-scale public education and research program — the Sjögren's Medical Awareness, Research and Treatment program, or S/MART program. On behalf of the Sjögren's Syndrome Foundation, I thank you for this opportunity to share these pressing concerns.

Sandra E. Brooks, M.D. *Society of Gynecologic Oncologists*

Dr. Vivian Pinn, Director, Office of Research on Women's Health and Members of the Task Force on "Beyond Hunt Valley: Research on Women's Health for the 21st Century" — I am Sandra Brooks, M.D., Director, Division of Gynecologic Oncology at the University of Maryland School of Medicine. I am here today in my capacity as a member of the Society of Gynecologic Oncologists (SGO). SGO is the only national medical specialty devoted to the study and treatment of women with reproductive organ cancers. These malignancies include cancers of the cervix, uterus, and ovary.

I am extremely grateful for the opportunity to provide public witness testimony on behalf of SGO in support of increased emphasis and funding by the National Institutes of Health, and particularly the National Cancer Institute, for gynecologic cancer research.

There are three main gynecologic cancers: 1) cervical; 2) uterine; and 3) ovarian. The incidence of each of these cancers, and the women developing these diseases, are different reflecting the unique biologic characteristics of these diseases.

Both the incidence and mortality for invasive cervical cancer have declined steadily in this country over the last three decades. Although only 14,500 women will develop cervical cancer in 1997, a third of them will die from this preventable disease. African-American women continue to experience an incidence rate that is nearly two times higher than the incidence rate for white women, and African-American women have a 56-percent, 5-year survival rate as compared with a 70-percent survival rate for white women.

Higher rates of cervical cancer are found in the American South as compared to other parts of the United States. This reflects the tendency of the disease to disproportionately affect women in rural areas and women in lower socioeconomic classes. Cancer of the cervix is a preventable disease if women are regularly screened using the Pap smear.

Cancer of the uterine corpus or endometrium is the fourth most common cancer among U.S. women and is the most common invasive gynecologic cancer. An estimated 34,900 women will be diagnosed with uterine cancer in 1997. Fortunately, this cancer causes a limited number of deaths, as evidenced by a 5-year survival rate of 83 percent.

In 1997, the American Cancer Society estimates 26,800 new cases of ovarian cancer will be diagnosed in this country and 14,100 women will die from ovarian cancer this year.

A relative survival rate of 90 percent can be achieved if ovarian cancer is diagnosed early, but unfortunately, 70 percent of women with ovarian cancer are not detected until the cancer has reached an advanced stage, which has an 80-percent fatality rate. The risk of a women developing ovarian cancer is three to five times greater if her mother or her sisters had or have ovarian cancer. Women who have been diagnosed with breast cancer are 70 percent more likely to develop ovarian cancer, than the general population.

Now, let me present some examples of current clinical research into the causes of and cures for gynecologic cancers:

In the area of cervical cancer research, the use of a lipopeptide vaccine has recently been approved for inves-tigation at the NCI. This clinical initiative targets the human Papilloma virus (HPV), which has been associated with over 90 percent of cervical cancers. The development of a therapeutic vaccine to treat advanced cervical cancer represents a novel and attractive alternative to current therapies. Also underway is the development of a prophylactic HPV vaccine with the potential to prevent the transmission of the HPV virus, and thus prevent cervical cancer.

Recently, in the area of ovarian cancer, the Gynecologic Oncology Group, one of NCI's Cooperative Groups, demonstrated a 50-percent increase in median survival time among women with advanced ovarian cancer who were treated with the combination of paclitaxel-based chemotherapy compared to the standard chemotherapy approach.

Areas for Emphasis: Priorities to Succeed in Gynecologic Cancer Research

SGO has been very supportive of Congress doubling the NIH budget over the next 5 years. SGO has supported this effort in the hope that additional priority would be placed on funding research that directly benefits the health of women, particularly women who are at risk for or are living with a gynecologic cancer.

Therefore, we would like to share with the Office of Research on Women's Health some areas that need attention and hold great scientific promise, if appropriate funding and research efforts are directed towards these issues.

1. *Gynecologic Oncologists as Primary Investigators in Independent Labs on the NCI Campus*

The issue of gynecologic oncologists as principal investigators in the intramural program is quite timely, with the building of the new clinical center and the emphasis on laboratory research during the fellowship training of a gynecologic oncologist. Increasing the number of principal investigators should increase the enrollment in screening and treatment trials in gynecologic cancer at the NIH clinical center. At present, there is not a fully trained and board eligible gynecologic oncologist with an independent lab on the NCI campus.

SGO would urge the Office of Research on Women's Health to work with Dr. Klausner, as we are, to ensure the creation of a Division of Gynecologic Oncology within the surgery branch of the intramural program at NCI. At a minimum, this division should include three independent labs where the primary investigators are fully trained gynecologic oncologists.

2. *Increased Emphasis on Early Detection and Prevention of Ovarian Cancer*

There is quite a difference in the survival rates of women who are diagnosed with cervical cancer and women who are diagnosed with ovarian cancer. The reason for this is that we have a very good method for diagnosing cervical cancer, the Pap smear. We do not have a test such as this for the detection of ovarian cancer. SGO is advocating that additional federal resources be directed towards increasing clinical trials for ovarian cancer prevention and detection.

3. *Specialized Program of Research Excellence (SPORE) for Ovarian Cancer*

Last year, Congress encouraged NCI to provide funding for a SPORE that was targeted at ovarian cancer research. A SPORE is a competitive grant mechanism to conduct translational research, where cancer centers are the applicants.

Unfortunately, we have yet to see a request for application (RFA) be announced for a SPORE specifically for ovarian cancer, but we hope that after the cancer center evaluations are finished and released, this will occur. We ask that the Office of Research on Women's Health monitor this situation until a SPORE, targeted for ovarian cancer, is funded by NCI.

4. *The Need to Train More GYN Scientists*

SGO asks that the Office of Research on Women's Health take on a greater role in encouraging research directed at cancers of the reproductive system. One way to do this is to have the Office of Research on Women's Health dedicate a small portion of their FY 1998 budget to partner with NCI to administer a young investigator program in gynecologic oncology research. Numerous grant mechanisms, like the R03s, the K08s, and the Clinical Associate Physician (CAP) program, already exist for the Office on Women's Health to use as a model. SGO, through its foundation, the Gynecologic Cancer Foundation, is working to partner with NCI to provide funding for young investigators to spend a year in the NCI intramural program, as part of their fellowship training.

Conclusion: Success Stories

Dr. Pinn, I greatly appreciate your time and attention to the need for additional resources for research being conducted to find the causes and subsequently the cures for gynecologic cancers. I would like to close today with some success stories. The success stories that I have had over the past several years are predominantly related to those women which have been referred after a disease is identified by a Pap smear or a relatively short time after an episode of postmenopausal bleeding. Typically, these women will have early stage disease and are completely curable. I have dozens of such women in my practice. These women undergo surgery for the most part and return to active and productive lives.

There are relatively fewer success stories with ovarian cancer, however, a few are exceptions. In particular, the case of a 45-year-old woman who experienced pelvic complaints and was seen immediately by her gynecologist who ordered a sonogram. The sonogram revealed a complex mass, the tumor marker was elevated. The patient was then referred to me in consultation and she underwent a comprehensive staging procedure for ovarian cancer. Although we call her disease "early," it had spread outside the ovary and to cells in the abdomen. She subsequently was enrolled in a cooperative group trial containing platinum and taxol and has been free of disease since that time. This vignette illustrates the importance of the following:

- early detection;
- prompt diagnosis and treatment without unnecessary delay;
- streamlined evaluation;
- prompt subspecialty referral; and
- access to clinical trials.

It is experiences such as these, that drive my colleagues and me to seek new ways to prevent, to diagnosis, and to treat women at risk for or who have gynecologic cancers.

I and SGO look forward to working with you in the years ahead on behalf of the women of this country and their reproductive health.

Summary

Both the incidence and mortality for invasive cervical cancer have declined steadily in this country over the last three decades. Although only 14,500 women will develop cervical cancer in 1997, a third of them will die from this preventable disease. African-American women continue to experience an incidence rate that is nearly two times higher than the incidence rate for white women, and African-American women have a 56-percent, 5-year survival rate as compared with a 70-percent survival rate for white women.

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In 1997, the American Cancer Society estimates 26,800 new cases of ovarian cancer will be diagnosed in this country and 14,100 women will die from ovarian cancer this year.

A relative survival rate of 90 percent can be achieved if ovarian cancer is diagnosed early, but unfortunately, 70 percent of women with ovarian cancer are not detected until the cancer has reached an advanced stage, which has an 80 percent fatality rate. The risk of a women developing ovarian cancer is three to five times greater if her mother or her sisters had or have ovarian cancer. Women who have been diagnosed with breast cancer are 70 percent more likely to develop ovarian cancer than the general population.

Given these statistics, SGO would like to share with the Office of Research on Women's Health some areas that need attention and hold great scientific promise, if appropriate funding and research efforts are directed towards these issues.

SGO would urge the Office of Research on Women's Health to work with Dr. Klausner, as we are, to ensure the creation of a Division of Gynecologic Oncology within the surgery branch of the intramural program at NCI. At a minimum, this division should include three independent labs, where the primary investigators are fully trained gynecologic oncologists.

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Ross C. Brownson, Ph.D. *Saint Louis University School of Public Health*

Increasing Physical Activity Among Minority Women in the United States

Decades of research indicate that physical activity is an important health-promoting and disease-preventing behavior. Physical activity has been shown to lowers risks of heart disease, hypertension, diabetes mellitus, some types of cancer, and osteoporosis.

One population that appears to be particularly vulnerable to hypokinetic-based risks is minority women. The limited information available indicates that minority women are less likely to be involved in physical activity than their white counterparts. In order to increase the prevalence of physical activity in this population, several research areas need urgent attention.

- *Assessments:* Most of the assessments used to measure physical activity were developed and tested on white men. Extrapolating male test results to their female counterparts may result in serious limitations in data analysis. Research is needed to develop appropriate assessment tools and implementation plans.

- *Identifying Barriers and Determinants:* Women, particularly minority women, have very different life situations than men. Research is needed to identify specific barriers and determinants of physical activity if interventions with this population are to be successful.

- *Community Interventions:* Community interventions addressing the specific needs of women are necessary. Policy changes that promote physical activity in communities may also help increase the prevalence of physical activity in women.

There is a shortage of well-known strategies for increasing physical activity in minority women. Development and implementation of these strategies will greatly benefit the health of our nation.

Alan P. Brownstein *American Liver Foundation*

The American Liver Foundation (ALF) is a national voluntary health organization dedicated to the prevention, treatment, and cure for all liver diseases through research and education. ALF consists of 26 chapters nationwide and provides information to 200,000 patients and families and over 70,000 physicians, including primary care practitioners and liver specialists.

Certain liver diseases have a disproportionate impact on women. The most significant diseases in terms of mortality and morbidity are primary biliary cirrhosis (PBC), autoimmune hepatitis, and hepatitis B.

Women's Liver Diseases

Primary biliary cirrhosis (PBC) is a chronic liver disease that causes slow, progressive destruction of bile ducts in the liver. Women are affected ten times more frequently than men. It is estimated that as many as 100,000 women are living with PBC — most of whom are undiagnosed. This disease advances slowly, is chronic, and often leads to life-threatening complications. Once cirrhosis develops, the only viable treatment is liver transplantation.

Autoimmune hepatitis is a progressive inflammation of the liver. It was first described in 1950 as a disease of young women, associated with increased gamma globulin in the blood and chronic hepatitis on liver biopsy. Seventy percent of all cases of autoimmune hepatitis are women. This disease is chronic and usually increases in severity over time resulting in possible liver failure. Liver transplantation is the only treatment of choice at the later stages of the illness.

Hepatitis B is a virus that causes the liver to become inflamed. It is estimated that 125,000 people contract this serious disease each year. Hepatitis B is responsible for 5,000 deaths annually, including approximately 1,500 from primary liver cancer and between 350 and 450 from fulminant hepatitis. Both men and women are at risk for contracting hepatitis B, however, women have the added risk of passing the virus on to their newborn children. It is estimated that 22,000 pregnant women in the United States are infected each year with the hepatitis B virus, an increase from the estimated 17,000 in 1991. Up to 90 percent of neonates of women who are carriers of hepatitis B become infected with the virus. Of the infants who develop chronic hepatitis B, one out of 12 will die prematurely of cirrhosis or liver cancer before they are 40 years old.

The Future for Women's Liver Diseases

The American Liver Foundation is dedicated to preventing, treating, and curing liver diseases through research and education. ALF recognizes that there are some significant liver diseases that disproportionately affect women. These diseases are problematical in that they are difficult to diagnose, often go untreated for long periods of time because there are no signs of illness, and result in life-threatening outcomes. For a majority of the women infected with any of these liver diseases the prognosis is poor. They look forward to debilitating symptoms as the diseases progress, resulting in liver transplantation or death.

ALF recommends that a research strategy be developed that includes basic science and clinical trials so that we may gain a better understanding of PBC and autoimmune hepatitis.

- Research in the areas of drug trials, involving a large number of patients around the world, exploring the potential use of several medications to lessen the symptoms produced by these diseases and the control of liver damage.
- Research into the causes and treatment for liver diseases affecting women.

ALF recommends education be conducted with both the public and professionals — education to improve women's awareness of the physiological functioning of the liver and the role it plays in many of the functions of the body. The is of particular importance for women of childbearing age who may have been exposed to hepatitis B virus, because a highly effective treatment is available for newborns.

- Educate women as to the risks they face as women when their livers are threatened with any one of these diseases. Through increased awareness, women may be able to help advise their primary physicians as to signs and symptoms that could lead to earlier diagnoses and possibly preventative treatments to forestall the complications of severe liver damage and mortality.
- Educate primary care physicians about the signs of these diseases so as to lead to earlier diagnosis and improved outcomes for women.

In closing, ALF commends the Office of Research on Women's Health for their concern and efforts regarding the health and well being of women. ALF recommends that more research into the causes and treatment of these diseases be conducted. Further, more education into the prevention of liver disease and awareness of the signs and symptoms should be done with the general public and in the professional medical community. These diseases produce debilitating symptoms and the outcome is usually death or liver transplantation. Your office offers a central repository for the concerns about women's health issues. Hopefully, more can be done to alleviate the suffering endured by women affected by these diseases.

Jacquelyn Campbell, Ph.D., R.N., F.A.A.N. *The Johns Hopkins University School of Nursing*

The Effects of Intimate-partner Battering on Women's Physical and Mental Health

Battering is defined here as repeated physical and/or sexual assault by an intimate partner within a context of coercive control (Campbell and Humphreys, 1993). The emotional abuse that is almost always part of the coercive control also has serious psychological consequences according to women themselves, but the actual effects on women's health have seldom been measured separately. In the most recent national population-based prevalence study of battering, 8 percent of women said they were currently being physically abused (Plichta, 1996).

Obstetrical and Gynecological Health Correlates

The forced-sex aspect of battering is directly associated with significant health problems with approximately 40 to 45 percent of all battered women being forced into sex by their male partners (Campbell, 1989). Relationship sexual abuse probably results in increased pelvic inflammatory disease; heightened risk of sexually transmitted diseases including HIV/AIDS; vaginal and anal tearing; bladder infections; sexual dysfunction; pelvic pain; urinary tract infections; unexplained bleeding; unintended pregnancy; and other genital-urinary-related health problems documented for battered women in several population-based, shelter and health care setting studies (Bergman and Brismar, 1991; Campbell and Afford, 1989; Campbell, Pugh, Campbell, and Visscher, 1995; Chapman, 1989; Eby, et al., 1996; IOM, 1994; Plichta, 1996; Sauncers, Hamberger, and Hovey, 1993).

Pregnancy can be a direct result of forced relationship sex and abuse during pregnancy, a continuation of the general battering. The body of research on battering during pregnancy show a prevalence of abuse during the current pregnancy ranging from 2 to 17 percent with prevalence of abuse prior to pregnancy (within the past year) ranging from to 3 to 9 percent (Gazmararian, et al., 1996). The highest prevalence in a large ethnically heterogeneous sample was found by a study that used the regular prenatal care nurse for a face-to-face oral inquiry at each prenatal care visit using the four-question Abuse Assessment Screen (McFarlane, Parker, Soeken, and Bullock, 1992), and colleagues (1994) found an increased prevalence (19 versus 10 percent) of abuse during the postpartum period also alerting us to the necessity of considering abuse beginning or resuming after childbirth as well as during pregnancy. Health-related correlates of abuse during pregnancy included substance abuse, smoking, less than optimal weight gain, and eating an unhealthy diet (Campbell, et al., 1992; McFarlane, Parker, and Soeken, 1996). In terms of pregnancy outcomes, there are now at least three studies that have documented an association of low birthweight with abuse during pregnancy, even controlling for other risk factors (Bullock and McFarlane, 1989; Parker, McFarlane, and Soeken, 1994; lzchei, et al., 1991), although other studies do not show the same association (O'Campo, et al., 1994; Amaro, et al., 1990).

Other Physical Health Problems

Increased health problems and health care seeking of physically battered nonpregnancy women are also well documented. In two population-based national surveys, women physically abused by a spouse or live-in partner were significantly more likely than other women to define their health as fair or poor (Gelles and Straus, 1990; Plichta, 1996). Abused women were also more likely to say they had needed medical care but did not get it (Plichta, 1996), and severely battered women had almost twice the number of days in bed due to illness then other women (Gelles and Straus, 1990). In the Bowker survey of self-identified battered women who had successfully ended the violence, the majority of women had sought help from medical professionals, a higher proportion than from other sources of help (Brendtro and Bowker, 1989).

Injury is the most obvious health effect of battering, and between 15 to 30 percent of women in emergency rooms (ER) report that they are currently in a violent relationship (Abbot, et al., 1996; Dearwater, et al., 1996; Goldberg and Tomlanovich, 1985; McLeer and Anwar, 1989). Domestic violence is a major cause of both injury and noninjury visits to the ER by women. Chronic pain was found to be the most frequent reason for visiting the ER in one sample (Goldberg and Tomlanovich, 1985), and is a common symptom of battered women in other settings (McCauley, et al., 1995). Although frequently described as somatization, this pain, as well as nonspecific neurological symptoms frequently documented in battered women, may be the result of aid, misdiagnosed, or never treated injuries. Obviously, the most severe health consequence of intimate-partner violence is homicide, causing more than half the homicides of women in the United States each year (Browne and Flanagan, 1991).

In the few recent studies of primary care settings, the percentage of abused women, from self report (rather than record review), has ranged between 5.5 to 25 percent (Gin, et al., 1991; McCauley, et al., 1995; Rath, Jarratt, and Leonardson, 1989; Saunders, Hemberger, and Hovey, 1993). Rath, Jarratt, and Leonardson (1989) found that, in the HMO studied, not only the battered women but also their children used health services 6 to 8 times more often than controls.

Other symptoms and conditions shown in controlled investigations to be associated with physical violence from intimate partners may be more related to the results — stress, including chronic irritable bowel syndrome, digestive problems, eating disorders, and other stress-related physical symptoms (Bergman and Brisman, 1991; Breslau, Davis, Andreski, and Peterson, 1991; Campbell, 1989; Druckman, et al., 1992; Kerouac, Taggart, Lescop, and Fortin, 1986; McCauley, et al., 1995; Stark and Flitcratt, 1985). Descriptive studies suggest that other physical conditions such as hypertension may also be related to abuse (McCauley, et al., 1996) and suggested in others (e.g., Kerouc, et al., 1986; Rodriguez, 1989). Although the suppression of the immune system from chronic stress has been investigated in other populations, the role of stress in the etiology of the frequent communicable diseases of battered women and their children (Kerouac, et al., 1986) has not been investigated.

Mental Health Consequences

Mental health sequalae to abuse are significant and prompt women to seek health care services as frequently as for physical health problems (Gleason, 1993; Saunders, Hamberger, and Hovey, 1993). The primary mental health response of women to being battered in an ongoing intimate relationship is depression, with prevalence ranging from10.2 percent (Weisman, et al., 1991) to 21.3 percent (Kessler, et al., 1994) to 31.9 percent when also including anxiety diagnoses (Plichta, 1996) in general population studies. In controlled studies from a variety of settings, battered women are consistently found to have more depressive symptoms and significantly higher diagnoses of major depression than other women (Bland and Orn, 1986; Gleason, 1993; Jaffe, Wolfe, and Wilson, 1986; McCauie, et al., 1996; Ratner, 1993). Even so, the need to assess for, and intervene if necessary, domestic violence, as well as depression, has seldom been recognized (Campbell, Kub, and Rose, 1996).

Higher rates (31 to 84 percent) of posttraumatic stress disorder (PTSD) have also been documented in battered women in shelters than in other women (Astin, Lawrence, and Foy, 1993; Gleason, 1993; Kemp, et al., 1995; Saunders, 1994; Woods and Campbell, 1991). The prevalence of PTSD in battered women in the general population (1.7 to 12.3 percent) is also higher than for nonabused women (Davidson, et al., 1991; Kessler, et al., 1995; Norris, 1992; Resnick, et al., 1993). Battered women would generally not complain of PTSO per se to a health care provider, but rather of sleep disorders or stress (McCauley, et al., 1995). Thus, there is substantial probability of misdiagnosis or lack of diagnosis of PTSD by health care providers.

Substance abuse is frequently seen as part of a trauma response, and abuse of both alcohol and illicit drugs has been found as a substantiated correlate of abuse during pregnancy in all of the studies where it was measured, as well as in several studies of clinical and shelter samples of battered women (Amaro, et al., 199?; Campbell, et al., 1992; Bergman and Brismar, 1992; McCauley, et al., 1995; McFahane, et al., 1994). Although Ratner (1993) found a substantial association of alcohol abuse and battering in a recent Canadian random-sample survey, Plichta (1996) did not find an association between intimate-partner violence and alcohol use (abuse not measured) in the United States. Plichta (1996) did find an association between intimate-partner violence and alcohol use (abuse not tranquilizer) use. Clearly substance abuse treatment programs for women need to address domestic violence, as are shelter programs becoming more inclusive of substance-abusing battered women in their interventions.

Conclusions

Clearly intimate-partner violence is a significant health problem that interfaces with many of the other most important women's health problems. Funding for violence-against-women research is currently concentrated within CDC and NIH, but neither of these agencies systematically investigate the interface of intimate-partner abuse and other major women's health problems. Therefore, other institutes of NIH need to have this area of investigation considered as a significant issue for research.

Molly S. Chatterjee, M.D. *Meharry Medical College*

The word "diversity" is heard everywhere in the community. In reality, abuse of faculty, discrimination, and harassment of minority women are still rampant in academic medicine. The purpose of this testimony is to voice the concern of American women, particularly of Asian and Indian origin. It is felt that American women of East Indian and other ethnic origin are not represented in the hierarchy in many important decisionmaking bodies. Look around in the advisory panel of ORWH. Check NIH, AAMC, and our nation's 125 medical schools. *AMA News* of November 10, 1997 mentions formation of a minority consortium. NMA, NHMA, and Native Americans are included in the partnership; but no mention is made about the Asian or East Indian groups, among others.

After serving the country for more than a few decades, these women are advised that there is no discrimination and if it exists "Discrimination is hard to prove." They are advised to leave, and move on to another job. Legal battle becomes expensive, time consuming, and emotionally draining. In academic medicine you can be fired without a cause! The universities will say, "We do not like her!" Again, the question is asked, "Are you facing sexual harassment?" No, these senior women are facing "gender harassment." This process of harassment is usually adopted by male middle managers that are unfair, egotistic, self-centered, incompetent, and arrogant, and are blessed by administration. Harassment continues to interfere with the education and career success of these women in medicine. Supervisors in academic medicine have seemingly taken a ploy for "genocide" of American women of other ethnic groups, particularly of Indian origin.

Statistics

Women now constitute about 42 percent of total enrollment in medical schools. The proportion of women in residency programs has grown to 34 percent. The proportion of full-time women faculty had grown to 26 percent in 1996. Of the 21,434 women faculty in 1996, just fewer than 10 percent were full professors and 19 percent were associate professors. For men, these proportions were 31 and 25 percent, respectively. Approximately 150 women currently chair medical school academic departments. About 308 women are division chiefs. Seven women are deans of medical schools and five are CEOs. AAMC recognizes that women continue to face extra challenges in progressing in academic medicine. About 10 percent of women faculty are of Asian descent. About 2.6 percent are female Asian M.D.s. Female Asians represent only 0.9 percent of all professors. Only 8 percent of Asian females are tenured.

Problems

- At LSU in New Orleans, Dr. Rao, a woman faculty member, pointed out the salary difference of female scientists in academic medicine during the ORWH public testimony session.
- Faculty member in the Chicago area has been terminated; promotion and tenure has been denied.
- History has been repeated in other universities in the Southwest, West, Northeast, Midwest, and elsewhere.
- American women of East Indian origin are excluded from leadership roles; they are harassed due to their national origin, age, and gender. They remain underrepresented. Their voices need to be heard and that is the purpose of this presentation.

Many times, these women are bypassed and not offered leadership positions such as "chairman of the department." The positions of division director is taken away, without cause. They are not provided with support, and a concerted effort is made for them to fail. Junior faculties, without adequate experience, are offered supervisory positions to torment and torture these women. These women are asked to do "scut" work, given responsibility without authority, they are deprived of practice earnings by unfair allocation, suppression of facts, and pressure tactics by group effort. Emotional trauma often leads to physical problems, broken relationships, difficulty in marriage, financial difficulty, and lack of a proper job. Senior nonminority women in academic medicine advise "speak slow and low, do not be abrasive." They do not understand the verbal and emotional abuse these women face. Their behavior is labeled as "coercive," "angry," "vociferous resistance," "coming on too strong to be effective," "not a team player," and "not following the group decision." Similar behavior from men, other things being equal, is considered perfectly acceptable. The colleagues, personnel office, and grants office, many times harass program directors of funded grants. Emotional trauma is aggravated by the insubordination of secretarial and administrative staff. The personnel in collusion with department chairs interfere with performance on a daily basis of these academic, hard-working women. Interfering with termination of insubordinate, incompetent employees hampers managerial skills. Their seniority is ignored. At every step concerted effort is made to frustrate them to make them quit their job. In the pursuit of their life-long dream, these women are often heartbroken without any peer support. Often times the family is neglected; children are inadequately supervised. These women faculty invariably experience professional isolation. They are attacked in open for their "accent" and sometimes age.

Solutions

- As recommended by AAMC, Deans need to develop departmental strategies to enhance the professional development of women and underrepresented minority faculty.

- To serve the diverse population of the United States, American women of Indian origin should have access to mentors and leadership programs. They need to be groomed for leadership positions and need to be represented at every possible decisionmaking committee.

Other suggestions:

- Read books such as *Hardball for Men,*
- Be a feminist,
- Read financial statements,
- Subscribe to the *Wall Street Journal,*
- Avoid wounded behavior,
- Develop a thick skin,
- Shine in multiple arenas,
- Be a women's advocate,
- Dream big,
- Indulge in self advocacy,
- Challenge the boss,
- Dance with the bear until the bear gets tired,
- Perform at their best,
- Develop a standard to select academic chairs,
- Acquire managerial skills,
- Get a mentor,
- Network, negotiate,
- Stop harassment by joining forces — if necessary by class action lawsuits, and
- Improve the educational and professional environment for women.

In conclusion, as academic medicine moves on to the next millennium, the only choice this country has is to make the leadership diverse. This can only be achieved by recognition; reward; and ethical, professional, and fair treatment of *all* underrepresented minority women faculty. Time has come to understand the need to include American women of East Indian origin in leadership positions of academic medicine. I hope this public testimony will challenge the stereotype and improve the academic medicine environment.

Bente E. Cooney, M.S.W. *National Osteoporosis Foundation*

I am Bente Cooney, Director of Public Policy at the National Osteoporosis Foundation (NOF), the only national nonprofit health organization solely devoted to reducing the widespread incidence of osteoporosis.

When I testified before you in September 1996, I described the human and economic toll of osteoporosis in this country. Since then, a new study published in the *Journal of Bone and Mineral Research* estimated the medical expenditures for the treatment of the 1.5 million annual osteoporosis fractures considerably higher than previously believed. Earlier estimates of $10 billion overlooked the expenditures associated with treating non-hip fractures, minority populations, or men. When expenditures were calculated for 1995 based on the more inclusive criteria, costs rose to $13.8 billion. This study presumes osteoporotic fractures caused almost one-half million hospitalizations in 1995, along with 2.5 million visits to physicians, and about 180,000 nursing home admissions.

Also, more people may be affected by osteoporosis than I reported last year. A report authored by NOF and based on the National Health and Nutrition Examination Survey (NHANES) data, estimates that in 1996, 23 million women over the age of 50 either have osteoporosis or are at risk of developing the disease due to low bone mass. This report includes all U.S. women, whereas earlier reports were limited to white postmenopausal women.

The same report estimates that by the year 2015, the number of women affected will increase to 35 million — largely due to the aging of the population. We must join forces to prevent this frightening statistic from becoming a reality.

Inspired by your efforts to identify a specific women's health research agenda, NOF asked the Research Committee of our Scientific Advisory Board to identify key areas for osteoporosis research. The Committee, headed by Dr. Robert Recker of Creighton University, has not yet finalized its report, but what follows is drawn from the initial results of that committee's work.

Human Research

The first and foremost priority is an overarching recommendation to increase clinical research. We have major gaps in our patient-oriented research. We are simply not making the necessary translation from basic research to benefits available to patients. Figuring out the mechanisms of disease is very important, but once we solve the puzzle, we tend to put it aside and move on to new challenges. The solution rarely gets transmitted to help the patient. This is in part because of a lack of support for this type of work, and in part because it is difficult to do. For example, there is concern that human gene or genetics research, which mistakenly has been labeled as "clinical research," may produce answers to questions, but not solutions to real patient problems. Finding the gene, or genes, responsible for a disease is simply not enough.

These are some examples of needed patient-oriented research:

- *We need human intervention studies and human experimentation to resolve unanswered clinical questions regarding vitamin D.* Our vitamin D research has been remarkable, however, it has stopped short of translation into improved public health. The unanswered questions regarding vitamin D are as follows: What is the optimum vitamin D status? Will optimizing vitamin D status reduce the fracture burden? How much vitamin D do typical adults normally produce in their own skin every day — summer and winter? What is the interaction between dietary calcium and vitamin D status? Finally, we need an inexpensive, reliable, and effective vitamin D preparation. Physicians cannot practice nutritional medicine without this kind of information.

- *Fluoride is an another example of our lack of knowledge.* There is good reason to believe that, in an appropriate dosage form and regimen, and with appropriate co-therapy, fluoride could be extremely useful, both in the management of patients who already have osteoporosis and in the rebuilding of bone mass of individuals who are osteopenic but have not yet fractured. But as one scientist noted, fluoride has three drawbacks: it is old, it is cheap, and it is nonpatentable. Because of the private enterprise system in the United States, nonpatentable preparations will never elicit the necessary investment by the pharmaceutical industry. We do not know what the right dosage is; we do not know the right dosage form; we do not know how to monitor therapy in terms of blood levels; and we do not know what blood levels have to be achieved in order to be effective. Thus, a potentially promising agent languishes.

- *We need human research on the incremental effectiveness and safety of combination therapies.* These combinations include simultaneous administration of calcium, vitamin D, male and female hormones, and bisphosphonates or other pharmaceutical agents.

- *We need psychosocial and quality-of-life studies.* Osteoporosis among older adults often involves vertebral fractures which are responsible for substantial pain, deformity, compromised function, and multiple social and psychological impairments. Deformity can wreck havoc with self esteem and mastery, but it can also cause pragmatic problems such as finding clothes. Depression appears to be a major problem in women with this disease. We need a better understanding the social and psychological variables of these different quality-of-life factors.

- *We need research on behavioral issues surrounding the widespread lack of compliance with well-known preventive measures in osteoporosis.* Why, for instance, do the majority of people who could benefit from estrogen replacement not take advantage of it? Why does calcium intake remain low after many years of research and education showing that increases in calcium intake are safe and effective in preventing osteoporotic fractures? Why is our elderly population so sedentary and our children getting less exercise when considerable research shows benefits of physical fitness among the elderly and among children?

- *We need research on methods of rehabilitation in the frail elderly who have suffered fractures.* There has been little research on how to engage patients in physical activity when they are suffering painful fractures, muscle weakness, and reduced endurance. We need research on methods of controlling pain in patients with osteoporosis. We need research on the origin of pain in patients with osteoporosis, particularly back pain.

- *It has been assumed, based on the genetics, that African-American women are not susceptible to osteoporosis.* Although it may be true that young adults have a higher bone density on average compared to Caucasians, it is not certain that the same could be said for women and men over the age of 50 years. Indeed, one researcher's experience is that African Americans are prone to develop osteoporosis as a result of low lifetime intake of calcium and vitamin D. Their skin pigmentation may decrease the capacity of the skin to produce vitamin D, making this population more prone to vitamin D deficiency and secondary hyperparathyroidism. Studies should be conducted in minorities to determine the extent of vitamin D deficiency and osteoporosis.

- *Exercise for the prevention of osteoporosis is an area that needs further exploration.* We lack good controlled clinical trials which evaluate the benefits of exercise on osteoporotic fracture outcome. Almost all studies examine muscle strength and bone density responses. Falling frequency is starting to be evaluated. However, the ultimate effect on fracture incidence has not yet been evaluated.

- *Exercise for bone health across the life span is an exciting concept.* One researcher describes the needs as follows:

– Youth to 25	Build bone mass and muscle strength.
– Ages 25–45	Maintain bone mass and strength; build flexibility to avoid injury.
– Ages 45–70	Maintain bone mass and strength; maintain flexibility; promote balance-building activities; check for sight and hearing loss; promote weight bearing.
– Ages 70+	Build balance, agility, and strength; check vision, hearing, shoe apparel, and home environment to avoid falls and injury.

- *Studies of secondary prevention would be most useful in osteoporosis.* Once an osteoporotic fracture has occurred in a person the chances are greatly increased that another one will occur in the future. Many people with known fragility fractures go untreated. We need research into the reasons for this and how we might target the population with current fractures for prevention of future fractures.

- *We need human epidemiologic research including research into the reasons for secular changes in fracture rates and difference in fracture incidence between countries.*

- *The role of androgens in osteoporosis prevention and treatment in women needs to be addressed.*

- *Does skeletal osteopenia during the growth spurt contribute to the rising incidence of bone fragility fractures during puberty?* Can it be modified by the environment which would lead to the reduction in incidence of fractures?

- *Factors that affect attainment of peak bone mass in young women need to be looked at.* Perhaps this question and more will be answered by the joint project between NIAMS and NICHD on osteoporosis prevention in children, for which an RFA was issued in June 1997.

- *Eating disorders and exercise-induced amenorrhea in young women need additional attention by researchers.*

Basic Research

- *The number one priority should be to investigate the biology of bone adaptation to mechanical loading.* The most important research to be done in this area is on the set point mechanism which senses loading and responds appropriately to control the skeletal adaptive response.

- *We need research on the inefficient repair of bone tissue micro damage.* At least one of the functions of the bone remodeling system is repair of micro damage. We do not understand how micro damage is detected and how it is repaired. Inefficient repair of micro damage is almost certainly a contributing factor in excess skeletal fragility.

- *We need research on the interaction between estrogens and cytokines, particularly to followup the concepts suggested by animal data.* We need research on the mechanism of estrogen action on bone. We need to identify and isolate osteoclast precursor cells.

- *We need research on the molecular basis for the cell-to-cell interaction that governs bone resorption and osteoblast activity in vivo.*

- *We need research on the cellular mechanism of the anabolic affects of parathyroid hormone, prosta-glandins, and fluoride on bone.* These are all anabolic agents and the search for effective anabolic treatment of osteoporosis should start with these known agents.

- *We need research on transcriptional control of osteoblast differentiation.*

- *We need research on the effect of cell matrix interaction in osteoblast and osteoclast proliferation and differentiation.*

- *Genetic studies are needed in osteoporosis.* Between 50 and 90 percent of variation of peak bone mass is inherited. Thus, we need to discover the genes associated with regulation of peak bone mass and to determine their function so that this function might be mimicked by pharmaceutical interventions. We also need studies of the genetic linkage to rates of bone loss. The genetic studies are large, expensive, and difficult. The best approach would be a cooperative effort including several osteoporosis centers and the National Institutes of Health, as well as industry.

- *Research is needed to understand the recently discovered relationships between important diseases of postmenopausal women: osteoporosis and breast cancer, depression, rheumatoid arthritis, stroke, and coronary heart disease.* Do these associations provide clues to etiology and preventive medicine?

In summary, the above presents just a partial listing of gaps in our knowledge about osteoporosis. Because osteoporosis is such a young disease in terms of research focus and public attention, the research needs are great on multiple fronts. While the major goals of osteoporosis research may be to uncover the molecular and cell biology of bone and the factors that regulate bone cell activity to identify the genetic and environmental risk factors that contribute to bone loss; there are numerous pressing patient-related issues that scream for answers. Sufficient methods for prevention, diagnosis, and treatment of osteoporosis still have not been identified. A comprehensive national strategy to address osteoporosis, including a coordinated program of basic, clinical, and behavioral research, is urgently needed before the baby-boom generation reaches the age of osteoporotic fractures. If we fail to do so, this disease will not only bankrupt our health care system, but also the lives of millions of women and men.

Zara Cooper, B.S. *Self, Mount Sinai School of Medicine*

Background

Genetic technology is moving forward at an increasingly rapid pace. At this time, scientists have identified more than 4,000 diseases as having a genetic component; and as our knowledge of genetics expands, we will continue to place it into the broader context of conditions that are multifactorial in nature. Cancer, heart disease, and diabetes all have a genetic component, and interest about a genetic link to mental illnesses mounts daily. Genetic diseases take an incredible toll on society — 10 percent of adults and 30 percent of children in hospitals have genetically related conditions. Genetic conditions have a significant impact on reproductive difficulties, and account for half of all spontaneous abortions, 5 percent of stillbirths, and are the leading cause of congenital malformations.

The center of this rapid advancement in genetic technology is the Human Genome Project — a global research effort, led by the National Institutes of Health and the Department of Energy, to identify the estimated 100,000 genes in the human genome. It is estimated that the project, now in its seventh year, will take 15 years and $3 billion to complete. New genetic discoveries are accompanied by the promise to identify their carriers and prevent resulting ailments. As technology moves forward, it is likely that costs associated with genetic testing will decrease and access to care will increase. Such discoveries promise medicine the ability to treat conditions pre-symptomatically, potentially eradicating some genetic conditions altogether. Prenatal genetic testing is becoming universal. In fact, the Office of Disease Prevention and Health Promotion's preeminent initiative, *Healthy People 2000*, has set a goal that 90 percent of women enrolled in prenatal care will be offered screening and counseling on prenatal detection of fetal abnormalities by 2000. In April of this year, the National Institutes of Health's Consensus Development Conference on Carrier Testing for Cystic Fibrosis (CF) recommended that providers recommend CF carrier testing for all pregnant women. This recommendation will likely make such testing the legal standard of care, and only gives further urgency to the need for discussion and consensus building around the topic of prenatal genetic testing.

However, progress does not come without a price. Population testing may send the message, implicitly or explicitly, that the value of a human life should be based on the presence or absence of a disease such as cystic fibrosis. This paper will address some key issues surrounding prenatal genetic testing, explore the health policy implications of this service, and recommend areas requiring further exploration.

Prenatal Diagnosis

Prenatal diagnosis has a history dating back to the 1950s. However, recent advances in genetic technology, increasing numbers of women having their first child after 35, and growing public awareness about the potential of genetic technology has brought issues surrounding prenatal testing to the forefront of the policy, medico-legal, and ethical agendas.

Prenatal genetic testing, which informs patients at risk if they are carrying an affected fetus, is now common during pregnancy. Indications for prenatal testing follow: (1) advanced maternal age (often 35 years at expected date of confinement); (2) previous child with a de novo chromosome abnormality; (3) presence of a structural chromosome abnormality in one of the parents; (4) family history of some genetic defect that may be diagnosed or ruled out by biochemical or DNA analysis; (5) family history of an X-linked disorder for which there is no specific prenatal diagnostic test (can use fetal sex determination to determine whether or not to terminate the pregnancy); and (6) risk of a neural tube defect.

Although it may appear that few pregnancies would be recommended for prenatal testing, almost all pregnant women are, or will be, affected by this technology. Couples who seek assurance that their baby won't have a genetic complication may seek genetic testing even if they don't fall into one of the above categories. Additionally, it was reported in one study that 43.3 percent of patients referred for amniocentesis, exclusively for advanced maternal age, had additional genetic risks or significant concerns regarding one or more genetic or congenital disorders.

Genetic Counseling

Medical genetics requires counseling skills exceeding the demands of everyday medical practice. This is largely due to the complexity of obtaining informed consent for genetic testing. Reasons for this have been characterized as follows: (1) genetic testing involves a family instead of a single individual; (2) it has unique meaning because in our culture genes signify absolute predictive power; and (3) genetics is probable in nature and physicians and patients both have difficulty working in these terms.

The goal of genetic counseling is to provide counselees with as much information as possible so that they understand the implications and options regarding the genetic disorder in question. Genetic counselors have graduate training and are certified by the American Board of Genetic Counselors, and work as a member of a health care team to educate and support families seeking genetic services.

Unlike many other professionals, genetic counselors are trained to be nondirective. This distinction is very important in the context of genetic counseling because of the complexity of ethical and moral issues at stake in family planning, reproductive services, and the possibilities of pregnancy termination. Respect for an individual's/couples beliefs and values concerning tests undertaken for assisting reproductive decisions, is of paramount importance and can best be maintained by a nondirective stance. However, there is skepticism about the applicability of nondirectiveness because body language and overall presentation of information can have a greater overall impact on patient perceptions than what is said.

Informed Consent and Cultural Sensitivity

Geller, et al., suggest that for informed consent to be adequate, medical professionals must be sensitive to the language, educational, and religious differences that exist among their patients, and between their patients and themselves. Furthermore, they suggest that obstacles to medical professionals providing genetic services with informed consent include: (1) lack of competency regarding genetics; (2) difficulty in providing information based on probabilities; (3) cynicism about informed consent; and (4) proclivity towards directiveness.

Patient autonomy is not a value shared equally by all cultures. European Americans and African Americans are more likely to believe that doctors should always be forthcoming with bad news than are Asian Americans and Hispanic Americans. In some cultures, disclosure requirements, signed forms, and individual decisionmaking may conflict with norms and expectations. Physicians and other counselors must conform to these cultural expectations in order to serve their patients well. Knowledge about health practices, values, and communication styles in other cultures is crucial for effective genetic counseling to occur in a pluralistic society.

Probability and abstract thinking are also key components of how genetic information is understood. Wertz, et al. found that pre-counseling interpretation of risk precedes all other variables when predicting post-counseling interpretation of risks. Counselors need to know how interpretation of risk varies by culture and ethnicity. This need is fairly acute when one considers that it is often the patient's ethnicity that places them in an at-risk group. Research is needed in this area to give providers guidance about the components of risk assessment within a cultural context. It should be noted that patients and providers do not always agree about the definition of risk. Patients seem to consider moderate, those numerical risks that counselors find to be high. Ultimately, however, the client thinks in terms of binary risk; the baby is effected or it isn't. Counselors must remain cognizant of how their presentation may influence their counselees' interpretation of risk.

Access to health care is a significant problem for many women of color, those having low income, and immigrants due to language differences. Other barriers include geography, poverty, and lack of knowledge about genetic services. Delayed access to prenatal services may cause women to miss the testing window, or prevent them from having the necessary time to interpret and internalize information regarding testing. Not surprisingly, it has been found that Latinas and African Americans are less likely to undergo prenatal diagnosis. This difference between the races could have significant consequences given that black women (76.9) have higher fertility rates than white (64.9) or Asian (66.8) women, and are less likely to receive early prenatal care.

Even when women do have access to diagnostic tests, they may not have access to the necessary counseling because of a dearth of genetic counselors outside of major academic centers. Because genetics is grounded in probability, patients must realize that their risk, or lack of risk, is rarely absolute. Clearly, a test result is invaluable without subsequent interpretation and discussion. Additional work should be done in the area of informatics to determine the best way to communicate genetic information and risk. Since one-on-one counseling is not possible in all cases, alternate communications vehicles, such as computers, should be investigated. Research efforts are currently underway.

Provider Assessment

Providers enter any relationship with their own values, such as ability to take risks, beliefs regarding termination of pregnancy, and willingness to accept and cope with illness. The lifelong implications of genetic decisions demand that counselees make decisions within the framework of their own values.

In 1996, the National Society of Genetic Counselors reported that of the nation's approximately 1,600 counselors, 94.9 percent were women. This is particularly significant because gender is the single greatest determining factor in how genetic counselors work with their patients. Women tend to be less directive and site respect for patient autonomy as their reason for withholding an opinion. Gender will also play a significant role in how patients are counseled by various medical specialists. According to the Council on Graduate Medical Education's (COGME) Fifth Report, *Women in Graduate Medical Training,* 59.6 percent of pediatric residents and 53.0 percent of obstetrics gynecology residents were women, whereas only 31.3 and 39 percent of internal medicine and family practice residents were women, respectively. Taken to its logical conclusion, patients of family prac-titioners and internists would be more likely to receive directive counseling.

Holtzman has reported that non-geneticist physicians were more likely to be directive in counseling than geneticists were and that family physicians were the least likely to be nondirective. Family physicians are often the gatekeeper to specialist care and play a vital role in many managed care programs. Thus, we must pay particular attention to the role of the family physician in genetic services provision, and ensure that education of family physicians includes the norms and recommendations set forth by recognized authorities in genetic care. The same survey found that pediatricians and obstetrician/gynecologists were four times more likely than geneticists to give patients their opinion when confronted with the same counseling situation.

Holtzman also found that there is a substantial knowledge gap even among physician providers of genetic services. Additionally, only 55.7 percent of obstetrician/gynecologists and 78.3 percent of pediatricians knew that there was virtually no chance of a couple having a child with cystic fibrosis if only one parent was a carrier. Furthermore, only 39.4 percent of obstetrician/gynecologists and 48.8 percent of pediatricians were able to calculate the chance of a couple, without a family history, having a child with cystic fibrosis. If our physicians are illiterate in the basic language of modern genetics, how can we expect them to properly educate patients and future physicians?

Prenatal counseling will almost inevitably raise the issue of abortion and contraception. It has been reported that physicians who are directive in counseling are more likely to attend religious services than those who are not. Furthermore, those offering opinions about abortion were 3.5 times more likely to attend religious services and 2.5 times more likely to be internists or family practitioners. It is not appropriate for physicians to counsel patients based on their own values.

Finally, we must acknowledge the need for more minority genetic counselors. According to the National Society of Genetic Counselors, over 92 percent of counselors are Caucasian. In 1992, the COGME reported that increasing the numbers of underrepresented minority physicians was “vital” to improving access to medical care for underserved minorities. They reasoned that minority physicians are more likely to work in underserved areas, minimize cultural and language barriers to care, and serve an important role as community leaders. According to the Council, “Cultural and language differences are best addressed by physicians from the respective minority group.” This applies to all providers of health care, and as such there is a dearth in the number of genetic counselors who can adequately meet the needs of minority patients.

Professional and Public Education

As the structure of health care delivery changes, nurses, physician’s assistants, and other allied professionals will also become more integral to the provision of genetic services. Therefore, all health professionals should be educated about the full scope of prenatal genetic testing including the technological, social, ethical, legal, and moral implications of such service. It is clear that experienced health professionals will require retraining in pre-natal genetic testing. This will be a significant challenge because more experienced professionals are likely to be geographically and intellectually dispersed. They may not even recognize the need for genetic training.

The American Society of Human Genetics (ASHG) has developed a core medical school curriculum to develop skills, knowledge, and attitudes about genetic services that are currently needed, and will become even more essential in the future. The ASHG recommends that genetics education be interwoven with all aspects of medical education in both the graduate and undergraduate years, and that problem-based learning is particularly well suited for genetics education because it involves integration of skills from many fields. A list of specific recommended competencies has been made available by ASHG. Medical schools must adapt these objectives to their unique curriculum and promptly incorporate genetics education as an integrated part of physician education.

Genetics education also provides an appropriate stepping stone for general ethics and communications education that already deserve more attention in provider training. The ASHG guidelines state “Students must learn to be sympathetic, non-judgmental, and non-directive counselors who recognize their own limitations, seek consultation whenever necessary, and become life-long, self-motivated learners.” Such qualities should be found in all providers of health care, genetic or otherwise. The need for genetic specialists will remain; nevertheless, all physicians must be as well versed in genetics as they are in pharmacology and physical diagnosis.

The educational challenge does not fall on the shoulders of professional schools alone. In order for a robust and fair debate about genetic technology to occur, the public must become erudite about genetics and the events it potentiates. Science education at the primary, secondary, and college levels, must all include an in-depth component about genetics that goes beyond rudimentary Mendelian Inheritance. The Committee on Assessing Genetics Risks states: “Broad public participation will be required to develop educational approaches that respect widely varying personal and cultural perspectives on issues of genetics, and are tolerant and respectful of individuals with genetic disorders of all kinds. Particular effort is needed to include the perspectives of women, minorities, and persons with disabilities who may feel especially affected by genetic testing technologies.”

Admirable efforts are being made by the ELSI program to promote education in public schools nationwide. However, more funding will be required to effectively arm today’s children with the information that they will require to be informed consumers of genetic information in the future.

The media has a particularly central role in the dissemination of genetic information. Most major newspapers have a health section, and television news often includes a regularly scheduled segment dedicated to health and medicine. Information provided by the media often makes a lasting impression. Thus, efforts must be made to provide science, health, and medical reporters with a basic genetic education so that they can relay information within a framework that is based in science. The ELSI project has already begun efforts to educate journalists via The Virginia ELSI Project, “The New Genetics: Education of Professionals,” and should continue to broaden its efforts.

Expectations, Women, and Pregnancy

One noteworthy effect of prenatal genetic testing is what many consider the geneticization of pregnancy. According to Lippman, one model of genetic counseling is in fact an assembly line approach to conception, separating out those products we wish to develop from those we wish to discontinue. New classes of lawsuits — wrongful birth and wrongful life — are products of new genetic technology. It has been said that these plaintiffs did not consent to delivering a defective child because they were not adequately informed about all of the risks. Most of these lawsuits stem from claims concerning improper information rather than technical failures in medical procedures. Thus, it is critical that providers take complete genetic histories and have a complete understanding of all implications of such testing.

It would not be complete to explore prenatal genetic testing without acknowledging its inextricable link to abortion. The abortion debate is certainly beyond the scope of this paper. However, if the *Healthy People 2000* objectives are to be met, and 90 percent of women should receive prenatal testing, then clearly all women must have access to the full array of reproductive options, including abortion. Mahowald states: “For individuals who cannot terminate the gestation of an abnormal fetus because of the cost of the procedure, prenatal diagnosis may not be worth the risk and discomfort that it entails.” Geographical distance also provides a considerable barrier to women who live in rural and other areas where abortion providers may be scarce.

Perhaps the greatest unknown about prenatal genetic testing is an understanding of how prenatal diagnosis really affects women. For screening initiated during pregnancy, the woman is usually tested for the trait before her partner. When an abnormal result occurs, it is the mother who ultimately decides if the fetus should be aborted. The burden of an affected child is great on the parents, families, and society, yet it is the mother alone who decides if it is too great for any of us to bear.

We must consider what genetic technology does to the experience of pregnancy and the perinatal period. Katz Rothman contends that decisions about abortion are always social rather than medical decisions. Will universal genetic testing for cystic fibrosis, as recommended by NIH, make mothers the gatekeepers of life? Prenatal testing forces women to consider an adverse outcome. What impact does this have on the psychological bonding between mother and child? What does it mean for a woman to know that she is carrying an “affected fetus”? These are the kinds of wrenching questions that must be answered before we make sweeping recommendations about genetic testing and introduce new technology to market. Prenatal genetic diagnosis has made a significant positive difference in the incidence of certain genetic diseases in specific ethnic communities; however, more data is needed before we can conclude that prenatal testing is beneficial to all expectant mothers.

The Federal Role

The Federal Government has a critical role in the area of prenatal genetic testing as both funder of most genetic research, and as the purchaser of the nation’s health care. Through Medicare and Medicaid, the Health Care Financing Administration (HCFA) is now the largest purchaser of managed care in the country, accounting for about 18 million Americans. Medicare has covered cytogenetic studies for the diagnosis or treatment of genetic disorders in a fetus. Coverage is also provided for MAFP, chloride and sweat tests for cystic fibrosis, and hematologic tests for sickle cell anemia. However, the switch to managed care has profound implications for prenatal diagnosis because many nonprocedure-related genetic services, such as counseling, are not covered by many health plans. Were the government to flex its financial muscle, comprehensive genetic services could become the standard of managed care nationwide.

Concern also exists about the future of insurance company involvement in prenatal diagnostic testing. Insurance is in the business of managing risk, and from the insurer’s perspective, what better way to manage risk than to have the power to predict which patients will become ill before they are even born? A case has been reported in which a couple from California, with a family history of cystic fibrosis, desired prenatal screening to determine whether their unborn child would be affected. The insurance company agreed to pay for the test under the condition that they would not insure the child if affected. Although insurance issues are beyond the scope of this paper, it is imperative that the government continue to take the lead in evaluating the insurance needs of those with genetic disorders.

Summary

Thus far, prenatal genetic testing policy has largely been constructed extemporaneously. This is largely due to unwillingness on the part of policy makers to enter into the volatile abortion debate. The result is nonuniform access to testing, underutilization by minority groups, unclear guidelines about genetic counseling methods, and uncertainty about the ability of women to utilize the full range of reproductive services. It is time for systematic scientific thinking and common sense to lead prenatal genetic testing policy. Before we make any more broad policy decisions, we must investigate many issues surrounding testing, counseling, and access.

Recommendations

Because patient decisionmakers and counselees are mostly women, the Office of Research on Women's Health (ORWH) of the National Institutes of Health should make prenatal genetic testing a research priority. According to ORWH, "Research is needed on the psychosocial, medical, legal, and economic impact of genetic testing . . . particularly for women in minority groups and people of different cultures."

Working with HRSA, CDC, and other NIH institutes and offices, ORWH should fund research to answer the following questions and issues:

- We need to ask the fundamental question: Is prenatal genetic testing good for women?
- What are the effects of prenatal diagnosis on mother/child bonding during the first year of life? (Especially those dyads where a genetic abnormality was found and the mother chose not to terminate.)
- Investigate further the role of culture and ethnicity in understanding genetic risks and perceptions about reproductive choice. We have an obligation to conduct research to determine the nature of varying interpretations of genetic risk by race, socioeconomic status, and previous life experience.
- Support efforts by the ELSI project, Department of Education, and others to explore alternate mechanisms for genetic education such as computers, multilingual pamphlets, and videos.
- Work with HRSA to complete a comprehensive workforce assessment of genetic professionals including counselors, physicians, and allied professionals. Special attention must be given to challenges of providing genetic counseling to expectant mothers in underserved areas.
- In an effort to increase representation of minorities in the counseling profession, ORWH should support grants to expand genetic counseling research and education in HBCUs and community colleges in predominantly minority areas.

Conclusion

This testimony provides a very brief overview of some of the complex policy issues surrounding prenatal genetic testing. It is intended to provoke thought and spark discussion about the role of the Office of Research on Women's Health and NIH in addressing these issues. I hope that you will keep this topic in mind during relevant working group and plenary session discussions.

Brenda Crabbs *Arthritis Foundation*

My name is Brenda Crabbs and I am here today to testify on behalf of the Arthritis Foundation. I would like to thank Dr. Pinn for the opportunity to speak about the critical issues facing women's health in the 21st century. Dr. Pinn, we appreciate your leadership on women's health issues and we look forward to working with you as we continue to push for research opportunities which will enhance the quality of life for all women.

I will speak today to the prevalence of arthritis in society and in women, and the economic, social, and psychological impact of the disease. I will highlight the advances that have been made in arthritis research and the areas in which research is critical to understanding the triggers of rheumatic diseases, such as the role of genetic makeup and hormones.

In addition, I will address the need for outcomes in women's health research to be measured not only in clinical terms but in whether these outcomes preserve the ability of women to function in roles which provide the greatest meaning in their life — the ability to work, to care for their home, and to be an active participant in the lives of their husbands and children.

In the United States today, 40 million individuals have arthritis and that number is projected to grow to 60 million by the year 2020. Evaluations of the economic impact of arthritis to society have been done in the aggregate for men and women. The cost to our nation of arthritis in lost wages, disability payments, hospitalizations, physician visits, and medications is close to $65 billion annually — representing over 1 percent of our Gross National Product.

The 100 forms of arthritis and related diseases are the most prevalent chronic conditions affecting women. Currently 23 million women have some form of arthritis and the number is expected to grow to 36 million by the year 2020. In terms of size and cost, arthritis is an enormous problem and growing rapidly. Arthritis discriminates against women by overwhelming numbers; rheumatoid arthritis affects three women to every one man, for systemic lupus erythematosus and fibromyalgia, the ratio is nine to one.

The economic, social, and psychological burden that arthritis imposes on women is enormous. First, arthritis is the leading cause of disability. Studies indicate that approximately half of patients working when diagnosed with rheumatoid arthritis become disabled within 10 years, suffering substantial earnings loses.

Arthritis is the condition reported by women as the leading cause of physical limitations in activities of daily living. The ability to function in highly traditional roles, such as shopping and maintaining family ties, are severely reduced for women who have rheumatoid arthritis. The impact of arthritis on psychological status has been noted in terms of depression, coping strategies, anxiety, cognitive changes, self-efficacy, and learned helplessness.

There are several research advances within the last 10 years which stand out for arthritis patients. The use of methotrexate as a safe and effective long-term treatment for rheumatoid arthritis has successfully controlled symptoms and reduced the need for steroids in adults and children. Researchers are exploring the use of methotrexate in treating other autoimmune diseases.

Research advances during the past decade have made Lyme disease an easily treated illness in most people. However, in some people, the disease fails to respond to standard antibiotic therapy. Research is being conducted to examine the genetic makeup of individuals who do not respond to standard treatment. In addition, vaccines against the bacterium that causes Lyme disease are being tested.

Joint replacement surgery, once confined to adults, has now become a more viable option for younger people. Improved surgical techniques and better implant designs have improved the longevity of implants and their performance.

Genetic research has uncovered genetic markers for an arthritis-related disease known as ankylosing spondylitis and rheumatoid arthritis, although the presence of the marker does not guarantee that the disease will develop. Research is continuing into the effort to identify the genes associated with the various forms of arthritis.

Perhaps the most significant gap for women in arthritis research is the role of genetic makeup and hormones on a woman's autoimmune system. In the autoimmune forms of arthritis such as lupus, scleroderma and rheumatoid arthritis, the immune system attacks the very elements of the body it is supposed to protect. Learning what sets off this deviation in the immune system will be a significant factor in finding a cure and developing more effective treatments for arthritis.

Further studies on the impact of pregnancy on women with rheumatoid arthritis and lupus are considered likely to yield important information. Pregnancy produces immunologic changes which have a different impact on women with rheumatoid arthritis than on women with lupus. Rheumatoid arthritis tends to improve during pregnancy while lupus is more likely to flare during pregnancy.

There are many questions that remain to be answered as to the role of a woman's physiologic makeup as a trigger for arthritis. Could a woman's body structure, designed to bear children, be a contributing factor to the cause of osteoarthritis? Is there a single arthritis gene or are a combination of genes involved? Finding the answers to these questions will provide critical clues to finding a cure for arthritis.

To date, we have learned much through our clinical and methodological research in rheumatology. We know that interventions must be measured broadly in terms of clinical, humanistic, and economic outcomes that are based in the reality of a woman's life. Of critical importance to the Arthritis Foundation is the use of comprehensive measurements to evaluate research outcomes in the lives of women. Outcome measures that have meaning for women with a chronic disease, such as arthritis, must include a measurement of functional status and an assessment of their quality of life. These outcomes must be realistic and relevant to women's lives. They must be developed to apply for a period of decades rather than months and they must place value in slowing the rate of decline in functional levels rather than maintaining functional status. It is imperative that good outcome measures in women's health research in the 21st century are quantifiable, include the patient, and consider health status in terms of a women's ability to function within roles of critical importance to her over the extended term of her life.

Frances Cuomo, M.D. *American Shoulder and Elbow Surgeons*

New priorities for research in women's health present themselves on a daily basis throughout the medical field, especially within the musculoskeletal speciality of orthopaedic surgery. Within our subspecialty of shoulder and elbow surgery, the American Shoulder and Elbow Surgeons are confronted with a vast and varied number of pathologies relating to the shoulder that are quite specific to the female gender. These disorders are responsible for significant economic loss, medical cost, and emotional and physical burden that profoundly affect not only women but the population as a whole. The three most common disorders related to the shoulder which primarily affect females include osteoporosis-related proximal humerus fractures, frozen shoulder syndrome, and instability of the glenohumeral joint in teenage females.

Proximal humerus fractures comprise approximately 5 to 7 percent of all fractures reported with 76 percent of humeral fractures noted in patients over 40 years of age. This incidence significantly rises beyond the fifth decade. While this is true for both men and women, the incidence is much greater in women. In a series of 249 fractures reported by Rose and co-workers, 69 percent occurred in patients over 50 years of age. Of these, 85 percent were in women and 15 percent were in men. Bengner and colleagues reported on 523 proximal humerus fractures of which 82 percent occur in patients over 55 years of age. Seventy-nine percent of these fractures occurred in women and 21 percent occurred in men. The rise in fracture incidence with age, and the higher incidence among females, are characteristic epidemiologic features of fractures associated with osteoporosis, which should be considered an important etiology in these injuries. Increasing osteoporosis-related fractures are linked to impaired vision, altered balance, decreased muscle trophism, overall poor health, and predisposition to falls in the elderly.

Elderly patients sustain proximal humerus fractures as a result of indirect and direct mechanisms of injury. The indirect mechanism consists of a fall unto the outstretched arm. In younger patients, this mechanism would often result in a dislocation because the strength of the bone is much greater than that of the supporting ligaments. However, in the elderly female with osteoporosis, the bone is significantly weaker than the ligaments and a fracture results. The direct mechanism of injury consists of a blow to the lateral aspect of the shoulder. This may occur as the patient stumbles and strikes the shoulder against a wall, the floor, or a piece of furniture at home. This usually results in less displacement than a fall on the outstretched arm.

Whatever the mechanism of injury, treatment is based upon the degree of displacement of the fracture. Treatment may range from nonoperative management with a sling and physical therapy to open reduction and internal fixation to reconstruct the shoulder or lastly, prosthetic replacement for fractures badly displaced or those in which the bone is to weak to hold internal fixation. Regardless of the method of treatment deemed appropriate, problems of obtaining healing, loss of fixation in soft osteoporotic bone, and stiffness plague the management of these difficult injuries.

Rehabilitation of these injuries is prolonged even in the most minimally displaced fractures. We have found that even with nonoperative treatment in the more minor fractures, these injuries require at least 12 to 18 months in order to maximize the outcome. Outcomes vary with regard to the severity of injury and the type of treatment with overhead function being most unpredictable in the elderly. The prolonged postoperative and post-injury rehabilitation, including physical therapy visits and assistance needed in the home, is a great strain for all involved.

It is for the above stated reasons that we feel this is a very important area for focus of additional research. Specific areas to concentrate upon include prevention be it pharmacologic, educational, or physical rehabilitation. A second area of research might include bone reconstitution methods once obvious loss has already occurred. Lastly, the area of fracture management is of utmost importance including improved methods of fixation and healing enhancement techniques in the bone with poor osteogenic potential.

Frozen shoulder syndrome is a disorder that has been described as a condition difficult to define, difficult to treat, and difficult to explain from the point of view of pathology. Adhesive capsulitis has continued to be one of the most poorly understood disorders of shoulder motion, posing significant challenges to the clinician. Much of the problem has stemmed from the fact that it has not been easy to define or clearly differentiate frozen shoulder from conditions with similar symptoms and findings but with distinctly different causes.

The suggested working definition of frozen shoulder is a condition of uncertain cause characterized by significant restriction of active and passive shoulder motion that occurs in the absence of a known intrinsic shoulder disorder. Primary frozen shoulder represents the idiopathic condition and secondary frozen shoulder is one in which that is associated with a known intrinsic, extrinsic, or systemic abnormality.

Although the exact prevalence and incidence of frozen shoulder is unknown, most studies report the cumulative risk for at least one episode to be approximately 2 percent. It is frequently found in patients between the fourth and sixth decades of life and is much more common in women than men. The non-dominant extremity seems to be more commonly involved, with most reported cases describing an affected left side. Bilateral involvement occurs in 6 to 50 percent of cases with 14 percent of these bilateral cases manifesting simultaneously.

Different pathologic mechanisms have been proposed to explain the cause of frozen shoulder, but all remain largely theoretic. Several investigators have proposed an autoimmune basis for frozen shoulder. Although some clinicians have reported high incidence of human leukocyte antigen B27 in patients with frozen shoulder, others have not confirmed this association. In later studies, serum IgA levels were found to be significantly lower in patients with frozen shoulder, and immune complex and C-reactive protein levels were increased. In general, however, sufficient evidence to support an immunologic theory has been lacking. Other etiologies which have been put forth include a biochemical basis, neurologic dysfunction, various endocrine disorders, as well as trivial trauma and psychological factors also being considered. Despite efforts in these directions, sufficient evidence to support these hypotheses has not been provided. It appears that the precise cause for the development of frozen shoulder remains largely unknown. The condition probably results from the combination of host factors (i.e., predisposition) and extrinsic factors (e.g., trauma, hormonal changes, collagen-vascular disease, diabetes mellitus).

The clinical presentation of frozen shoulder syndrome typically presents with a female patient between the ages of 40 and 60 reporting a gradual loss of function associated with vague discomfort about the shoulder after minimal or no trauma at all. These symptoms, which are often worse at night, usually begin insidiously. Overhead and behind the back activities become especially difficult to perform as motion is diminished many times to no more than 50 percent of overhead elevation and complete loss of internal and external rotation. These symptoms closely resemble those found in patients with rotator cuff problems, thereby requiring a careful physical examination to consider frozen shoulder as the primary condition or one that is secondary to a specific shoulder problem. The clinical hallmark of the physical examination is limitation of active and passive range of glenohumeral motion. Pain may be absent when the shoulder is moved within its free range but is almost always painful at the extremes of motion and may be severely painful throughout the range depending on the timing of presentation.

The natural history of frozen shoulder has been described as consisting of three phases, the initial or painful phase is characterized by diffuse shoulder pain and progressive stiffness. This may last 3 to 9 months and is followed by the stiffening or frozen phase. During this phase, pain is diminished in a more comfortable but severely restricted range of motion. This may last up to 12 months. In the thawing phase, motion and function gradually improve over the next 12 to 42 months, although to a variable degree. Shaffer and associates have found that 50 percent of nonoperatively managed patients were symptomatic at an average followup of 7 years, with a measurable restriction of motion in 60 percent of cases. Although early presentation seems to be associated with a more favorable outcome, manual labor, female gender, and dominant arm involvement have been implicated as poor prognostic factors. In general the natural history of frozen shoulder is uncertain — additional randomized, prospective studies are needed.

Although frozen shoulder tends to respond to nonoperative management, this can take well over 1 year of significant incapacity to achieve adequate results. During this rehabilitation, there is often significant time out of work with the financial and emotional burden which necessarily ensues. Treatment techniques involve manipulation under anesthesia and open or arthroscopic release of the shoulder which may return motion and function more quickly but not affect the overall outcome. Prospective, randomized studies are desperately needed in this area to determine the most cost-effective treatment program which also optimizes results.

Other areas of research include the pathogenesis. Is there a hormonal, menopause-related etiology or is this primarily a vasculitic phenomenon? Main areas of research for frozen shoulder syndrome appear to lie in both its pathogenesis and efficacy of treatment options.

Lastly, there is a large group of patients who suffer from what is known as atraumatic multidirectional instability of the glenohumeral joint which was first described by Neer in 1980. For the purpose of this discussion, atraumatic instability is defined as instability that is insidious or spontaneous in onset with no history of significant trauma inducing the first episode of instability. For example, a person who experiences a first dislocation or subluxation of the shoulder while performing a minimal activity such as reaching overhead. Asymptomatic hyperlaxity of one or both of the shoulders is not at all uncommon. This is typically seen in children who have hyper-laxity but do not experience symptoms of instability or dislocation. Problems arise when the hyperlaxity begins to cause symptoms and complaints. Symptomatic instability of this nature is very commonly seen in the teenage female. The stereotypical patient is a young female with bilateral shoulder instability or hyperlaxity, symptoms and signs of posterior or multidirectional instability, and often generalized ligamentous joint laxity. The next description would also include hyperextension of the elbows and knees, hyperextension of the metacarpophalangeal joints of the hand, and the ability to bring the thumb down onto the volar surface of the forearm.

Patients with multidirectional instability typically experience their first episode of instability in their early teens, often before the age of 16. It is uncertain why this time frame can turn hyperlaxity into instability. The onset of menarche raises questions as far as implication with the transition from asymptomatic to symptomatic in the young female.

The pathogenesis may be congenital or acquired. True congenital hyperlaxity causing instability probably is uncommon, as evidenced by the fact that instability is uncommon in children. Most of those that are seen probably are secondary to stretching of the capsular ligamentous tissue by repetitive microtrauma, such as that caused by overhead activities (throwing, tennis, swimming). Why the female teenager is so much more frequently subjected to this disorder around the time of menarche and early thereafter raises the question of a hormonally related phenomenon.

Management of this difficult problem is complex and quite time consuming. Questions arise as to why some patients respond to rehabilitation and others do not. If a nonoperative management treatment regime is elected, this requires daily exercises for at least 6 to 9 months to completely assess the efficacy of this approach. Should failure of a nonoperative treatment program occur, then surgical intervention is warranted but also carries with it a 1-year postoperative physical therapy and rehabilitation program in order to optimize results. Both of these treatment programs are quite costly and time consuming as well as being responsible for a significant amount of time lost from school and daily activities.

Future areas for research are sorely needed in the area of shoulder instability in teenage females. Questions regarding the possibility of a genetic predisposition versus a process which is activated during menarche, and possibly hormonally related, need to be answered. The third category of rehabilitation is a very important area for research as well as basic science studies on the glenohumeral ligaments of the female shoulder.

The above shoulder and disorders represent a significant group of musculoskeletal pathologies afflicting women which are very worthy of new and continued research. Any support which can be given to the advancement of knowledge within these areas would be worthy and greatly appreciated by all those who suffer from them as well as by all of the dedicated physicians within the American Shoulder and Elbow Surgeons who have dedicated their time and efforts in the quest for alleviation of pain and disability caused by these disorders.

Thank you sincerely for your time and consideration of these matters.

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Leilani Doty, Ph.D.

Community Partners and University of Florida Health Science Center

Problems in Health Promotion and Disease Prevention

Most symptoms are evaluated and treated outside the formal medical care delivery system by the family health gatekeeper who synthesizes lay medical knowledge from multiple sources: personal experience with illness; vicarious experiences of morbidity in nuclear, peripheral, and public networks; and information gleaned from assorted professionals including health practitioners and the media. A major gap in knowledge exists in the area of women and family health: self-perceived health needs and the translation of those needs into appropriate, accessible health education, and clinical services. In particular there is a gap in the health needs perceived by the woman who typically is the health gatekeeper of the family unit, for it is the woman who treats the symptoms, monitors the trajectories of chronic disease, transmits health information, teaches health practices, secures appointments, and administers medication. Further, there is difficulty in providing health education and services in ways that reverse the upward spiral in health costs, prevent life span disease, and promote healthy lifestyles.

Community Partners' Study

A creative solution to this problem lies in a model project under development in Gainesville, Florida through the leadership of Community Partners, a group comprised of volunteers. Community Partners links the University of Florida faculty and students, especially from the Health Science Center, with people diverse in age and cultural backgrounds from the public school system; community health services; civic, philanthropic, and volunteer organizations; and city and county governments. An interdisciplinary group, Community Partners, was formed in 1996 to plan community-based activities involving Dr. Henry W. Foster, Jr., the Senior Advisor to President Clinton on Teen Pregnancy Reduction.

The mission of Community Partners is health promotion and disease prevention. Community Partners has combined a variety of resources to study the health needs of the most underserved, local citizens. The study examines health needs, health behavior decisionmaking, household and environmental risks, and self perceptions of health. Students from the health profession from the University of Florida teamed up with local high school students to interview household heads and to photograph neighborhood settings to evaluate subjective and visual-objective health. In assessing the health promotion needs of the community, the researchers have identified key members including teens, adults, and elders of the underserved communities to train as health messengers. After learning health messages through training in the Health Promotion School, the health messengers will share their health messages with peer groups and neighbors, especially to foster health promotion behaviors in the community health gatekeepers, typically the woman of the family. The Health Promotion School will train the volunteer health messengers to address, in culturally sensitive ways, strategies that promote health and prevent disease over the life span.

Evaluation of Outcomes

Outcomes of the Health Promotion School will be measured through pre- and post-course tests of changed health professional students' competence in community health promotion and disease prevention; through community patterns showing use of health facilities such as emergency rooms; by changes in health issues awareness; and in changed numbers of prospective students from the community seeking entry to health training programs at the public high school, the community college, and the University of Florida.

Summary

There is a need for research support for projects that partner academic health centers with community groups in a collaboration to identify and address the cultural diversity of the community and the self-perceived health needs of the citizens, especially the family health gatekeeper, typically the woman — the primary health decision-maker and provider of lay medical care in the family. Empowering key members of the underserved community to serve as health messengers for peers should result in appropriate, acceptable, accessible, cost-effective ways to promote healthy lifestyles over the life span of women and their family members.

Carolyn M. Dresler, M.D. *National Task Force on Women Smoking and Lung Cancer*

Lung Cancer and Women

Lung cancer is the number one cause of cancer death in women, exceeding the deaths from breast cancer by 22,000 per year. Between 1950 and the present, there has been a 550 percent increase in the numbers of deaths in women due to lung cancer. In 1991, 36 percent of all lung cancer deaths were in women and by 1996, this had risen to 41 percent. Thus, the lung cancer death rate is decreasing in men, but continues to climb in women.

Approximately 48 million people currently smoke in the United States — 25.3 million men and 22.7 million women. Although data had suggested that smoking prevalence appeared to be decreasing as of 1991, more recent surveys have demonstrated that the percentage of smokers has increased from 27.5 percent of students in grades 9 to 12 in 1991 to 34.8 percent in 1995. In addition, these 1995 data demonstrate that girls and boys are now smoking at equivalent rates: 34.3 percent and 35.4 percent, respectively. This increase in the prevalence of smoking is likely to reflect an increase in the incidence of lung cancers in the near future, particularly in women.

Epidemiologic studies have demonstrated that women have a 1.4 to 2.9 times higher risk of developing lung cancer than men, when the amount of tobacco exposure is controlled. In large case-controlled studies, the odds-risk ratios for women have been consistently higher in women than in men. Authors of these studies have hypothesized that women may be more susceptible to tobacco-related carcinogens for a given level of cigarette consumption, particularly when examined for the prevalence of the histological subtype of lung cancer — adenocarcinoma.

In addition to the risk factor of tobacco exposure, women may also be affected by their exposure to estrogens and/or progesterones. Studies have demonstrated increased risk of lung carcinomas, particularly adenocarcinomas, in women with increased exposures to estrogens. Estrogen is a known "growth hormone," and has been identified as a risk factor in the development of adenocarcinomas in the breast, endometrium, and ovary.

According to the NIH Accounting Office, approximately $100 million was spent in 1996 for lung cancer research. This amount is compared to $600 million for breast cancer research ($300 million from the NCI and $300 million from the Department of Defense) and over $1 billion for AIDS research. This allocation is inappropriately distributed for the health and societal costs resulting from the respective diseases.

The growing epidemic of lung cancer in women is an exceedingly important health problem, not only in our society, but of grave concern in the rest of the world. Women in exploding numbers are taking up smoking around the world. The particular risk of women, smoking, and lung cancer is not at all understood. It is imperative that serious, in-depth, and well-funded research is directed to the multidimensional health problem of women and lung cancer.

Laura Flawn, M.D. *Scoliosis Research Society*

The Scoliosis Research Society is a research-oriented society dedicated to the pursuit of gaining knowledge about the causes, cures, and prevention of scoliosis and related spine deformities. As a representative of this Society, I would like to draw your attention to certain particular gender-specific spinal problems. Eighty percent of adult symptomatic scoliosis occurs in women. Progressive curvatures cause mechanical arthritic back pain, radicular or nerve root pain, loss of standing or sitting balance with trunk decompensation, and possibly even neurologic deficits.

Other spine disorders affecting primarily women are spondylolisthesis (both developmental and degenerative), and postmenopausal osteoporotic compression fractures and related deformities. These are very disabling problems adversely affecting both quality of life and function. We would like to draw your attention to these potentially devastating health problems and ask your involvement in directing research and promoting education into both treatment as well as prevention.

The Center to Improve Care of the Dying
George Washington University
and Institute of Medicine

Janet Heald Forlini, J.D.

My name is Janet Heald Forlini and I am here on behalf of both The Center to Improve Care of the Dying at George Washington University as well as the Institute of Medicine. Both of these institutions are dedicated to improving care at the end of life and I am pleased to be here today to let you know how important it is that you are focusing on this field of study.

Because of the myriad advances in medical technology, Americans are living longer, healthier lives. Most of us now die at an old age and from a protracted chronic illness. As such, the need for improved services at the end of life is greater now than it has ever been. Women have special concerns for end-of-life care: we die older, more lonely, poor, and often with prolonged disability. We also much more commonly provide care for seriously ill family members.

The aging of the "baby boomers" has been one impetus for society's recent focus on improving care for dying people. Debates over physician-assisted suicide and pain management have also become commonplace. We at The Center to Improve Care of the Dying are working to ensure that public policy is guided by data and thoughtful deliberation. The Institute of Medicine's Committee on Care at the End of Life, has written a blue print of recommendations from which the Office of Research on Women's Health can build.

To effectuate enduring reform, we need to know so much more about what can, and should, be done. Where is there the most room for improvement? What new treatments in service delivery strategies would really improve the experience for patients and families? Research is necessary to answer these questions. The NIH Office of Research on Women's Health has the opportunity to make a real change, by helping to force a focus on the lives of the seriously ill with eventually fatal illness.

Death and dying will inevitably affect all of us; but these issues are especially pertinent for American women. First of all, women tend to live longer than men and are unable to afford supportive care during the last years of their lives. In 1990, the projected life expectancy for a man was 72 years while for a woman it was 79 years (National Center for Health Statistics. *Health, United States, 1993*. Hyattsville, MD: Public Health Service, 1994 (1975-1990)). Given these statistics, there exists a major role for the NIH Office of Research on Women's Health to play. Now is the time to improve cultural expectations, financial situations, and end-of-life care for women facing death and dying in America.

The Committee on Care at the End of Life at the Institute of Medicine called for more research into the physiology of symptoms at the end of life as well as the mechanisms of symptom relief. The committee also noted some more specific questions which deserved increased attention as we age. (A summary of the committee's most important findings and specific recommendations for research possibilities are attached to the end of this written testimony.) As health care providers react to financial pressures and patient care is made not only more compartmentalized but also more impersonal, what are the outcomes? What are the trends in patient assessment, charting in patient records, and pain measurement? What are the patterns of enrollment, continued enrollment, and disenrollment by seriously ill patients in both managed care and traditional health care settings? These are the types of questions which need to be answered *now*. To do so, we need accurate research and data gathering — the NIH Office of Research on Women's Health can encourage that.

The Institute of Medicine noted other end-of-life queries ripe for focus. Discussions regarding the legalization of physician-assisted suicide often note the importance of "competence" of the requesting patient. Model statutes, as well as the law considered by Oregonians 2 weeks ago, include "competence" as a requisite to assistance with suicide. Yet, there is no working definition for this term. Physicians have long been using subjective judgment to accurately judge patient competence. There need to be screening tools developed, providing universal methods for assessment. Researchers could also conduct trials using low-risk interventions to target strategies for improving quality of life for dying individuals.

Why should these questions be tackled by a committee focused solely on women's health issues? As mentioned earlier, American women are more subject to need quality care given the extended life expectancy. And, if such quality care can be provided in the home, rather than in an acute care setting, it generally will be women who are providing it. How can we work together to guarantee that American women do not need to dread the ends of their lives?

According to a 1988 study done by the House of Representatives Select Committee on Aging, 72 percent of all care givers are women, one-third wives, one-third daughters and one-third other women. (House of Representatives Select Committee on Aging. "Exploding the Myths: Caregiving in America." Comm. Pub. No. 100-665. Washington, D.C.: U.S. Government Printing Office, August, 1988.) Many of these women are caring for children simultaneously. The average age of these women is 57, but one in four of these care providers is between the ages of 65 and 74, and 10 percent are over 75.

Improvement needs to be made in other contexts besides the hospitals and doctors' offices. Business owners should encourage caregiving in the home by allowing for extended family leave. Studies have shown that almost 60 percent of employed care givers report that caring for loved ones interferes with their work. If a woman has to fear the loss of a job, and therefore often her health insurance, how can she afford to stay home and take care of her dying husband? Sometimes, the husband will be forced to enter a nursing home, costing the family and the system more money than necessary. Other times the women will bear the caregiving and also the penalty of a thwarted work life. Addressing this requires research and education.

Bereavement is also an issue that is often neglected in the continuum of care. What is the relationship between the care giver experience and the recovery of the family members once the patient has died? Are there certain social and demographic characteristics that make the grieving period better for some than others? Do certain ethnic groups handle death differently than others? These questions deserve answers. We can all benefit by figuring out the answers.

The Center to Improve Care of the Dying works to ensure that health care options at the end of life are tailored to individual needs. To see a tangible difference in what we can all expect when dying, our focus needs to be one of comfort care and symptom relief, rather than one of cure and acute care, regardless of individual needs. Through the efforts of the Office of Research on Women's Health, perhaps we can work together to change that focus. Sometimes cure is not always the appropriate goal for a dying patient. Perhaps if we changed our conceptual framework to one of "*caring*" rather than one of "*curing*" we could all expect a better death. The National Institutes of Health's Office of Research on Women's Health has the ability to push others to confront these.

The following is a summary of some of the most relevant conclusions and themes of the Institute of Medicine's Committee on Care at the End of Life:

- Too many dying people suffer from pain and other distress that clinicians could prevent or relieve with existing knowledge and therapies.
- Significant organizational, economic, legal, and educational impediments to good care can be identified and, in varying degrees, remedied.
- Important gaps in scientific knowledge about the end of life need serious attention from biomedical, social science, and health services researchers.
- Strengthening accountability for the quality of care at the end of life will require better data and tools for evaluating the outcomes important to patients and families.

The committee concluded that the knowledge and understanding that currently exist are insufficient to guide the practice of evidence-based medicine in the appropriate direction. The National Institutes of Health has done almost no research on end-of-life care. Research has focused almost exclusively on prevention, detection, or cure of disease. NIH could add to these questions of symptom control, quality of life, and care giver effects on long trials. Methods development is important to define and measure outcomes, including patient and family perceptions about death, and to monitor and improve quality of care for Americans at the ends of their lives.

The Institute of Medicine made seven specific recommendations in an effort to address the existing deficiencies of our present care system. Recommendation #6 is directed at the National Institutes of Health and other research organizations. It reads:

Recommendation 6: The nation's research establishment should define and implement priorities for strengthening the knowledge base for end-of-life care. The research establishment includes the National Institutes of Health, other federal agencies (e.g., the Agency for Health Care Policy and Research, the Health Care Financing Administration, the National Center for Health Statistics), academic centers, researchers in many disciplines, pharmaceutical companies, and foundations supporting health research. One step is to take advantage of clinical trials by collecting more information on the quality of life of those who die while enrolled in experimental or treatment groups. A further step is to support more research on the physiological mechanisms and treatment of symptoms common during the end of life, including neuropsychiatric problems. Pain research appears to supply a good model for this enterprise to follow. To encourage change in the attitudes and understandings of the research establishment, the committee urges the National Institutes of Health and other public agencies to take the lead in organizing workshops, consensus conferences, and other projects that focus on what is and is not known *about end-stage disease and symptom management and that propose an agenda for improvement. Demonstration projects to test new methods of financing and organizing care should be a priority for the Health Care Financing Administration. For the Agency for Health Care Policy and Research, the committee encourages support for the dissemination and replication of proven health care interventions and programs through clinical practice guidelines and other means.*

Julie Fleming Graham, M.Ed. *Oglethorpe County Primary School*

As the mother of a child who bravely fought cancer for 10 months before losing the battle, and as a public school administrator who sees primary and elementary school age children who face medical challenges daily, I feel I can justify my testimony that many women's health issues directly impact the learning of these students.

I would like to speak from personal experience before addressing childhood illnesses that I see everyday in the public school.

At 29 years of age, I was both financially and emotionally prepared to be a first-time mom. Not only was I happily married, my husband and I both had advanced degrees in education and we both were more than willing to accept the responsibilities that were required of parents. I was ready to put my career on hold and, as I look back, I still have no regrets staying home to be a full-time mom. If there is such a "thing," I had the perfect pregnancy. If there is such a "thing," I had the perfect child; a seven pound, healthy boy who for 6 years never had any illness more than a runny nose. For 7 beautiful years, this child, Mark, led a lifestyle some children only read about. He was the most blessed child in the world; he was reared in a stable and happy home with parents who loved him enough to say "no" when needed and to say "yes" when appropriate.

Because we had the "perfect" child, my husband and I were happy to have only one child, who at 4 years old began asking for a baby brother. At 35 years of age, we brought another son, Lee, into the world and for 5 months we were the epitome of the "Clever Family." I thrived on being at home with my two boys and the thought of resuming a career back in the public school was the furthest thing from my mind. My whole world revolved around my two sons and my husband. In September, 1986, our "perfect" world collapsed. Our 6-year-old son, Mark, became uncharacteristically defiant and hard to please. He had little to no appetite and was having difficulty urinating. Because we were in transition from our military home in Ramstein, Germany to temporary living arrangements in Georgia to our final destination, Kirkland Air Force Base in Albuquerque, New Mexico, we dismissed Mark's change in behavior to an upset in his routine and our lifestyle. Our goal was to quickly get settled in New Mexico so Mark could resume some normalcy; thus eliminating any stressors for him.

After 10 years, it is as painful to write about Mark's illness and death as it was when we were living through the nightmare. If we could pinpoint the problem; if we could point a finger; if we could find answers, maybe we could accept his pain and death with more understanding.

In September, 1986, Mark was diagnosed with Rhabdomyosarcoma, cancer of the bladder. On July 20, 1987, 3 days after his seventh birthday, he lost his battle with cancer. His death certificate states: Cause of Death–Uremic Poisoning.

During our many trips to the Pediatric Oncology and Radiation Clinic at the University of New Mexico Hospital, time after time I saw moms, in particular, who shouldered the responsibilities of their sick child's needs. This is not to imply that dads were not caring or involved, it merely says that moms usually were (and still are) the family member going to the hospital, sitting through the treatments, and basically serving as the communicator for the family with the doctors and nurses. Had I not already been a full-time mom, I would have had to resign my position at work because the day in and day out care required was overwhelming. I am convinced that my being in a position full time to devote to Mark's medical needs was one reason we were able to carry on.

Unfortunately, I saw many families where the father would "throw the towel in" and claim he could not take it anymore. Never did I see a mom give in. For the past 10 years, I have made a summer pilgrimage to the University of New Mexico Hospital to volunteer in the Pediatric Oncology Clinic just to work with children and families who are dealing with cancer. I see the same pattern in families I saw in 1986. Usually the mom is the care giver and the parent who burdens the medical responsibilities. This, in my opinion, greatly impacts women's health issues. Moms, many who are single, have to deal with financial burdens, stress, and maintaining some sort of stable life for the sick child and, of course, siblings if there are any. In most families, I have seen that providing support for siblings is just as important as providing chemotherapy for the child with cancer.

My experience as a public school teacher for 13 years prior to my introduction to the world of childhood cancer was a plus for me because I was well prepared to listen to the doctors and to follow instructions. Early on I conveyed to Mark's doctor, Dr. Marilyn Duncan, that I would stand back and let her deal with the medical "end" while I dealt with the emotional "end." Without having read a single book on how to deal with cancer, I knew that if I could keep Mark motivated and focused on living the life I knew a 6-year-old should live, we could win part of the war with cancer. I trusted and respected Dr. Duncan from the moment I met her. I was open minded enough to listen to her and do what I was supposed to do. Her advice to us was to keep Mark's life as normal as possible. She said Mark would let us know his limits. All I needed was her permission to get him in school. With that stamp of approval, I began working with Mark's first grade teacher who was truly a gift from God. She loved Mark enough to make him do his work, yet she was sensitive enough to acknowledge his limitations.

Looking back on the situation now, I shudder to think how Mark's teacher and principal were able to comfortably allow our son to attend school without their fear of a potential lawsuit. I say that because Mark had a central line in his chest that could have been ripped out while playing on the playground. Because of Dr. Duncan's continual assurances that Mark would be fine, I willingly encouraged the school to work with us with the understanding that we were fully aware of the severity of his medical condition and we understood their limitations as to the amount of protection they could give him. Mark learned quickly to play near his teacher while on the playground and, as Dr. Duncan had said earlier, Mark set his own limits without them having to be imposed on him. There were many many days I would take Mark to school only to sit in the car with our 4-month-old, Lee, in case the school needed to contact me immediately. I was so much more at ease knowing I was within hollering distance of him. Mark never knew the days Lee and I sat in the parking lot waiting for him to go home. There were only a few days that he was able to attend school all day.

Throughout the entire 10 months, I had sense enough to realize that I had to take care of myself because if I got down physically or mentally, I would not have been any help to Mark. During this time, I was trying to be a loving and caring mom to our baby, Lee. “Moms helping moms” seemed to be the topic of discussion when we met at the cancer clinic. We shared our stories. We cried and laughed together and we provided shoulders to lean on when the news from the doctor was not good. This emotional support group was a vital necessity then and it is just as necessary today when I talk one-to-one with moms during my summer trip to the University of New Mexico Hospital. If I had the time and resources, I would travel to the clinic at UNM and volunteer my help at least four times a year. The sick child is well cared for and I believe that the Pediatric Oncology Clinic at UNM is doing a wonderful job of offering support to family members including siblings.

For years I dealt with the guilt of believing I had done something to create the “tumor.” Intellectually I knew different, but not knowing what created this monster I chose to find fault with myself in particular. Ten years after my son’s death, I can now talk about his ordeal. Not only did I lose my son, I lost my husband to a divorce, and the family unit that we once were. For 5 years after our son died, my husband and I lived under the same roof but we never talked. The pain was horrific. Fortunately for the two of us, we chose to move on and today we are friends and are able to at least talk about Mark for a short period knowing the conversation will soon end.

Knowing firsthand what it was like to sit in our son’s principal’s office and explain Mark’s limitations and our educational expectations for him, I am acutely aware of parents needs when they now sit in my office and explain to me the medical difficulties their child faces. As a teacher and now as a principal, I have had to relearn sensitivity towards children’s and parent’s needs. What is a major medical concern to a parent is, in my opinion, trivial compared to what our son had to endure.

Since 1972, I have worked in several different public schools and in each I have found a common bond: children with diverse medical and special needs. What is so alarming to me is the increase in numbers of children who need to be served by a special education teacher for either a segment of the day or for the entire day. As an administrator for the past 10 years, I have had a lot of direct contact with other administrators, teachers, students, and their families to validate that there is a growing need in our schools to provide more financial, educational, and counseling support. The most important health issues impacting our children’s learning are, in my opinion: attention deficit disorder (ADD), fetal alcohol syndrome, learning disabilities, diabetes, behavior and emotional behavior disorders, asthma, allergies, mildly and moderately handicapped, and OT/PT/OHI (orthopaedically handicapped or other health impaired).

Those children who have been clinically diagnosed as ADD and who have supportive teachers and parents will, in time, succeed. For those children whose parents refuse to accept that there might be an attention problem and who do not support the school’s efforts to help the child, we find a student who always becomes a major behavior problem thus creating an environment that is not conductive to learning for anyone. We, meaning the school, *never* suggest medicine, but we do recommend that the parent take the child to a pediatrician for a complete physical. We have an alarming number of children in our primary school of 522 who are ADD or who have ADD characteristics. We know that attention deficit is a real disease, a brain disorder. Something different is going on in these kids' brains. When the component of hyperactivity is added, thus ADHD (attention deficit with hyperactivity), other behavior in the child is evident. We always encourage parents to become involved with our school and to become familiar with teachers and administrators and to keep an open working relationship with them to design strategies through our Student Support Team to help their child with ADD or ADHD symptoms. ADD or ADHD children are especially difficult for teachers to deal with. Every single teacher on our faculty has been through staff development courses, attended seminars, and worked with counselors and pediatricians to help them cope with ADD/ADHD children. As supportive as teachers are, and as willing as they are to make every modification possible, the emotional and physical strain of meeting these children's needs and the needs of the other students is overwhelming. I am surprised we have not lost more excellent teachers in the process. It is not surprising to me that many parents are opting for private school or home schooling just so their child does not have to come in second place to the needs of those children who require an inordinate amount of time and energy. The Student Support Team meetings, the eligibility meetings, teacher and parent conferences, and the gathering of anecdotal data to document the child's behavior are extremely time consuming for a teacher, especially if she does not have any teacher assistant working with her.

We certainly cannot say a child is a "fetal alcohol baby" but when we see an increase in the number of children with physically and emotionally challenging needs and Kindergartners who throw severe tantrums, we always make initial contact with our Department of Children and Family Services (DFACS) and the Health Department to secure a realistic background on the mother during her pregnancy. These children are hard to reach and much harder to motivate. The growing number of special needs preschoolers in our rural county of 9,000 is unbelievable. We are fortunate to have a support network through the University of Georgia to help us identify preschool-age children who are in need of early intervention either in the area of speech, physical, mental, or emotional needs. For those children who have had at least 2 years of competent intervention, they are more ready for our 5-year-old Kindergarten program in the public school. Many of our young mothers of these children are in their late teens compounded by the complications of trying to meet the needs of their child while at the same time trying to find their place in life. Fortunately for our school, we have a part-time school counselor who works directly with these mothers offering them information on support services through our local agencies such as mental health, DFACS, and the health department, to name a few. We see so many two parent families, families where the mom is the single parent, and homes where the grandmother is trying to raise a second generation. This breakdown in the traditional family unit is challenging to us because, in many cases, there is not communication between parents, making it more difficult for the school to find a balance between what is best for the child while at the same time trying to effectively communicate with both parents.

In our school alone we have, in our 3- and 4-year-olds special needs preschool class, 16 children who are either MID or MO (mildly or moderately handicapped) or OT/PT/OHI (orthopaedically handicapped or other health impaired). In our kindergarten class of 173 5-year olds, we have one child who is identified as mildly autistic. He has a full-time teacher assistant. In each of the eight homeroom kindergarten classes we have at least one or more students who are going through the SST (student support team) process to help teachers define strategies to provide for students who are exhibiting ADD characteristics or behavior characteristics. These students are generally referred to as having BD (behavior disorder or conduct disorder). We are careful not to begin labeling children at this age, but when behaviors dominate the class environment to the point the other children cannot learn, intervention has to begin. Most of these children come to us from our special needs preschool as SDD (significantly developmentally delayed). One kindergarten class has a very bright student who has cerebral palsy.

Our first grade class of 174 has two children who each have their own teacher assistants. One child is autistic and the other qualifies for a self-contained special education class but whose parents refused that service. A diabetic first grader brings his insulin bag to school every day and we check his blood sugar level daily. His mother repeatedly reminds us that she could own the school if we fail to check his blood sugar level. It is noteworthy to mention that because of our school size and because we are not a wealthy county, we cannot afford a school nurse. Needless to say, this puts an additional burden on our teachers and office staff.

Our second grade class of 167 students has two children who qualify for a self-contained behavior disorders class but who are not being served because of the refusal of the parents. One child, in particular, will probably be referred to a special school out of our county because of his daily outbursts of defiant and belligerent behaviors which we cannot control. This child's father murdered his girlfriend last year in front of the second grader and it was not until this year that some of his aggressive behaviors began to surface.

A group of children who do not qualify for special education, but who require individualized medical attention, are those who suffer daily from allergies or asthma. A typical day in the office is seeing a cadre of children who come through for either their morning or mid-day dose of ritalin, allergy medication, or who use their personal breathing machines. Children with asthma and allergies seem to be on the rise in our schools. Students are absent more during the Spring, and according to their parents, it is always an allergy/asthma-related problem. Although I cannot scientifically prove this, I am convinced our schools indirectly contribute to the problem by allowing classrooms to be carpeted. While some may argue that carpet is pretty, cuts down on noise, is cheaper than tile, and is warm to sit on, I argue that carpet is a haven for germs, mold, odor, and other unseen microorganisms. When a primary school age child has an accident on the floor, it is almost an impossibility to completely clean and sanitize that area. Bodily fluids such as mucus from the nose, blood, urine, saliva, and sweat are excreted onto the carpet making it a “bedroom” for an unsanitary environment. I have discussed this issue with our superintendent and he wholeheartedly agrees with me that carpet does indeed pose medical risks for our children, but the bottom line for our school, and many other schools, is that it is more cost effective to replace carpet rather than to install tile. Because I am in a position to make sure the janitors do their jobs, I am particularly observant to make sure the carpeted classrooms where children work, play, rest, and waller, are vacuumed and cleaned daily. To add insult to injury, we seem to be plagued with an overdose of roaches in our building that is 42 years old. Although the building is old, it is well built and a source of pride for the community. Hopefully, when our taxpayers vote for the special local option sales tax (SPLOST), they will vote “yes” thereby providing much needed money to renovate our building. Old pipes, holes in floors, and standing water all contribute to our roach problem. When we spray for bugs, we aggravate allergies. When we do not spray, we allow roaches to roam the halls. It is truly a no-win situation because the problem is there, yet there seems to be no fail safe answer.

As I reflect on the medical challenges educators face in the public schools everyday, I immediately think about the "Mark Fite's" in the world who go to school with central lines, bald heads, no appetites, and a desire to be normal. I am blessed to have been Mark's mom. He taught me the true meaning of pain, perserverance, self control, integrity, and indominable spirit. I greet the ADD/ADHD, autistic, diabetic, BD, EBD, MI, MO, OT/PT/OHI, and LD children with loving arms every morning and thank God they will never have to endure vincristine or radiation. I now can smile and offer a loving hand when a child comes into the office needing a bandaid for a simple cut. I can now recognize the need to be sympathetic to the crying mother who tells me her baby cannot come to school because his tummy hurts. Dear Lord, save this poor mom from ever having to deal with a life threatening illness. Everyday, more than 5 million children in this country swallow drugs or inhale sprays to help them fight against ailments such as ear and throat infections and asthma. Mark would have willingly swallowed a mid-morning pill to get rid of his cancer. He fought 10 long months, but because of his will to live like a normal 6 year old, he was able to maintain a full life with the support of his devoted family and doctors like Dr. Marilyn Duncan.

Phyllis Greenberger, M.S.W. *Society for the Advancement of Women's Health Research*

Good afternoon. I am Phyllis Greenberger. I am pleased to be here today among so many distinguished researchers and advocates for women's health research. I want to thank Dr. Vivian Pinn and her colleagues at the Office of Research on Women's Health for inviting me and for organizing this important meeting. Along with many of you in the audience, I can remember when a forum on women's health was considered revolutionary. I am glad that enough progress has been made since the initial Hunt Valley meeting that there is now a need to assess the state of women's health and women's health research in the context of today's knowledge. The issues that will be discussed and analyzed at this meeting are at the cutting edge of scientific knowledge.

I would like to begin by offering a capsule view of the Society for the Advancement of Women's Health Research, of which I am executive director. The Society was founded 6 years ago by scientists, researchers, and activists because of a mounting concern that the health of American women was at risk due to the biases and inequities in biomedical research. The Society, working with others, exposed striking inequities in biomedical research including inadequate funding for research on diseases primarily afflicting women; the lack of interdisciplinary research and longitudinal data on women's health care issues; the exclusion of women from clinical trials; the lack of gender analysis; and the dearth of female researchers.

Since 1990, the Society has made notable contributions on Capitol Hill and within the medical and scientific communities. It has served as a catalyst for advances in women's health, including strengthening policy ensuring women's inclusion in federally funded clinical research, the establishment of a permanent Office of Research on Women's Health at the National Institutes of Health, and advocating for increased funding for the National Institutes of Health.

The Society sponsors professional and scientific meetings, including an annual Congress on Women's Health. It publishes studies and reports based on these meetings, produces educational videotapes, and sponsors the peer-reviewed publication, *Journal of Women's Health*. The Society's recent public education efforts include "Get Real," a health education program for young women 18 to 24, developed in partnership with the Office of Women's Health of the U.S. Public Health Service.

Now, I would like to address the specific area that the Society believes is the next frontier for women's health research — gender-based biology. It is a testament to the work of all of us here, as well as others in the private and public sectors, that there is recognition that gender differences exist. And while we still may encounter a great deal of skepticism, no one has to convince us. Why gender differences exist is another question, and that is the area to which the Society is turning its attention.

The Society's President, Dr. Florence Haseltine, describes the need for the concept of gender-based biology in the following words. And I quote: "In other disciplines, like genetics, for instance, there is a body of knowledge that focuses what a scientist does and how she, or he, approaches a problem. The power of a discipline resides in the fact that when a new idea is produced, immediately, the idea is integrated into an already existing body of knowledge. For scientists and doctors, this existing firmament of knowledge guides their thinking and assists them in patient treatment and care."

"Therefore, when we talk about women's health and research, we are talking about gender differences. At the Society, we are beginning to provide this idea with a structure that can be discussed by people from different scientific disciplines. We call it gender-based biology."

Gender-based biology involves the examination of the basic biological and physiological differences between men and women. We believe this protocol has implications for research, clinical practice, disease prevention and manifestation, medical education, and public health policy.

I would like to illustrate the concept of gender-based biology with a few examples, the first of which is from the field of genetics. We know from Medelian genetics that basic chromosomal patterns are inherited from the joint contribution of DNA from our mothers and fathers. At times, the genetic content of only one parent is expressed. This phenomenon is called "imprinting." When imprinting occurs, DNA from only one parent is expressed while the imprinted gene is not functional.

At the Society's 1995 Scientific Advisory Meeting, Dr. Louise Wilkins-Haug, medical director of the Antenatal Diagnostic Center at Brigham and Women's Hospital, noted instances in humans where imprinting has been linked to specific genetic malformations, such as Prader-Willi and Angelman syndromes. What is of particular interest is that when the maternal set of genes is expressed, and the paternal genes are lacking, a person gets Prader-Willi syndrome; when the opposite occurs, the paternal set of genes is expressed, and the maternal genes are lacking, a person gets Angelman syndrome. Dr. Wilkins-Haug called for further investigation into the determinants of this phenomenon.

At the same meeting, Dr. Eric Orwoll, associate professor of medicine and chief of endocrinology and metabolism at the Oregon Health Sciences University, addressed gender differences in the human skeleton. He noted that there is a difference between men and women in periosteol bone formation which is not promoted by estrogen. Dr. Orwoll recommended researchers exploit these differences in bone biology between men and women in order to understand how we can intervene in osteoporosis, a painful disease that affects both men and women.

Dr. Ernst Wynder, president of the American Health Foundation and principal investigator on a retrospective analysis of lung cancer cases between 1981 and 1994, stated that the study suggests that “women may be more susceptible to DNA-damaging carcinogens (including those in tobacco smoke) than men.” He thinks it is likely that there is “an endogenous factor that increases a woman’s risk (of lung cancer).” Dr. Wynder speculates, “...women begin smoking later than men, they smoke fewer and lighter (tar) cigarettes than men...and yet they have a higher risk of developing lung cancer.” And he offers three possible explanations for the variations in risk — gender differences in metabolism; gender differences in certain enzymes which may be part of drug metabolism; and the influence of estrogen, whether naturally produced or taken as medication.

Dr. Jean Hamilton, Betty Cohen professor of women’s health at the Medical College of Pennsylvania and Hahnemann University, noted that “physiological studies in humans have long revealed ... (gender) differences in multiple mechanisms affecting drug absorption and bioavailability, distribution, metabolism and elimination.” She stated that for drugs metabolized by the liver and some primarily excreted through the kidney, “... (gender) differences have been observed with females showing greater bioavailability and slower apparent clearance.” According to Dr. Hamilton, gender affects multiple mechanisms underlying pharmacokinetics. This means that these effects cannot be altered merely by changing dosage on the basis of weight.

Dr. Ruth Merkatz, senior advisor to the commissioner of the Food and Drug Administration, stated that since the 1993 guideline on the participation of women in drug evaluations was published and comments were received, it has become apparent that “there are important scientific questions about gender-based biology and gender analysis that affect (clinical trial) design.” She further emphasized that “these warrant careful attention and scrutiny in an effort to promote both internal and external validity in scientific research.”

The Society believes that an organized and methodological approach to gender-based biology could promote a better understanding of why gender differences exist and their implications. We should, in addition to identifying and accepting gender differences, ascertain why these differences exist. What are the mechanisms underlying the differences? What do the differences tell us about a system as a whole? What are the implications for disease manifestation and treatment. The Society believes that answers to these questions could strengthen our understanding of health and disease.

As I so briefly illustrated, scientists from a variety of disciplines have observed basic biological differences between the genders that significantly impact disease development and treatment. There is increasing evidence to support the study of gender-based biology, which until now has been produced as a byproduct of other research. As we at the Society work to provide a framework for this area of study, we would appreciate your keeping us informed of any new findings that you or your colleagues observe.

Because of the potential significance of a gender-based biology protocol, serious attention by the scientific and medical establishment is necessary. The potential implications of gender-based biology — for research, clinical practice, disease prevention and manifestation, medical education, and public health policy — invite more rigorous investigation. Just as the discovery of the double helix revolutionized the field of human genetics in the early 1960s, the practice of clinical medicine could be dramatically different if the theory of gender-based biology receives adequate attention in the research community.

Letha Y. Griffin, M.D. *American Orthopaedic Society for Sports Medicine*

I am pleased to present the following testimony on behalf of the American Orthopaedic Society of Sports Medicine (OASSM).

Over the last several decades, there has been a marked rise in the number of women participating in recreational and competitive sports. For example, the number of women athletes in our high schools rose from approximately 300,000 in 1971 to almost 2 million in 1990 — nearly a sevenfold increase. Colleges are seeking to provide women with scholarship opportunities equal to men, and although only 96 women competed for the United States in the 1972 Olympics, 280 women competed in 1996 with the U.S. women's teams making an extremely strong showing in multiple sports.

Unfortunately, as the number of women athletes has grown, so have the numbers of injuries they sustain. These injuries are of great concern to us in the AOSSM. Unfortunately, for many of these injuries we lack a clear understanding of the factors which cause the injury, and therefore we are handicapped in constructing adequate preventative programs.

Moreover, many treatment programs for these injuries are controversial and greater funding for outcome studies is needed to resolve these controversies. Questions which need to be answered include: Should women's injuries be treated similarly to men's? Should their rehabilitation programs be structured differently? What are the psychological responses of women to their injuries and how do these influence outcomes? Research must be done to discover these answers if we are to secure safe participation for our women athletes.

Noncontact injuries to the knee's central ligament or the anterior cruciate ligament (ACL) is an example of such an injury. This ligament is a key stabilizer of the knee joint. Injuring it can predispose the knee joint to recurrent injury and subsequent arthritis. The rate of ACL injuries in the general population is approximately 0.38 percent per thousand per year. However, this rate is markedly increased in athletes participating in pivotal sports such as basketball, soccer, volleyball, and skiing.

A study done by Arendt and Dick on the incidence of ACL injuries in collegiate soccer and basketball, utilizing the National College Athletic Association Injury Surveillance System data from 1989-1993, confirmed previous reports that ACL injuries were twice as frequent in women soccer players as in men and four times as frequent in women basketball players. Further substantiation of this increase in ACL injuries can be found throughout the literature published in the 1980s and 1990s.

Recently, this marked increase in the incidence of ACL injuries in women athletes has attracted the attention of the news media as illustrated by the many local news articles, such as this one, which have appeared in various towns throughout the United States describing local sports heroes whose participation was halted by an injury to this ligament. Many of you may remember reading this article which appeared in the February 1995 issue of *Sports Illustrated* and brought national recognition to the epidemic proportions of ACL injuries among those women participating in high-risk sports.

Although several authors of ACL injury surveys in women athletes have looked at the mechanism of ACL injuries, they have not speculated as to the cause. Arendt and Dick suggest the cause for the increased incidence of ACL injuries in female athletes is probably multifactorial, and suggested several intrinsic and extrinsic factors that might contribute.

Intrinsic factors include:

- Joint laxity
- Limb alignment
- Femoral notch dimension
- Ligament size
- Hormonal influences

Extrinsic factors include:

- Muscular strength
- Neuromuscular control
- Body movement
- Skill level
- Shoe-surface interface

All of these factors have been mentioned as probable causes. The degree to which each of these factors may contribute to this injury, and the interrelationship between multiple factors, remains largely unknown. The emotional consequences of this all too frequent injury is great not only for the athlete and her family but also, frequently, to teammates and to the entire school. The financial impact is also large and is not only carried by the athlete, her family, and their medical insurer, but ultimately by society in general.

More money allocated to muscular skeletal research gives us the financial ability to pursue the studies needed to identify the causes of this and other commonly occurring injuries of female athletes. It is only after we understand the *causes* of these injuries that we can begin to develop adequate prevention programs. The goal, ultimately, is through prevention to markedly decrease the occurrences of these dreaded injuries that occur, all too commonly, resulting in significant consequences to our young people.

Andrew A. Guccione, Ph.D., P.T. *American Physical Therapy Association*

The American Physical Therapy Association is pleased to provide a summary of its written testimony to the Office of Research on Women's Health. The Association believes that research is especially needed in the following areas:

Prevention of Chronic Conditions

- There needs to be continuing research emphasis on the prevention of osteoporosis and hip fractures.
- The influence of exercise and physical activity on balance activities, including the prevention of falls, should be studied more extensively.
- Additional research is needed on the benefits of exercise for the prevention of disease and disability.
- Research is needed to identify strategies that can be employed during childhood, adolescence, and adulthood to encourage women to develop good health habits.

Chronic Conditions

- Increased research is needed on chronic conditions and diseases that impact the quality of life of older women in the United States.
- Research is needed to identify the most effective way to reduce musculoskeletal impairment and improve function.
- Research on intervention for osteoporosis, including studies on the clinical effectiveness of weight bearing is indicated.
- Research on rehabilitation interventions which improve functional status following stroke is indicated.
- Additional research is needed on quality of life in individuals with diabetes.
- Research on the prevention and treatment of cardiovascular disease through cardiac rehabilitation for women is needed.
- Additional research is needed to improve urinary incontinence treatments, including therapeutic exercises, electrotherapeutic modalities, and biofeedback.

Recreational and Sports-related Injuries

Investigations into the prevention, causes, and treatment of athletically related musculoskeletal injuries, especially knee injuries, are needed.

Environmental

Attention should be given to interventions which influence the outcome of women with carpal tunnel syndrome and other repetitive strain injuries. In particular, research is needed to identify practical, effective ways to protect workers from job-related musculoskeletal risks, including repetitive stress syndrome.

Additional Topics

- Biomedical research should be expanded to ensure emphasis on conditions and diseases unique to, or more prevalent in, women of all age groups.
- Research is needed to investigate the effect of interventions, including surgery, on female anatomy as well as the impact of these interventions on women's health.
- Research is needed to study the etiology and treatment of the high incidence of musculoskeletal problems in menopausal and postmenopausal women.
- Studies that investigate how exercise can promote healthy aging in women are especially indicated.
- Investigations targeting the identification of domestic violence by health care professionals are necessary.

Recommendations to Promote Research on Women's Health

- Promote efforts to include women in clinical trials, including choosing study site locations and hours that are conducive to participation by women.
- Promote funding for programs that foster women's health research.
- Expand the mission of the Office of Research on Women's Health to monitor funding for women researchers and career opportunities.

Betty B. Hambleton *Health Resources and Services Administration*

HIV/AIDS Among Women

The proportion of total AIDS cases attributable to women is increasing, rising from 7 percent in 1985 to 20 percent in 1996. HIV infection is the third leading cause of death among women ages 25 to 44, and the leading cause of death among black women in this age group. Black and Hispanic women are disproportionately affected, accounting for 59 percent and 19 percent, respectively, of cases reported for women in 1996 — rates that are 17 and 6 times higher than for white women. In 1994, transmission via heterosexual contact surpassed transition via drug use; however, sexual contact with a drug-injecting male accounts for the majority of heterosexually acquired AIDS cases among women.

As the federal agency that provides health care to underserved and vulnerable Americans, the Human Resources and Services Administration (HRSA) focuses many initiatives on addressing the health needs for improving the health status of women. In addition to the community-based health centers offering primary care clinical and screening services, and support for the education and training of the health professional workforce, special services are funded through the Ryan White CARE Act (RWCA) of 1990, administered by HRSA's new HIV/AIDS Bureau, to assist HIV-positive, substance-abusing women, better integrate comprehensive primary care and HIV-related care, and to prevent perinatal transmission of HIV.

Title I of RWCA funds eligible metropolitan areas most severely affected by the HIV/AIDS epidemics. About 30 percent of clients are women, many of whom participate on planning councils established to assess needs, gaps in care, and to set priorities. Title II provides formula funding to states and territories to improve quality, availability, and accessibility of health care and support services for people living with HIV disease; nearly 28 percent of these clients are women. Under Title III, public and private nonprofit entities are funded for outpatient primary care and early intervention services. Of 83,000 HIV patients receiving health services, 794 were pregnant women. An assessment is underway of current HIV counseling and testing services delivered to women of childbearing age and pregnant women in the Community and Migrant Health Center, Health Care for the Homeless, Health Care for Residents of Public Housing, and other programs administered by HRSA's Bureau of Primary Health Care. Title IV funds public and nonprofit entities to increase access to research and comprehensive, community-based systems of care for children, youth, women, and their families. Fifty-three percent of the clients are adolescent or adult women, and more than 25 percent of newly enrolled clients are pregnant women and mothers. The Women's Initiative for HIV Care and Reduction of Perinatal HIV Transmission develops models of care that enhance outreach, counseling, and testing services for women. In 1996, the network of projects provided counseling to more than 12,000 women.

The education of primary health care providers about HIV-related issues is carried out through HRSA's National AIDS Education and Training Centers Program. More than 400,000 providers have been trained under this program since 1991.

HRSA will continue to monitor changes in health needs of women with HIV/AIDS. Research will be carried out to better understand the utilization and effectiveness of its programs and services on the behavior and health status of these women.

Jo Hannafin, M.D., Ph.D. *Orthopaedic Research Society*

The Orthopaedic Research Society is an organization of close to 2,000 individuals (M.D.s and Ph.D.s) who do research on the musculoskeletal system. In her testimony Dr. Hannafin, an orthopaedic surgeon specializing in sports medicine, as well as a researcher studying tendon and ligament healing, will provide information on the role of women in the Research Society and in the Orthopaedic Research Community, as well as presenting data on the advances and unanswered questions pertinent to the Women's Health Initiative. Specific areas which need additional research which will be discussed are:

Osteoporosis — especially in the younger woman, a field in which there are numerous questions.

Injuries in the female athlete — with emphasis on increasing numbers of women in sports and recent data on the types of injuries, and the questions that must be addressed in the future.

Musculoskeletal consequences of breast cancer therapy — with insights into the advances that have been made in the treatment of breast cancer, and the established effects of some of these therapies on bone.

Susan L. Hendrix, D.O. *Wayne State University*
Detroit Medical Center

My name is Susan Hendrix and I am an obstetrician/gynecologist representing Wayne State University and the Detroit Medical Center. I am the principal investigator of the Women's Health Initiative, Detroit Clinical Center, and Director of the Medical Center's Center of Excellence in Women's Health. I am here today to add three areas to the future research agenda in women's health.

Disease prevention and medical (not surgical) treatment for disease are high on the priority list for women of all ages. Ectopic pregnancy, pelvic prolapse, and alternative treatments for menopause are three conditions readily available for prevention, treatment, and clinical trial research.

Ectopic Pregnancy

Ectopic pregnancy, the implantation of the fertilized egg outside the uterine cavity, is the most common cause of maternal death in the first 12 weeks of pregnancy. The incidence of ectopic pregnancy has increased approximately threefold from the 1970s to the 1990s. The increase is attributed to many factors, including an increasing incidence of pelvic inflammatory disease, use of tubal reconstructive surgery and assisted reproductive technologies for infertility, use of tubal ligation for sterilization, and use of intrauterine devices. Ectopic pregnancy is associated with an annual cost exceeding $1 billion in the United States.

Technological advances over the last 10 years now allow for early diagnosis. Specifically, highly sensitive blood tests for detecting pregnancy hormone, high-resolution ultrasound, and the aggressive use of laparoscopy have allowed clinicians to identify and treat this condition earlier in its course. Surgery has been the mainstay in the treatment of patients desiring future fertility.

It is because of these technological advances that we are now able to diagnose ectopic pregnancy without using surgery, including laparoscopy. Recently, methotrexate, a medication used in higher doses for the treatment of cancers, has been successfully used to treat patients with ectopic pregnancy. Use of ultrasound, combined with blood tests, allows patients to avoid surgery and the complications of surgery, reduces health care costs by reducing the need for hospitalization, and possibly improving long-term fertility. Studies are needed to determine the most effective and safest treatment of ectopic pregnancy, as well as determine which treatment affords optimum potential for future pregnancies.

Pelvic Prolapse

Genital prolapse (the detachment of the uterus, vagina, rectum, and bladder from their normal support) is a common condition in women. It is not clear who will develop pelvic prolapse or why, but the condition progressively worsens with age, and prevention measures at an early age are impeded by difficulties in identifying patients at risk.

Little is known about the risk factors. Obstetric trauma has long been thought to be the most important factor in the cause of prolapse. Childbirth, in particular, has been thought to damage pelvic connective tissues and nerves, leading to subsequent prolapse and/or urinary and fecal incontinence. Other considerations include the role of prolonged labor, birthweight, and vaginal operative delivery on the risk of urogenital prolapse.

Surgical management of this condition is the gold standard. However, more research is needed to better understand the causes of this condition and ways to prevent it.

Alternative Menopausal Treatments

Because physicians cannot answer their health questions, menopausal women are taking matters into their own hands. They want coordinated, comprehensive, and preventative health care that is based on cutting-edge research. For many women, traditional approaches to the treatment of menopause are unacceptable. Estrogen replacement therapy causes some patients to have irregular vaginal bleeding, breast tenderness, or an increase in headaches. Others may have had breast cancer or fear an increased risk for breast cancer from the hormones.

They are turning to alternative treatments, including phytoestrogens and herbal remedies, for symptom relief or disease prevention. They feel safer with these therapies. However, “natural” does not necessarily mean safer or better treatment. The strength of plant products can vary and there is no quality oversight to the production of these products. Women need to realize that just because they appear in a health food store, doesn’t mean they’ll do no harm. Only clinical trials on the safety and efficacy of these products will answer that question.

Mary Hepburn, B.S. *Self*

I am not a doctor of research into women's health, but hopefully my life as a disabled woman will shed some light on this important topic. Although I am pleased to address this group about women's health in the 21st century, I have gone through a lot of soul searching about what my experiences can offer.

Disabled women have confronted many obstacles in health that alter their lifestyle, both long and short term. Hearing a diagnosis of multiple sclerosis (MS) in 1981 affected all choices of my life.

With the diagnosis of MS, the person's coping skills are front and center. Obviously, there is physical imbalance, but also an emotional and spiritual imbalance. A balance among all three creates a lot of turmoil for the individual and the family. Examples would include the changing of the job experience, thanks to a voluntary early retirement from NIH in 1994. The need for around-the-clock help causes limited privacy. There are bound to be changes in these areas.

If you've ever undergone any home remodeling or renovation, you might have an idea of the turmoil that has turned my world topsy-turvy and caused chaos — and some days total frustration.

This trip is the most recent example of the planning and logistics that have become part and parcel of my life as a disabled woman. There were many phone calls between Nebraska and Maryland about minute details, of which most people are not aware. For example, a care giver would have to accompany me. It was necessary for me to drive 5 hours to a major airport, because commuter flights aren't accessible for me and my wheelchair. Special arrangements had to be made ahead of time with the airline to accommodate my situation. Arrangements for a specialized taxi that accommodates wheelchairs would be necessary. How would I get from the wheelchair to the bed since I cannot stand? Would I take my Hoyer lift? Would the lift even fit under the motel bed? What other accommodations would be necessary? Endless lists were highlighted and rewritten many times. Spontaneity was out the window.

I recently encountered a mammography machine that is designed for those women who can stand. The contortions that my body had to endure to conform to this machine were almost comical afterward — but not during.

Any kind of exam by a doctor is a challenge to get from the chair to the examining table. Just imagine.

Another obstacle is the obvious change in surroundings. First, in the work world, I was conditioned by the good old-fashioned work ethic. Now, if only my body would do what it is supposed to do ... Instead, I've had to take a detour in order to satisfy the need to be productive in other ways or change my priorities. I write a weekly column for the local newspaper. I tutor adults in reading at the local community college. I teach junior high students about the world of journalism. I participate in church activities. The list keeps going.

There have been the obvious physical changes that have occurred. A bystander will see the wheelchair and conjure up all sorts of thoughts and opinions. "Obviously, this person is mentally as well as physically handicapped." In reality, these are two different issues.

Before I left NIH in l994, I wrote a column about what it's like to be disabled. It seemed to me that some colleagues assumed that I turned into a walking human being when I left the building at 5 p.m. Nice thought.

Not only did I have to deal with physical limitations, but the mental transition couldn't be avoided. Decisions had to be made. My body was failing me, but there was no way my mind was going to follow suit. I had to keep my wits about me. The support, understanding, and concern of family and friends would be essential to my future. As well, my faith kept me grounded. My "why me?" quickly turned into "Why not me?"

I continue to forge ahead and tackle each day's challenges and obstacles head on. Yes, there will be detours along the way. That is a given circumstance and also my challenge.

Nicolette Horbach, M.D. *American Urogynecologic Society*

The American Urogynecologic Society (AUGS) is a medical society composed of over 700 members who specialize in providing the continuum of care to women with disorders of the pelvic organs including the diagnosis and treatment of urinary and fecal incontinence, pelvic organ prolapse, infections, and voiding disorders.

Prevalence statistics regarding the number of women suffering from disorders of the pelvic floor are difficult to ascertain because of significant underreporting of these conditions.

It is estimated that 50 percent of parous women lose pelvic floor support, resulting in prolapse. Of these women, only 10 to 20 percent seek medical care for their symptoms. The overall prevalence of all causes of urinary incontinence is reported to be approximately 40 percent less. Less than half of the women with incontinence report their symptoms to their health provider, and most wait at least 5 years before seeking care.

The National Center for Health Statistics reports that nearly 400,000 operations are performed annually for these conditions. Recent research suggests that women have a 11.1 percent lifetime risk of undergoing a single operation for pelvic organ prolapse and/or urinary incontinence.

The estimates regarding the direct costs of urinary incontinence have increased from $10 billion in 1987 to $16 billion in 1994. Only 4 percent of these dollars is used for the diagnosis and treatment of urinary incontinence; the remainder was spent on management of the problem.

I would now like to share with the Task Force three activities that the American Urogynecologic Society feels will help to uncover new knowledge that will improve the health of women with pelvic floor disorders.

The first is to convene an inter-institute working group in the area of pelvic floor dysfunction research.

The second is to work with NIH to find a mechanism and funding source to support training and career development awards for new and young investigators interested in careers in incontinence and pelvic dysfunction research.

And the third objective is to assist NIH in developing an RFA in FY 1998 with the intent of funding three to five small pilot grants in the area of incontinence and pelvic floor research.

Mary Lloyd Ireland, M.D. *Ruth Jackson Orthopaedic Society*

Mobility: A Key Ingredient for Enhancing the Quality and Length of Women's Lives

Women must adopt an active lifestyle if they are to maintain good physical and mental health. Yet there are many threats to a woman's mobility. Societal biases still hamper women's opportunities to participate in and enjoy athletic activities. Women's physical and anatomical differences from men have not been fully appreciated by coaches and trainers, placing girls at unnecessary risk of pain and injury. As women age, they undergo the special stresses of mineral-depleting osteoporosis and become vulnerable to many kinds of fractures. Hip fracture represents an especially important risk to women since it has such a serious impact on independence and quality of life.

Women's tendency to become less active with age exacerbates their susceptibility to a myriad of health problems including obesity, heart disease, depression, and diabetes. Inactive women often become trapped in a downward spiral of poor health and immobility. The loss of a woman's mobility often results, directly or indirectly, in her premature death.

Physical activity is a critical element of a healthy and satisfying lifestyle. We must learn more about how to promote movement among women, and how to circumvent the social and biological processes which threaten their mobility.

Anne Kasper, Ph.D. *Boston Women's Health Collective*

Our definition of women's health includes women's experiences with their bodies and their sexuality, and their interactions with the health and medical care system, as well as specific biological conditions or diseases mostly affecting women. Our purpose is to work in the public interest to empower women by providing them with the best information available. We support them in making decisions for themselves and their families, with providers who respect and encourage their participation and responsibility. We have focused on the normal in each lifestage and reproductive transition because so much medical information has focused on diseases, or defines normal life transitions as inherently deficient and unmanageable without medical intervention and surveillance. We research and describe nonmedical, self-help approaches and medical treatments, believing that true informed consent includes both. From the start of our work, we have named race and class, gender, and sexual preference as key determinants of health and important human rights concerns. We are advocates for women who use the system, and work with professionals and consumers who organize to change it. We call for greater roles for women in governance of a system which impacts them so profoundly, since that system depends on women's unpaid caregiving labor on behalf of vulnerable and chronically ill family members. We bring a critical lens to the conduct of research and the practice of medicine, and actively pursue evidence of treatment effectiveness as essential to rational decisionmaking. Our scrutiny of the doctor-patient or practitioner-patient relationship has intensified under managed care since providers working under these plans may no longer be able to give the best advice and information. As we work with the media, we bring essential feminist gender analyzes to health issues whose reality and impact is often distorted by gender-neutral or color-blind approaches, or biased by special interest.

We call on ORWH and NIH to research more intensive methods for dissemination of information about true determinants of health, normal processes of development across the life span, and the importance of public interest, evidence-based perspectives in health, and medical decisionmaking. This research would include finding methods to disseminate the ineffectiveness or potential harm and abuse, and to illuminate ethical issues, as well as reporting the effectiveness of biological research or treatment approaches. We cite examples from maternity care, gene research, development, and use of medical technology (especially in normal women), diet and exercise benefits, smoking in girls, the impact of poverty and social class on mortality, women's overwork in workplace and home combined, barrier method contraception, and nonmedical approaches to HIV/AIDS care, in order to illustrate how additional research is needed to examine the impact of research and the implementation of research, on the lives of women from a variety of backgrounds. We also call for greater utilization of methodologies already in use, or piloted recently, such as enhanced Consensus Development Conferences, and the Urban Women's Health regional "Report Cards," in order to come at research issues with greater community perspective and input.

These are some of the issues we feel deserve further research. We would be pleased to work with ORWH and researchers in elaborating on these approaches. Thank you for the opportunity to speak before you today.

Marlene Keeling *Chemically Associated Neurological Disorders*

Research on women's health for the 21st century must address the issue of silicone implants which includes toxic chemicals of known neurologic, carcinogenic, and teratogenic effects in relationship to the mothers' and unborn children's exposure

Exposure to chemical toxins has become an urgent global problem. Much of our knowledge regarding neurotoxicity of specific chemicals, in particular, has not been found in the laboratory; but rather has come from outbreaks of human neurotoxicological disease due to excessive environmental and industrial overexposures as a result of both accident or ignorance. With methyl mercury and PCBs, neurotoxicological illness was not restricted to the adult population; children born to exposed mothers also suffered lasting neurological and behavioral effects as well.

It is now commonly accepted that the developing nervous system in the unborn child is especially sensitive to chemical toxicity. Research on lead, alcohol, methyl mercury, and PCBs indicate that infants and children may be at an increased risk of exposure in the womb and during breast feeding.

As we approach the 21st century, I ask the Office of Research on Women's Health to focus on one source of probable chemical toxicity that has not been adequately researched. Silicone, silica, and its components have not only been used in implantable devices but are used in cosmetics, medicine, the food we eat, on the tips of needles, and in hundreds of other products. It may be found in shampoos, conditioners, lipsticks, bath gels, makeup, and deodorant that you rub on your skin every day. Research now clearly shows that it is not inert in the body, as previously purported by the chemical industry.

With more than 100,000 implanted women having been diagnosed with severe illness, now is the time to do the critical research that should have begun 30 years ago.

Some of the serious problems seen in a large number of implanted women include peripheral neuropathy, demyelinating neuropathy, atypical neurological disorders, cognitive dysfunction, organic brain disorders, and immune dysfunction. Just like latex is now recognized to cause an allergic reaction, silicone has the ability to produce human hypersensitivity in as high as 26 percent of implanted patients as documented by the published research of Dr. Ira Finegold, current President of the American College of Allergy and Immunology.

We need to have the following questions answered:

- Is silicone, silica, or its components a lipid soluble neurotoxin?
- What part does an allergic hypersensitivity to silicone, silica, or its components play in the incidence of chronic illness?
- Does silicone, silica, D4, or other components act as a synthetic estrogen or estrogen blocker?
- Do the reports of increasing cases of multiple myeloma in young women with breast implants indicate a cancer latency factor?

Gwendolyn Puryear Keita, Ph.D. *American Psychological Association*

On behalf of the American Psychological Association (APA), I would like to commend Dr. Vivian Pinn for her leadership on advancing research on women's health. We would also like to convey our deep appreciation for recognition of the importance of psychosocial and behavioral factors in women's health and the inclusion of behavioral and social scientists in the development of the new women's health research agenda.

We are the largest scientific and professional organization representing psychology in the United States. APA's membership includes more than 151,000 researchers, educators, clinicians, consultants, and students. APA's mission is to advance psychology as a means of promoting human welfare, as a science, and as a profession. APA has a long history of involvement in women's issues, in particular supporting and encouraging behavioral and social science research to address women's health.

Despite increased focus on medical and epidemiological aspects of women's health, research has not adequately addressed psychosocial and behavioral factors that contribute to health status. In May 1994, APA, in collaboration with a number of federal agencies and professional organizations, sponsored an interdisciplinary conference entitled "Psychosocial and Behavioral Factors in Women's Health." The purpose of the conference was to highlight the extensive research implicating behavioral and psychosocial factors in a number of major chronic diseases and conditions that influence women's health across the life span.

The "Research Agenda for Psychosocial and Behavioral Factors in Women's Health" evolved out of the conference. It was developed by the conference advisory committee, which included experts from across disciplines, institutes, and federal agencies — including the Office of Research on Women's Health — and represented a broad range of women's health concerns. The research agenda builds on the growing body of knowledge in women's health and articulates a set of priorities for the next generation of research studies.

The research agenda defines research priorities pertaining to specific diseases and health practices that greatly affect women. The diseases included are those that show high mortality or morbidity rates for women and that may cause great physical disability, lowered financial resources, and poorer quality of life. Some of the priorities delineated support important priorities for women's health identified at the beginning of this decade in the U.S. Department of Health and Human Services' *Healthy People 2000*.

Our interdisciplinary Advisory Committee felt that a Research Agenda for Women's Health should be guided by the following principles:

- The focus of research should be on understanding how the experiences of groups affect health-related issues, rather than on simply documenting group differences or differences between women and men. Women are a heterogeneous group whose experiences may vary with ethnicity and race, marital status, parental status, education, income, occupation, sexual orientation, labor force participation, and geographic location (e.g., urban vs. rural).

- Gender-related psychological, behavioral, and social factors, and their interrelationships with biomedical factors, are important to consider in understanding disease and health. Like ethnic status, social class, and age, gender is associated with social realities that are different for women and men.

- Psychological and behavioral factors are important predictors of well being, vulnerability to disease, and disease outcomes. Research is needed on the psychological factors that influence health, including risk reduction, coping behavior, self-efficacy, perceptions of control, social support, and depression.

- Quality of life is an important outcome measure and includes a sense of well being, functional health, and engagement in the psychological and social world.

- A life span, developmental approach is important in understanding health practices and outcomes. The stage of a woman's life influences behavior and also provides a context within which health-related behavior and illness can be understood.

- Contextual factors represent cross-cutting issues that must be considered in designing, implementing, and interpreting research results in order to enhance traditional biomedical research and offer new insights. Thus, women's health issues should be studied within the following contexts:

  - *Relationships:* How do women's relationships affect health status, health behaviors, and health attitudes? How do health behaviors, attitudes, and health status affect women's relationships?

  - *Ethnicity:* How do women's ethnic backgrounds shape their health, health behaviors, and attitudes?

  - *Resources:* How do financial and structural resources enhance or limit women's health options?

  - *Status and power:* How do women's social status, work status, and power within relationships limit health options or affect health status?

  - *Gender expectations:* How is health status affected by gender expectations for mothering/primary parenting and caregiving for others who are sick or in need; expectations to serve as an emotional support system for others; and expectations for housework and other household tasks.

Our research agenda was developed with these factors in mind.

In closing, we propose that ORWH use our research agenda as the foundation upon which ORWH builds its new research agenda. This would avoid duplication of effort and enable women's health researchers, federal agency personnel, and policy makers to most effectively address women's health research and would go a long way in furthering the much-needed federal commitment to improving the health of America's girls and women. Copies of the research agenda are readily available for your use.

Thank you again for the opportunity to participate in this hearing and for your leadership on research on women's health.

Ann Kolker *Ovarian Cancer National Alliance: Ovar'coming Together*

I am Ann Kolker, a founder and board member of the Ovarian Cancer National Alliance: Ovar'coming Together. The Alliance, formed last spring, is the creation of leaders from the growing number of ovarian cancer groups across the country. These groups united to establish an umbrella group, the Alliance, because they believe that it is essential to have a coordinated effort that will put ovarian cancer policy, education, and research issues squarely on the agenda of national policymakers and leaders in women's health. This conference is our public debut.

I have a straightforward message: it is urgent that researchers, clinicians, and policymakers dramatically expand awareness of, and resources devoted to, ovarian cancer with the goal of significantly improving early detection. The tragedy of ovarian cancer is that more than 50 percent of the women who have it *die within 5 years of diagnosis* because the vast majority of women are not diagnosed until the cancer has reached late stage, when it is too late to cure.

There are, of course, several reasons for this serious state of affairs. One is that awareness of ovarian cancer in the medical community is limited. Because it is not a common disease — affecting only one in 55 women — it is not "on the screen" of many primary care doctors who first see women who report abdominal discomfort, bloating, bleeding, or some of the other common symptoms. Gaining the attention of the medical community about ovarian cancer is a top priority of the Alliance. Another concern is that many at-risk women are unaware of symptoms, which are often subtle, and not unique to ovarian cancer. Thus, another Alliance priority is to educate women about this disease so that when symptoms occur, women request appropriate testing. The third problem that dooms so many women to late-stage diagnosis is the imperfect status of diagnostic tools and the absence of a simple, cost-effective, and reliable screening mechanism for ovarian cancer. This is where many of the researchers, clinicians, and policymakers here today can help the ovarian cancer community the most. An immediate Alliance priority is the development of a screening mechanism, as simple and accessible as the Pap smear or mammogram. We urge those of you here today to make this a top priority too, and to urge colleagues to do the same. Until such a screening device is available, early stage ovarian cancer will continue to be missed too often and many thousands of women will continue to die needlessly.

Despite the many new life-saving therapies developed in recent years, and the infusion of new funds designated for ovarian cancer research, much more research must be done to gain a better understanding of key aspects of this disease to dramatically improve the survival rate. We urge that as the women's health research agenda for the 21st century is set by this conference, the compelling needs of ovarian cancer be given top priority. The 183,000 women currently living with ovarian cancer, our sisters, daughters, and granddaughters, and the millions of at-risk women around the country look to your leadership and support.

Virginia T. Ladd, R.T. *American Autoimmune Related Diseases Association*

Dr. Pinn and representatives of the Office of Research on Women's Health (ORWH) at the National Institutes of Health (NIH), my name is Virginia Ladd and I am the Executive Director of the American Autoimmune Related Diseases Association (AARDA). AARDA is the nation's only organization dedicated to raising awareness of early warning signs of autoimmune diseases and promoting collaborative research efforts to cure autoimmunity. I appreciate the opportunity to testify about the need for the women's health community to increase its focus on the category of over 80 chronic autoimmune diseases, which target women about 75 percent of the time. ORWH would serve the health needs of American women by making autoimmunity a central priority of its agenda.

This testimony will focus on two related areas. First, I will discuss autoimmunity as a women's health issue, with a focus on the problems women frequently experience as a result of delay in correctly diagnosing an autoimmune disease. Second, I will address the need to understand autoimmunity as a category of diseases, like cancer, as well as the need to conduct collaborative research on autoimmunity — the common link to many chronic diseases which are currently independently treated and studied.

Autoimmunity Is a Major Health Issue

Autoimmunity is a debilitating condition in which the immune system attacks the body's own tissues or cells. Autoimmunity is the root cause of over 80 serious, chronic diseases including connective tissue diseases such as lupus (inflammation of connective tissue), rheumatoid arthritis (joints), and scleroderma (skin); neuromuscular diseases including multiple sclerosis (nervous system); and endocrine diseases including Graves' disease/hyperthyroidism and Type I (insulin-dependent) Diabetes. The entire family of autoimmune diseases affects an estimated 50 million Americans, and the cost of treating these chronic conditions is estimated at $86 billion annually.

In September 1997, the *Journal of Clinical Immunology and Immunopathology* published a study, conducted with AARDA's support, that examined the prevalence and incidence of 24 autoimmune diseases. The study estimated that over 8.5 million Americans suffer from one of these 24 diseases. Moreover, the researchers found that almost 240,000 people develop one of the 24 diseases annually. Graves' disease is the most prevalent of the diseases included in the study — about 1,152 per 100,000 people. Rheumatoid arthritis (about 24 per 100,000) and thyroiditis/hypothyroidism (22 per 100,000) were the diseases with the highest incidence rates.

Autoimmunity Is a Major Women's Health Issue

As the Office on Women's Health at the Public Health Service recognized when it focused on autoimmunity during its *Healthy Women 2000* conference in Washington last year, autoimmunity is largely a women's health problem. Autoimmunity usually strikes a woman during childbearing years and some research may suggest a link between a woman's heightened hormonal activity during this life period and autoimmunity. Indeed, autoimmune reactions may be responsible for about 60 percent of infertility problems, creating additional physical and emotional burdens associated with reproductive difficulties.

Taken together, autoimmune diseases represent the fourth largest cause of disability among women in the United States. Autoimmune diseases strike three times as many women as men, and the female:male disparity is even greater for some individual autoimmune diseases. For example, the female:male ratio for Hashimoto's thyroid disease is 50:1; for lupus, Graves' disease, and chronic active hepatitis, the ratio is approximately 9:1.

Autoimmunity is known to have a genetic component, and tends to cluster in families as different diseases — a mother may have lupus; her son, juvenile diabetes; her sister, antiphospholipid diseases; and her mother, rheumatoid arthritis. Moreover, people with autoimmunity often experience more than one autoimmune disease. AARDA commends ORWH for its recently announced collaboration with other institutes at NIH — including the National Institute of Allergy and Infectious Diseases, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Institute of Diabetes and Digestive and Kidney Diseases, and the National Institute on Aging — to fund a 5-year grant for basic preclinical research on the genetic susceptibility to autoimmune diseases.

For many women, getting a proper diagnosis for an autoimmune disorder proves as difficult as living with the disease itself. Several factors contribute to misdiagnosis or late diagnosis which delay proper treatment. Symptoms of autoimmunity vary both among the different autoimmune diseases and within a particular disease. The symptoms may come and go, and may be difficult for a woman to describe with precision to her physician. And the impact of autoimmunity on more than one body system can impede and confuse diagnosis.

The physical and psychological toll of misdiagnosis and late diagnosis for sufferers of autoimmune diseases can be substantial. In the first place, of course, no early diagnosis means no early treatment. Significant tissue or organ damage can occur during the time lag in pinpointing an autoimmune disease, worsening the chronic and painful health burden that a patient will bear for the rest of her life.

The psychological impact of late diagnosis may also be devastating. The difficulty in identifying symptoms may result in a physician not taking the patient's complaints seriously. A survey conducted by AARDA found that over 65 percent of patients with autoimmune diseases have been labeled hypochondriacs in the earliest stages of their illness. Thus, the undiagnosed autoimmune patient may struggle with self doubt, even questions of sanity, during the years it may take to obtain a correct diagnosis. Furthermore, the multiplicity of symptoms and affected body systems may cause the patient to endure a long series of unsuccessful tests and procedures from a range of specialists attempting to diagnose the problem. Kelly Ripken, wife of Cal Ripken, Jr. of the Baltimore Orioles, had a typical experience. She was examined by five specialists over several years before she was correctly diagnosed with Graves' disease.

The problems in obtaining a timely, accurate diagnosis of autoimmunity overwhelmingly affect women, who represent approximately 75 percent of all autoimmune patients. ORWH is well positioned to take a leading role in organizing a concerted education and research campaign to improve recognition and early testing for autoimmune diseases, and in promoting basic research into autoimmunity, the root cause of all of these diseases.

Discovering the Root Cause for All Autoimmune Diseases Depends on Basic Research

As indicated above, the problems with timely recognition and diagnosis of autoimmune diseases partly result from the fragmented way in which the medical community approaches autoimmunity. Unlike cancer, which is an umbrella category for a range of diseases (e.g., breast cancer, leukemia, non-Hodgkin's lymphoma, etc.), autoimmunity has yet to be embraced by the medical community (and the public) as a category of disease. Autoimmune diseases fall into such disparate areas as rheumatology, endocrinology, neurology, cardiology, and dermatology; consequently, there has been no general focus on autoimmunity as the underlying cause.

Our efforts to encourage greater communication and coordination among different parts of the research community working on autoimmune disorders has borne some fruit. This year, both the House and Senate appropriations subcommittees with jurisdiction over NIH have urged the NIH Director to explore the creation of an autoimmune coordinating body to "improve the use of existing research funds and facilitate the application of important findings among the many research programs dealing with autoimmune diseases" at NIH. Additionally, it is encouraging to see the cooperation of four institutes and ORWH with respect to the grant for research into the genetics of autoimmunity, the role of co-stimulation of immune cells, and the mechanism of induction, perpetuation, and injury caused by the autoreactive response.

These steps indicate progress, but they alone are not enough. ORWH has a substantial opportunity to increase the visibility and focus on autoimmunity as a common cause of diseases that disproportionately affect women. AARDA strongly urges ORWH to push for collaborative efforts to conduct basic research that would bear fruit for all autoimmune diseases, rather than continuing to focus more narrowly on individual diseases.

There have been exciting breakthroughs in research focused on new treatments for autoimmune diseases, notwithstanding the dearth of basic collaborative research into the root cause of autoimmunity. For example, new treatment modalities, such as oral tolerization, have shown promise for several autoimmune diseases across clinical categories. Such success in treating multiple diseases underscores the common link among the different diseases, and should encourage the next phase of autoimmune research: basic research to discover the root cause of autoimmunity. Basic research will yield information that benefits the treatment and diagnosis of all autoimmune diseases and represents the most promising approach to finding a cure.

Conclusion

ORWH, perhaps more than any other office or institution, has the capability to substantially improve our country's approach to autoimmunity. Efforts to channel additional resources to basic biomedical research on autoimmunity will encourage the coordination of currently fractured research efforts. Such collaboration will also promote the increasingly supported view that autoimmune diseases are connected by common threads. Furthermore, such research efforts will concurrently stimulate greater awareness and knowledge of autoimmunity among the medical community and the public, thereby aiding early diagnosis and treatment. AARDA urges ORWH to seize this timely opportunity to address one of the leading and most vexing health problems facing American women.

Mary Lamielle *National Center for Environmental Health Strategies, Inc.*

Thank you for the opportunity to testify before the Office of Research on Women's Health, Bethesda, Maryland, November 17, 1997.

My name is Mary Lamielle. I am director of the National Center for Environmental Health Strategies, Inc., based in Voorhees, New Jersey. The Center is a national not-for-profit membership organization fostering the development of creative solutions to environmental health problems with a focus on indoor pollution, chemical sensitivities, and environmental disabilities. Founded in 1986, the Center has become a preeminent source of public information, educational materials, and technical support and input on research to the government on environmental illnesses including sick building syndrome, chemical sensitivities, Gulf War syndrome, and related disorders.

We have been the pathfinders in the area of multiple chemical sensitivities (MCS): initiating the New Jersey study of chemical sensitivity by Nicholas Ashford and Claudia Miller; testifying before Congress on the Indoor Air Quality Act on three occasions; securing HUD recognition of multiple chemical sensitivities as a physical disability; and ensuring that guidelines under the Americans with Disabilities Act address this issue. I also worked to secure the first Congressional funding for research on MCS and served on all subsequent research panels.

For a dozen years, we have assisted and tracked those sick or disabled by low-level chemical exposures at home, at school, at work, and in the community. We typically receive hundreds to as many as a thousand requests for information a month from individuals who suspect that they have been injured by low-level chemical exposures, or who have developed MCS subsequent to such an exposure event.

Patients most frequently report an initiating event such as a pesticide application, new carpet installation, remodeling activities, solvent exposures, inadequate ventilation, or poor air quality. Following this exposure event the patient will find, over time, that she reacts to more and more different substances and products at lower and lower exposure levels. Clusters of symptoms will be triggered on a day-to-day basis upon exposure to a diverse array of common substances and products including pesticides, perfumes, auto and diesel exhaust, tobacco smoke, air fresheners, deodorizers, dry cleaning fluid, hair spray, and other personal products, just to name a few. Those patients who cannot remove themselves from such exposures will generally find that their health declines rapidly, and that they experience significant levels of illness and disability.

Based on a number of government and university-based studies, it appears that number of individuals reporting sensitivity to everyday chemical exposures is on the rise, with women reportedly outnumbering men in such surveys. Little research has been done to help us understand the phenomenon, address the health issues for those who report chronic illness and disability, provide treatment protocol, or protect public health.

Over a decade ago, in July 1987, the Board on Environmental Studies and Toxicology at the National Academy of Sciences held a workshop to examine indoor pollution and chemical sensitivity. Experts at this workshop issued a now famous, off-the-cuff estimate that "approximately 15 percent of the U.S. population have an increased allergic sensitivity to chemicals commonly found in household products, such as detergents, solvents, pesticides, metals, and rubber, thus placing them at increased risk to disease." The consensus from the meeting — further research is needed to examine the extent of this public health problem and the role that indoor pollutants, particularly from consumer products, play in promoting chemical sensitivity. Despite this auspicious beginning, the first government-sponsored workshop on MCS was not held until 3 years, 8 months later. It took directed Congressional funding and another 2 years until the Agency for Toxic Substances and Disease Registry created an expert panel and convened a neuroscience workshop in Baltimore. To date, little research has taken place to illuminate this issue.

Meanwhile, industry, segments of the medical community, and insurance companies are among those groups who have been and remain tremendous obstacles to investigating and acting on MCS. They have succeeded in creating a hostile environment for patients who must frequently depend on the goodwill of family members, friends, and society to meet their overwhelming needs.

A research agenda to investigate multiple chemical sensitivities and related disorders is long overdue. I would urge you, on behalf of our membership and those in the United States and around the world suffering with this devastating problem, to examine the compelling needs of those disabled by MCS, and to assign the highest priority to this significant and growing public health problem. If the apparent rise in MCS patients is accurate, progressive loss of tolerance for everyday chemical and environmental exposures may have profound consequences for the public health and society.

Marian C. Limacher, M.D. *American College of Cardiology*

Unanswered Questions About Heart Disease in Women

Coronary heart disease (CHD) is the leading cause of death in American women. While not comprehensively studied over previous decades, information now exists about risk factors, diagnosis, management, and prognosis for women with CHD. Differences between men and women are evident in many aspects of the CHD spectrum of evaluation and outcomes. For some increases in mortality, differences have been shown to be related to increased levels of other features that impart higher risk, including older age, more advanced disease, and more concomitant diseases, rather than gender-specific factors. Some reports suggest bias in decisionmaking when diagnosing or treating women. Much more information is needed to determine the sources of differences and the adjustments needed to improve the outcome of women with CHD.

Topics recommended for further research include: assessing risk factor intervention (particularly diabetes); primary prevention of CHD with cholesterol-lowering agents with consideration of the potential interaction with hormone replacement therapy; programs to improve health behaviors, in general, and programs designed to reduce teenage smoking and increase physical activity, in particular; treatments for obesity and their impact on CHD; algorithms for diagnostic testing; studies to assess optimal therapy for men and women to eliminate biases and produce evidence-based guidelines; studies on survival of myocardial infarction; assessing appropriate dosing of new agents for women and men; and studies to assess the impact on aging vs. gender on diagnostic and therapeutic decisions and in assessing outcome.

Lisa Lindahl *Epilepsy Foundation of America*

Good Afternoon. I am Lisa Lindahl and I am here today representing the Epilepsy Foundation of America (EFA). I am the Chair of the Foundation's Women and Epilepsy Initiative and a member of the Board of Directors. I appreciate the opportunity to provide input to the NIH Office of Research on Women's Health on developing a research agenda for the 21st century.

I am submitting to you a brief EFA statement which discusses women's health research needs and epilepsy. I urge you to incorporate these recommendations into the report you will be developing. We hope that this report will help drive the momentum to double the overall funding for NIH. EFA and other voluntary health agencies advocate for increased societal commitment to funding medical research in order to meet the many existing basic and clinical research needs and opportunities.

I will not spend my time this afternoon reviewing the EFA statement we are submitting. Instead, I wish to use this time to talk to you as a woman with epilepsy who is giving a voice to the over one million other women in the United States who have epilepsy.

We are a group in critical need and without sufficient attention. Our lives will remain vulnerable to a host of serious consequences if left ignored.

Dramatic? Yes, but true nevertheless!

Let me first say that *all* people with epilepsy face many challenges. To a significant degree, these challenges have little differentiation due to gender. However, what has not been widely understood is the role the female hormonal cycle plays on these differences.

Greater understanding is the essential first step! Parity in women's health care effects *all* women. Women have rallied behind greater research efforts for breast cancer and for heart disease. It is now the time for greater research efforts for women with epilepsy.

What are some of the issues that such a focus could explain? I will briefly outline a few:

- Will the onset of menses affect the type or severity of a girl's seizure disorder?
- Is fertility affected at all?

- Can women with epilepsy have safe pregnancies? Healthy babies? Should they breast feed?
- Is the effectiveness of anti-epileptic medication impacted by a woman's hormonal fluctuations?
- Does medication work the same way on women as it does on men?
- What happens as menopause begins and progresses?
- Are there any interactions between anti-epileptic medications and the therapies prescribed for menopause?

I am sure you will agree these are reasonable questions and I am sure you will not be surprised that we do not have a extensive scientific body of knowledge to answer all these questions. Without the scientific information in this area, we are left with guesswork.

This is not a "new" problem. Epilepsy, or the "falling sickness" as it was known in ancient times, is one of the earliest disorders to be chronicled. As I understand, the first documentation of a seizure pattern unique to women was made in the late 1800s. A Dr. Gowers, in 1881, reported that about half of his female patients seemed to have more seizures before or during their menstrual cycle. Nothing more appears in the literature until 75 years later when a paper by Dr. Laidlaw, in 1956, described "catamenial epilepsy" — a prevalent pattern in women of hormone-sensitive seizures. No further inquiry was made until the 1980s, nearly 30 years later.

So, beginning in the 1980s, a few brave and curious souls began to do research. One researcher even used hormones to control seizures in some women. Although the work truly began in the 1980s with a few talented researchers, the surface was hardly scratched. What is critically needed is a complex and far-reaching field of inquiry. We must not allow another century to pass.

No, we must not allow more time to pass without listening to the needs and voices of real women with real issues... epilepsy issues. The quotes that follow are real. The first comes from Darlene.

I had my first seizure just after I found out I was pregnant. I miscarried the baby. My husband blames me for losing the child, even though intellectually he know it's not my fault. It has paralyzed our relationship... Epilepsy is not a disease, it's a disaster. — Darlene

AND

from Jane we hear...

I live with the agony of my seizure disorder every day when I see what is has done to my child. I feel like I can't even ask my husband to take on much responsibility for caring for our child because what happened is my fault. I can't help but feel guilty, even if it's not by fault. (This is in reference to her 12-year-old child who was born with congenital birth defects; allegedly a result of her anti-epileptic drugs.)

You have heard from Darlene and Jane, now I want to share some of my story. I was diagnosed with absence seizures at the age of 3. The rest of my history is similar to many I have heard since working with the Epilepsy Foundation: First convulsion at puberty; fear regarding childbearing due to faulty and/or no information; a long bout with serious overmedication; lack of any physician recognition regarding the apparent difference in my ability to tolerate "typical" therapeutic levels of anti-epileptic drugs (AEDs); personal choice for undermedication and use of lifestyle management control; lack of physician recognition of my seizure pattern as it related to my hormonal cycle; and now, my current challenge is being perimenopausal and not knowing what that may mean in terms of the on-going quality of my life and my ability to lead a fairly productive one.

These are just a few stories. Countless other stories of women with epilepsy are left behind in our files, waiting to make sense of their stories — waiting for answers.

In conclusion, let me reiterate what I said at the start. I am taking a turn today being the voice of the over one million women in this country who have epilepsy. Collectively, we urge you to start the process that will result in women receiving accurate data, informed medical care, and increased quality of life. Do the research. Institute the testing programs. Find the answers. Develop the solutions.

I encourage you to move forward with a sense of urgency. The help we need will take a long time to discover, develop, and disseminate. We need to focus our energy on those girls and young women of today so that they may have a chance to be spared the discrimination, anguish, fear, and insufficient medical choices to properly guide their life.

Toward A Women's Health Research Agenda

The Epilepsy Foundation of America has had a longstanding commitment to research and has recently focused efforts on advocacy to promote more research on women's health issues. Specifically, EFA has established the Women with Epilepsy Initiative (WEI) to advance the cause of further research, to guide diagnosis, enhance clinical care, and improve the quality of life for women who have seizures. As new information is gathered through scientific investigation, strategies for improving the quality of life of women with seizure disorders may be effectively implemented.

More than one million women and girls in the United States have epilepsy (seizure disorders). Seizures and exposure to AEDs may alter female reproductive function and may have a negative effect on pregnancy and reproductive health. For instance, women with epilepsy are at greater risk for pregnancy complications, while fetal exposure to AEDs increases the risk of birth defects. Efficacy of hormonal contraceptives may be compromised by interactions with drugs to control seizures. Recent studies show that fertility is lowered and sexual dysfunction affects nearly one-third of women with seizure disorders. Complicating these concerns, many women with epilepsy are seen by health care professionals who are unfamiliar with these unique issues. A lack of research in this area compounds the problem. In addition, very little research has been done on behavioral and psychosocial aspects of epilepsy for women which effect quality of life.

Identifiable Advances in Women's Health Research and Epilepsy

Although research on women's health issues unique to women with epilepsy is very limited, a basic body of knowledge has been developed. Research has established:

- a clinical relationship between hormones and seizures — hormones effect epilepsy and epilepsy effects hormones, and that there is a relationship between hormones and seizures at puberty, over the menstrual cycle, and at menopause;
- women who have epilepsy experience sexual dysfunction more often than women who do not have epilepsy;
- fertility may be compromised and the higher failure rate of contraceptives in women taking AEDs effects a woman's ability to plan her family;
- risks during pregnancy are significantly greater for women with epilepsy than the population-at-large and include risk of maternal injury during seizure, risks to the fetus caused by teratogenic anti-epileptic drugs, ruptured membranes, preterm delivery, and even fetal death;
- women with epilepsy face a constellation of behavioral and social adjustment problems including parenting, employment, and depression, among others.

Despite basic knowledge in some of these areas, we do not yet know how the research findings that are available may be utilized for effective treatment, leading to improved quality of life for women with seizure disorders.

Barriers to Conducting Outcomes Research in the Field

While the federal government, industry, private foundations, and individual donors devote funds to support epilepsy research, very little funding is targeted to examine women's health issues specifically. Drug trials have traditionally not included women with epilepsy, and thus, clinical efficacy and problems with side effects are not evaluated prospectively. An epidemiological basis of understanding about women with seizure disorders is needed to establish a sound understanding of the population as a whole and to gather information about subgroups and subcategories of experience with seizures, seizure management, and women's health — such an epidemiological basis is not currently available. A national database is needed on pregnancy, birth, and infant outcomes of women with seizure disorders.

More funding, inclusion of women of all ages in core research, and in-depth baseline data are very much needed to proceed with carrying out a meaningful outcomes research agenda.

Area(s) in the Field That Need Further Examination

Numerous areas require extensive research:

- *Birth outcomes:* issues around teratogenic drugs and pregnancy must be explored to address the serious problems of infant mortality and birth defects; we currently do not know enough about the association between folic acid and decreased risks of serious birth defects, or actual outcomes from folate use;
- *Reproductive health:* incidence of reproductive endocrine disorders in women with epilepsy must be examined, including concerns about anovulatory cycles and polycystic ovarian disease; impact of this on general health, such as cardiac functioning and other metabolic issues, are poorly elucidated or understood;
- *Family planning/contraception:* increased risk of contraceptive failure (of hormonal contraceptives) needs examination; need to understand if contraceptives effect seizure control;
- *Hormone replacement therapy:* need findings to establish relative risk-benefits of HRT for women with epilepsy;
- *Bone health:* poorly understood in women with epilepsy, especially with regard to usage of anti-epileptic drugs;
- *Hormone-to-seizure/seizure-to-hormone relationships:* need to understand reasons for changes in seizures and seizure control at puberty, during the menstrual phases, and at menopause;
- *Behavioral and psychosocial issues:* impact of epilepsy on factors of neuropsychological functioning and independent living must be examined more thoroughly including learning, memory, depression, employment, and parenting, among others.

It is important to the overall research agenda for women's health and seizure disorders to be interdisciplinary. Geneticists, molecular scientists, endocrinologists, neurologists, obstetricians, and gynecologists are among the key participants in a comprehensive, interdisciplinary research process. Collaborative efforts and synthesis of findings are essential to integrate the research across many relevant disciplines.

With a sound research base in place, we will have more opportunity to ensure women with epilepsy are healthy mothers, have healthy babies, and have an improved quality of life.

Randall McCoy *CareTrends Health Education and Research Institute*

Background and Rationale

The population in the United States continues to grow and age.[1] With increases in the elderly population, the humanistic and economic costs of chronic diseases are escalating at astounding rates.[2] Several diseases are particularly prevalent in the elderly including cancer, heart disease, and osteoporosis.[3] The most effective intervention for these diseases are preventative measures. All of these diseases result in morbid and often fatal complications. In order to delay or prevent the complications associated with these progressive diseases, very costly therapeutic interventions must be implemented. Osteoporosis is a very costly disease that can be prevented/treated with early intervention and diagnosis. Therefore, early diagnosis and prevention of osteoporosis should be at the forefront of health care.

Osteoporosis is Prevalent

The prevalence of specific diseases varies in the population. Occurrence of breast cancer is 7 percent, prostate cancer is 8 percent, diabetes is 6 percent, and heart disease is 28 percent of the total population. Osteoporosis occurs in 37 percent of the population in which one-third of those with osteoporosis are men. In the 1990s, an annual estimate of 2.5 million hip fractures and 5 million vertebral fractures resulting in pain, disability, loss of independence, and 375,000 deaths is occurring due to osteoporosis.[3] This will increase as the elderly population continues to grow. At present, the risk for a 50-year-old white woman to have a fracture related to osteoporosis is 30 to 40 percent.[4] Therefore, osteoporosis is a predominant, devastating disease in the United States.

Osteoporosis is Costly

Osteoporosis has a profound, negative impact in the economic domain along with being devastating to its victims' quality of life. Costs are currently more than $20 billion per year, with a projected cost by the year 2010 of $60 billion.[3,5] Due to the age of persons being treated for osteoporosis, the majority of funding for treatment comes from publicly financed health care programs. Costs include treatment for fractures, acute-care hospitalization, and rehabilitation. Complications following fractures, such as deep vein thrombosis, pulmonary edema, congestive heart failure, and pneumonia, further add to the costs. In addition, 49 percent of males and 54 percent of females on Medicare with osteoporosis-related hip fractures are discharged from the hospital to skilled, long-term care facilities.[6] In a Medicare study, 25 percent of persons in long-term care with hip fractures had been there for 1 year after the fracture.[7] Furthermore, osteoporosis is the leading contributing factor in the premature death of older women. Thirty-three percent of the women who suffer hip fractures will die within 2 years of the fracture.[2] Thus, the impact on health care utilization and humanistic costs are enormous.

Other costs of osteoporosis in the humanistic realm include functional limitations, reduced quality of life, loss of independence, and inability to work.[2] Many women with advanced osteoporosis report a loss of self esteem. Clothes no longer fit correctly and buying new clothes to fit properly can become difficult. The victims report they can no longer reach items on the upper shelves in the grocery store or in their kitchens and can no longer see over the steering wheel to drive. Women with advanced osteoporosis often experience shortness of breath due to reduction in the size of the thoracic cavity as the spine collapses and the rib cage comes to rest on the pelvic bone. This "compression" of the abdomen impacts negatively on the function of the digestive system and often results in constipation. Furthermore, not only does osteoporosis shorten the lives of many women, it turns their golden years into years of tragedy. Loss of independence leads to being forced to move from their homes. Often, the move results in loss of contact with their support system of family and friends. In addition, many elderly will spend the remainder of their lives in an environment they did not choose or want for a residence. Therefore, the staggering economic and social cost of osteoporosis places a heavy burden on the health care system.

Osteoporosis is Easily Detectable

No dependable tests are available that can predict who will develop cancer or heart disease in individuals as they age. Unlike heart disease or cancer, osteoporosis can be detected early in its existence by a simple x-ray test known as a Dual Energy X-ray Absorptiometry (DEXA) scan that is extremely accurate.[8] Furthermore, osteoporosis is not a disease of the aging exclusively but begins much earlier in life. Evaluation of bone mass at menopause at the hip, spine, and wrist can predict who will develop osteoporosis later in life with a high degree of reliability. Identified individuals at high risk for osteoporosis can receive nutrition, exercise, and lifestyle interventions which will delay or prevent osteoporosis development.[3]

Osteoporosis is Preventable

Variations of bone mass accumulation during childhood and adolescence are an important component as a risk factor of developing osteoporosis later in life. Increasing bone mass in childhood and adolescence through education and intervention can be one of the key components to osteoporosis prevention.[9] Screening of young adults must be done to identify those persons requiring intensive intervention to prevent osteoporosis complications in the future.

Nutrition is one of the major factors in the prevention of osteoporosis. Adequate calcium and vitamin D intake in children and adolescents are necessary for increased bone mass.[10] One researcher has estimated that the risk of fractures at age 70 could be doubled by low calcium intakes in the first 30 years of life.[9] In addition, a significant body of research exists to demonstrate that women who have received adequate nutrition, particularly calcium and vitamin D, have a lower rate of osteoporosis.[3] Other nutritional factors can affect bone mass. Excessive amounts of salt and animal protein increase bone loss and should be avoided.[11,12] Therefore, intensive nutrition education and intervention are mandatory and should contribute to osteoporosis prevention. Lifestyle is an additional factor in osteoporosis prevention. In children, a positive association exists between physical activity and bone mass affecting skeletal mass later in life.[13] Exercise can also reduce bone loss in older women.[14,15] Exercise must be weight bearing or strength and resistance training.[3] Therefore, exercise education is essential to prevent osteoporosis. Other lifestyle aspects that affect bone health are smoking and excessive alcohol intake. Smoking cessation education and intervention is obligatory.[3] Furthermore, excessive alcohol consumption contributes to decreased bone mass.[16] Lifestyle changes must be included in osteoporosis prevention.

Osteoporosis is Treatable

Pharmacological therapy is used to treat osteoporosis. The therapy of choice is hormone replacement therapy, specifically estrogen. Estrogen therapy at menopause has been proven successful in maintaining bone mass, for the majority of women, for the duration of the therapy. However, as soon as estrogen therapy is withdrawn, loss of bone mass will resume. There are other FDA-approved therapies for osteoporosis. At least one of these approved therapies has been shown to effectively protect bone mass. In addition, in many patients, medications from the bisphosphonate class will increase bone mass by 5 to 7 percent.[17] Thus, in addition to behavioral modification, there are a number of effective pharmacologic agents available for the treatment of osteoporosis. Compliance with medication treatment is not reliable. While estrogen therapy has been the treatment of choice for osteoporosis, only 15 percent of women who are prescribed estrogen continue to take the hormone 12 months after the initial prescription is filled. Very little data exists describing the rate of compliance for other agents used for osteoporosis treatment. Due to inherent difficulties with the bisphosphonates, further study is necessary to evaluate the compliance with medication regimens.

Osteoporosis Data are Needed

Currently, no ongoing, long-range program exists to determine bone mass in premenopausal women and, in particular, female teens. Studies are required to determine the need for therapies to stabilize bone mass in young women who may have seriously depleted skeletal mass. Dietary surveys in the United States report decreased calcium intake in adolescent females. This population does not consume the recommended daily allowance for calcium at a time when their need for calcium is high. In addition, teen pregnancies produce added need for calcium which is not being met with sufficient calcium intake. These factors, at a young age, contribute to low bone density as women age which leads to increased fractures.[18,19] Similarly, little is known about the adolescent development of the male skeleton and to what extent risk factors such as poor diet, lack of exercise, and smoking have on skeletal mass in the general male population. Bone mass measurements are not routinely done in men unless there is an underlying disease state or they are on a therapy that would warrant monitoring of bone mass. While osteoporosis in men is increasing with longer life spans, there is little data to support theories that men have higher levels of depleted bone mass than traditionally has been thought.[20] Baseline data is needed on the prevalence of low bone mass in males between 20 and 50 years of age and from 51 and beyond. Given the prevalence of the risk factors in the general population, osteoporosis is, and will continue to be, a major public health problem and a much greater problem than generally is recognized. We have reached this conclusion for several reasons. We have been involved in a clinical trial of a drug thought to be effective in the treatment of women with osteoporosis and established vertebral compression fractures. Approximately 4,000 women have been screened since mid-October, 1996 in the northern Plains states of Montana, Wyoming, North and South Dakota, portions of northeastern Nebraska, and northwestern Iowa. Women between the age of 55 and 80, who have no previous history of cancer and are currently taking no other medications for osteoporosis, are eligible for screening. Women who qualify for the study, based on health history, receive a DEXA scan of the lumbar spine and hip to determine if bone mass is equal to or more than two standard deviations below the young normal. If so, x-rays are taken of the spine to determine the presence of at least one compression fracture defined as a 15 percent deformity. At several of the screening sites, nearly 70 percent of the women receiving DEXA scans have qualifying bone mass. Approximately two-thirds of that number have qualifying fractures and osteoporosis.

The women with low bone density and spinal fractures, who are otherwise asymptomatic and have sought no medical treatment for their osteoporosis, may not truly represent the population of women in that age group in the region. However, the level of incidence is sufficiently high in this group to call into question the prevalence of osteoporosis in the general population of women in this age range. Since most of the drug studies for treatment of osteoporosis in postmenopausal women exclude women with prior history of cancer, no matter how much time has passed since the disease occurred, little to nothing is known about the status of bone mass in that specific population.

In the earliest recruiting efforts for the clinical trials, bone scans were offered to women of any age in order to heighten awareness of the study and to encourage younger women to bring their mothers, aunts, and grandmothers to the osteoporosis screening. While the number of premenopausal women scanned was small, the results were alarming. We demonstrated a trend to indicate that the number of women in the population with low bone density may be higher than originally thought, due to the prevalence of many risk factors such as excessive smoking, alcohol consumption, lack of regular exercise, and poor diet.

Given the diversity in the population being scanned, there is great concern that the incidence of osteoporosis in the general population is much greater than current estimates. Furthermore, there is a paucity of data on the incidence of low bone mass in the premenopausal population. As far as is known, no provider will pay for a baseline DEXA scan in premenopausal women or in younger men, even where there is a strong family history of the disease. Therefore, we propose a national, longitudinal osteoporosis project to identify persons at risk for the disease and provide health education to decrease the prevalence of osteoporosis.

Objectives and Specific Aims

The status of bone mass and skeletal health in the United States must be addressed more vigorously. Osteoporosis is a major public health problem today and is certain to grow in the future. There is the potential to save billions of dollars in health care costs if a proactive approach to prevention and early treatment is taken. However, there is insufficient data to determine the magnitude of the problem in the population. In addition, little is known about the impact of preventative measures taken by young adults which may drastically reduce the likelihood of developing osteoporosis and paying the high economic and humanistic costs in their later years of life. Therefore, the overall, long-term goal of our program is to provide screening and health education to the general public to decrease the prevalence of osteoporosis. The specific aims of this proposal are to:

- develop accurate epidemiological information on the number of men and women of various ages in the United States who have clinically significant low bone mass;
- determine to what degree behaviors can be modified and how behavior modification impacts on skeletal health;

- determine if educational intervention in young women will change behaviors and improve skeletal health in late adolescence;
- determine compliance rates in women who have been placed on bisphosphonates, calcitonin, and other therapeutic regimens;
- evaluate the usefulness of biological markers in monitoring the study populations; and
- reduce costs to publicly funded health care programs.

Contemplated Approach to the Problem

To conduct the study, subjects will be recruited throughout the country. Participants will be recruited from the following populations:

- women between 16 and 18 years;
- men between 20 and 50 years;
- men over 50 years;
- premenopausal women — greater than 20 years of age; and
- postmenopausal women.

Briefly, subjects will be followed for 10 years. Bone density scans will be provided at 6-month intervals throughout the 10 years. During this time, information will be gathered from the subjects concerning current diet, medication, exercise, smoking, alcohol consumption, and past or current drug use. Education will be provided during the 10-year study period tailored to each population regarding nutrition, exercise, and other components which affect osteoporosis development. Compliance with osteoporosis prevention practices will be evaluated including medication adherence. Multiple interventions with ongoing reinforcement will be key in altering lifestyles of the subjects who will know their bone density and can be proactive in caring for their own skeletal health, both in the present and future.

Furthermore, we will evaluate, using the subject population and a control population, the impact of the proposed intervention on the cost of care related to osteoporosis; and evaluate quality of life in the subject population to see if we are making the positive impact we are proposing. As noted above, osteoporosis is a very expensive disease both in terms of dollars spent on the care of its victims and the loss of self esteem and self worth it inflicts on its victims. We wish to measure to what extent the proposed medication, diet, and exercise regimens impact positively on quality of life for these individuals.

The study will be conducted in ten regions throughout the country (see Longitudinal Osteoporosis Project attached). Each regional program will be managed by a recognized authority in the area of osteoporosis. Two specially equipped buses will be assigned to each region. Each bus will house a bone densitometer (DEXA) and a digital radiographic unit. This equipment will allow us to measure bone mineral density and to get accurate X-rays of the spine and hip to determine the presence of fractures and their severity. Also, each bus will have sufficient equipment on board to permit the drawing, collection, and processing of blood and urine samples on which to perform bone marker assays.

While there are a significant number of DEXA devices across the country, the instruments will be on mobile buses for this project. This method was chosen for the following reasons:

- In order to maximize compliance and continued participation in the study, it is necessary to take the DEXA scan units to the study population for as much convenience as possible.
- The greatest degree of consistency between data collected in each region can occur with the same means of study delivery. In addition, fewer machines will be used nationwide and can be standardized to the same phantom and calibration standards.
- Data will be compiled and analyzed in a central data facility. All results of the project will be published in appropriate, peer-reviewed journals as soon as possible.

Cost

The total cost of this program for the 10-year project period is estimated to be approximately $208 million or approximately 0.75 percent of the current annual cost of osteoporosis to publicly funded health care programs.

We are proposing to conduct this project in two phases.

Phase I — Planning Phase: $3 Million. We would like to start this project with an 18-month planning phase which would afford us the opportunity to design the study, including the survey and educational materials needed; evaluate several centers to select the best one to serve as the data management center; and to build one mobile research laboratory that will be used to test public acceptance of the study and the efficacy of the educational and survey instruments.

Phase II — Operational Phase: $205 Million for the 10-Year Study. The planning period will be followed by the study phase in which we will conduct the full study in the ten regions of the United States noted below. We project that this portion of the project will cost, for the total 10 years of the project, approximately $205 million which is less than 1 percent of what publicly funded health care programs currently spend on osteoporosis-related health problems each year.

Longitudinal Osteoporosis Project: Regional Division of the Continental United States

Region	Buses	States
1	2	Alabama, Florida, Georgia, Mississippi
2	2	Kentucky, North Carolina, South Carolina, Tennessee
3	2	Arkansas, Louisiana, Oklahoma, Texas
4	2	Idaho, Montana, Oregon, Washington, Wyoming
5	2	Arizona, Colorado, New Mexico, Utah
6	2	California, Nevada
7	2	Illinois, Indiana, Michigan, Missouri, Ohio, Wisconsin
8	2	Iowa, Kansas, Minnesota, Nebraska, North Dakota, South Dakota
9	2	Delaware, Maryland, New Jersey, Pennsylvania, Virginia, West Virginia
10	2	Connecticut, Maine, Massachusetts, New Hampshire, New York, Rhode Island, Vermont

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Nancy K. Mello, Ph.D. *Harvard Medical School*

Drug and Alcohol Effects on Reproductive Function

Alcoholism and drug abuse are frequent problems among young women in their early reproductive years. A number of neuroendocrine abnormalities are associated with chronic drug and alcohol abuse; abnormalities that may impair fertility and/or compromise neurobehavioral development of the offspring. Neuroendocrine abnormalities in women are expressed clinically as disorders of the menstrual cycle, i.e., annovulation, luteal phase dysfunction, and amenorrhea. Disorders of prolactin regulation, expressed as hyperprolactinemia, sometimes associated with galactorrhea, are also observed. The risk for spontaneous abortion is a frequent concomitant of alcohol and cocaine abuse. Alcoholism is also implicated in early menopause, but the cocaine epidemic is too recent to evaluate its effects on menopause.

Most drugs of abuse can cause these menstrual cycle disorders. Polydrug abuse probably exacerbates the severity of these disorders as well as complicating interpretation of the role of cocaine, opiates, or alcohol per se. However, many menstrual cycle disorders have been replicated in animal models of drug and alcohol self-administration under controlled conditions. Moreover, annovulation, luteal phase dysfunction, and hyperprolactinemia also have been observed in normal healthy social drinkers studied on a clinical research ward for 35 days. Such pre-clinical and clinical studies, conducted under controlled conditions, provide compelling evidence that abused drugs disrupt the menstrual cycle in otherwise healthy females.

Unanswered Questions

- The possible mechanisms by which cocaine, opiates, and alcohol disrupt the menstrual cycle are unknown.
- The anatomical locus of cocaine, opiates, and/or alcohol's primary impact on the hypothalamic-pituitary-gonadal-adrenal axis is also unknown.
- The extent to which menstrual cycle disruptions are reversible if drug abuse stops is unknown.
- The effect of tolerance to chronic drug or alcohol exposure on reproductive function is unknown.
- The implications of neuroendocrine abnormalities induced by drug and/or alcohol abuse for abnormal fetal growth and development is not understood.

Interactions Between Menstrual Cycle Phases, Abused Drugs, and Treatment Medications

In addition to the adverse effects of abused drugs on the menstrual cycle, the menstrual cycle also can influence the effects of abused drugs as well as treatment mediations. Recent evidence suggests that the hormonal profile associated with the follicular, periovulatory, and mid-luteal phases of the menstrual cycle may influence the reinforcing effects of abused drugs. It is possible that the subjective and toxic effects of abused drugs are greater at some menstrual cycle phases than at others.

There is also increasing evidence that the efficacy of some therapeutic agents may vary as a function of menstrual cycle phase. It is important to evaluate the ways in which the hormonal milieu of each phase of the menstrual cycle may modify the effectiveness of medications as a function of hormone-related changes in the pharmacokinetics and pharmacodynamics of the medications. Preclinical and clinical studies should be conducted to address these important issues.

Unanswered Questions

- How does therapeutic drug effectiveness vary across menstrual cycle phases? What is the physiological basis for these variations?
- How do gonadal steroid hormones influence the effects of abused drugs and analgesic drugs?
- How do drug abuse treatment medications that are opioid antagonists (naltrexone, buprenorphine) effect menstrual cycle function? (Since gonadotropin release is under endogenous opioid inhibitory control, opioid antagonists are often used clinically to treat infertility disorders and could enhance fertility).

- How do phases of the menstrual cycle, particularly premenstrual dysphoria (called late-luteal phase disorder in *DSM-IV*), affect initiation and exacerbation of alcohol and drug abuse patterns.

Unanswered Questions Relating to Hormonal Effects on Immune Function and Vulnerability to AIDS

Cocaine has major stimulatory effects on the hypothalamic-pituitary-adrenal axis. Pharmacokinetic analyses have revealed a very close temporal concordance between plasma cocaine levels and plasma ACTH levels in humans. In addition, cocaine administration causes a significant increase in plasma cortisol levels following an antecedent increment in the pulsatile release of ACTH. Recent studies have highlighted the importance of glucocorticoids in modulating immune function in human immunodeficiency virus (HIV) infection. Cocaine administration may enhance both risk for HIV infection and severity of progression of HIV. Development of medications for the treatment of cocaine abuse and dependence should involve evaluation of drug effects upon the hypothalamic-pituitary-adrenal axis.

Opportunities for Research

Animal models of reproductive function and drug abuse. Research on these issues is facilitated by the availability of animal models of drug and alcohol self-administration. Neuroendocrine control of the menstrual cycle in rhesus females is almost identical to that of human females, so long-term, repeated measures designs are possible. In animal models, the possible confounding effects of polydrug abuse, malnutrition, and other medical disorders is eliminated.

Technological advances in endocrine research. Analysis of the anatomical locus and type of functional disruption caused by alcohol and cocaine at each level of the hypothalamic-pituitary-gonadal axis is facilitated by the availability of a number of provocative tests of endocrine function. These provocative tests can be used to stimulate each component of this complex interrelated system. Moreover, advances in the quantitative analysis of hormone release patterns permit more precise assessment of the effects of abused drugs and treatment medications, LH pulse frequency, and amplitude changes over the menstrual cycle. During the follicular phase, the pulsatile release of LH is quite rapid, about 1.4 pulses per hour. LH pulse frequency and amplitude builds to a crescendo that culminates in ovulation. Then LH pulses slow during the luteal phase and pulse amplitude is highest at the middle of the luteal phase. Clinical studies have shown that many infertility disorders are associated with infrequent LH pulses of low amplitude throughout the menstrual cycle or no LH pulses at all. It is possible that alcohol and cocaine may disrupt pulsatile release of essential gonadotropin hormones to result in amenorrhea and other menstrual cycle disorders. The discovery of the importance of LH pulse frequency was first made in the rhesus monkey model and rapidly translated into clinical treatment.

Summary Recommendations and Comments

- Analysis of the effects of alcohol and drugs on neuroendocrine function requires *integrative physiological* studies in women or in the whole animal because of the complex interrelationships between each component of the hypothalamic-pituitary-gonadal and hypothalamic-pituitary-adrenal axis.

- Animal models of female endocrine function are essential for controlled studies of the acute and chronic effects of alcohol and drugs on neuroendocrine function. Major discoveries in reproductive biology have been made in the female rhesus monkey model because it so closely approximates neuroendocrine regulation of the menstrual cycle in human women. The rhesus monkey drug self-administration model also is useful because monkeys will self administer most drugs that are self administered by man.

- Studies of the effects of therapeutic drug regimens (e.g., buprenorphine, LAAM, naltrexone), as well as drugs of abuse on normal reproductive function in females, should be conducted. Pharmacotherapies for the treatment of alcoholism and drug abuse often have direct effects on the endocrine system.

- In an effort to redress the decades of neglect of issues clinically related to women's health in mental and addictive disorders, Congress should appropriate *additional* funds for the establishment of a series of *special research centers* focused upon the impact of drug abuse and alcoholism on women's health, broadly defined. Since menstrual cycle normalcy is a gender-specific, unique feature of women's health throughout the reproductive years, the impact of substance abuse on female neuroendocrine function is one important aspect of health in women.

- In view of the trend towards an aging American population, and the relative longevity of women in comparison to men, special attention should be paid to the impact of alcoholism and drug abuse on the health of perimenopausal and postmenopausal women. Recent evidence that social drinking can increase estradiol levels in postmenopausal women on estrogen replacement therapy by over 300 percent suggests the importance of evaluating drug and alcohol effects in this group. Drug-induced changes in estradiol could alter the complex risk-benefit ratio of hormone replacement therapy in postmenopausal women.

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Virginia Miller, Ph.D. *Mayo Foundation*

My name is Virginia Miller. I am an Associate Professor of Surgery and Physiology representing the Women's Health Care Council from the Mayo Clinic, Rochester, Minnesota. The Women's Health Care Council is a group of 20 physicians and scientists appointed by the Board of Governors to address mechanisms to improve women's health care through clinical practice, education, and research. The Mayo Clinic and Foundation is a private, multidisciplinary, integrative practice with three primary locations in Rochester, Minnesota, Scottsdale, Arizona, and Jacksonville, Florida, and regional practices in the upper Midwest.

Priorities for women's health through the 21st century should encompass the entire scope of a woman's health experience including prevention, early detection, intervention, and rehabilitation programs. Several areas are identified in which the resources available at the Mayo Clinic could be used to advance women's health. These are:

- Translating outcomes from clinical trials to the community setting.
- Applying innovative prognostic, predictive, and early detection diagnostic procedures to appropriate populations for women at risk for cardiovascular disease, cancer, and osteoporosis.
- Translating knowledge from basic sciences to relevant populations of women through integrative, mulitdisciplinary approaches.
- Understanding basic mechanisms of disease processes with an emphasis on cardiovascular disease, ovarian cancer, and anabolic therapies for bone.
- Establishing smoking cessation and other rehabilitation programs tailored to meet the unique needs of women.

Ann Mulligan *DES Cancer Network*

The DES Cancer Network is a national nonprofit consumer advocacy organization that addresses the special needs of women who have had clear cell adenocarcinoma of the vagina or cervix — a cancer linked to prenatal exposure to the synthetic estrogen diethylstilbestrol or DES.

The mission of the DES Cancer Network is to provide surviving clear cell cancer patients with ways to contact and support one another; to offer assistance and information to newly diagnosed patients who are undergoing treatment; and to support those women whose clear cell cancer is terminal.

DES daughters are at increased risk for a rare cancer of the vagina or cervix, called clear cell cancer. So far, clear cell adenocarcinoma has been found in DES daughters between the ages of 7 and 42.

Clear cell vaginal or cervical cancer, the “signature” cancer of DES, is linked to in utero exposure to DES. Typical treatment includes radical hysterectomy, vaginectomy, lymphadenectomy, and vaginal reconstruction.

Radiation is often used with surgery. The current estimate is that one in 1,000 DES daughters are at risk for developing clear cell cancer.

It continues to be important for DES daughters and their physicians to be aware that there is no specific age after which the risk for clear cell cancer is over. At this time, the upper-age limit for the development of the cancer is unknown. Researchers report that it is possible that “the age for the greatest potential hazard to the DES-exposed has not yet arrived.”

Questions to be Answered

There are several issues related to DES exposure and clear cell cancer which should be made a priority for research at NIH.

- What are the risks for DES daughters as they enter menopause?
- What are the benefits and risks of estrogen/hormone replacement therapy for women who were prenatally exposed to the synthetic estrogen diethylstilbestrol?
- Are DES daughters at increased risk of developing clear cell adenocarcinoma at perimenopause?
- Is there another incidence peak of clear cell cancer at menopause?
- Clear cell adenocarcinoma was known before DES in postmenopausal women. What might the experience of DES daughters be when they reach the age when clear cell had previously been diagnosed? Are we headed for an explosion of clear cell cancer cases?
- What are the best treatments for clear cell adenocarcinoma? Is surgery, chemotherapy, or radiation most successful?
- What is the an effective treatment for recurrences of clear cell cancer?

Mary Lynn Newport, M.D. *American Society for Surgery of the Hand*

Thank you for allowing me to present this testimony on behalf of the American Society for Surgery of the Hand. Our 1,500 member organization consists of orthopaedic, plastic, and general surgeons who spend the majority of their time dealing with disorders and injuries of the hand and upper extremity. The mission of this society is to improve the outcome for individuals with upper extremity disorders and injuries through education, research, representation, patient advocacy, and community service. I also serve on the American Academy of Orthopaedic Surgeons' Task Force on Women's Health, with whom this testimony was developed.

I would like to address three musculoskeletal problems in the upper extremity which have a significant impact on women. These are fracture of the distal radius, carpal tunnel syndrome, and osteoarthritis of the basilar joint of the thumb.

The first issue I would like to address is that of fracture of the distal radius, or Colles' fracture, named after Abraham Colles who first described this wrist fracture in 1814. He stated at that time that, while there might be a residual deformity, a complete and painless resumption of function should be expected. This attitude should have been disproved by a significant body of recent research, but still lingers today (Stewart; Jupiter). This fracture usually occurs as the result of a simple fall at home. It comprises approximately 10 percent of all adult fractures, making it one of the most common fractures we see as orthopaedic and hand surgeons. There is a peak incidence of this adult fracture in the seventh decade. Women are affected seven times more often than men. In addition, there is a threefold increase in the risk of hip fracture after Colles' fracture with its attendant 25 percent mortality rate within 1 year of injury. It has become clear to us that: (1) Colles' fractures are not, in and of themselves, a benign entity, worthy of little or no attention; and (2) that sustaining a Colles' fracture is a clear indication of osteoporosis with all its attendant risks.

One of the reasons Abraham Colles felt this fracture should not be significantly worried about was that it occurred in older people, usually after retirement from the work force, and that some patients with this fracture actually do fare well, despite significant deformity. We have found, however, that many patients do not do well unless treated carefully and aggressively. There is frequently loss of motion, pain with motion, and significant weakness of pinch and grasp after healing of these fractures. Even when treated appropriately, these fractures can severely affect one's ability to function independently, especially in the face of any other medical condition, such as cataracts, diabetes, or osteoarthritis of the thumb or lower extremities. This loss of independence produces a significant impact on the patient and the patient's family, who must now help at home in all aspects of personal care and transportation. Otherwise, this burden must be assumed by home health organizations with its attendant expense.

The expense in suffering and in financial terms clearly increases exponentially if the wrist fracture is but a harbinger of an osteoporotic hip fracture. While there is an increasing understanding of osteoporosis, its risk factors and treatment, at the present time there is almost no data or interest in connecting those large numbers of patients with wrist fractures with the endocrinologist so that their osteoporosis can be categorized and treated, hopefully before the hip fracture occurs.

As our population ages, this fracture must receive the attention it deserves not just from the surgical but also from the global medical and social standpoint so that patients can be returned to a functional and independent existence and future problems are mitigated or prevented by aggressive intervention. With the aging of our population, this problem will only increase. In addition, as you have undoubtedly been made aware, our young women are not consuming adequate amounts of calcium as teenagers, the time of maximum bone building, making osteoporosis and all of its complications an even greater threat to our future. We would, therefore, ask that you seriously consider the Colles' fracture as an indicator of osteoporosis and support research which can determine who might be at risk for Colles' fracture (i.e., how to prevent the fall which breaks the radius) and which might determine, once a Colles' fracture is sustained, if there are any indicators which might determine who specifically might be at risk for future hip fracture.

The second area of hand surgery which significantly affects women's musculoskeletal health is the subject of carpal tunnel syndrome. Carpal tunnel syndrome is defined as a compression of the median nerve as it runs through the carpal canal of the wrist. This canal is formed on three sides by the bones of the wrist. The roof is formed by a thick unyielding structure — the transverse carpal ligament. Through it runs the nine flexor tendons of the fingers and the median nerve. Carpal tunnel syndrome is characterized by numbness and tingling in the thumb, index, and long fingers, by weakness and clumsiness of pinch and grasp, and pain in the palm and fingers.

It is estimated that approximately 400,000 carpal tunnel surgeries, done to relieve pressure on the median nerve, are performed in the United States each year (Palmer). This makes it one of the most common surgical procedures performed today. Assuming longevity to the age of 70, there is an estimated incidence of carpal tunnel syndrome of 11 percent in women compared with 3.5 percent in men (Stevens). This increased incidence in women is secondary to a number of factors known to be associated with carpal tunnel syndrome including pregnancy, menopause, use of oral contraceptives, and hysterectomy. Factors associated with carpal tunnel syndrome, but not associated with gender, are history of a distal radius fracture, obesity, physical inactivity, and wrist depth/width ratio (though this is typically smaller in women). In addition, we know the incidence of carpal tunnel syndrome is increasing, with a 30 percent increase between 1965 and 1980 (deKrom). While some of this increase might be attributable to work factors, such as the increasing population of women in the work force and the increasing use of keyboarding as a work activity, the vast majority of patients with carpal tunnel syndrome are those with no attributable cause, i.e., an idiopathic presentation, albeit with a number of associated factors. The mean age of occurrence is 54 years, but this too appears to be changing, with an increasing percentage of younger patients. The pathophysiology of carpal tunnel syndrome is not clearly understood. It is known that pressure within the carpal canal is increased in patients with this condition (Gelberman). It would appear that in these patients the tenosynovium surrounding the flexor tendons becomes thickened and its increased mass increases pressure overall within the canal and compresses the more yielding median nerve, thereby blocking microcirculation within the nerve and causing the typical symptoms of numbness, tingling, and pain. The pathology is known but the cause of this thickened tenosynovium has not yet been delineated.

The financial impact of this condition is substantial, both in medical costs and lost or minimized wages and in time lost from work. The major thrust of research on this condition is mainly on the best operative technique. Only recently have any efforts been made on behalf of workers to modify their workstation to make it more ergonomically appropriate. It is unclear, however, that this approach is effective. A lifestyle modification, shown to be beneficial, has been to increase the general physical activity and fitness of workers. We know that our American population as a whole is less active than it should be and there is a significant percentage of our population who are obese. It is far too simplistic to suggest that carpal tunnel syndrome is caused only by inactivity or obesity and that all cases could be prevented or treated by instituting aerobic exercise programs. The cause of idiopathic carpal tunnel syndrome is multifactorial, even in the workplace.

The large number of patients in general, and women in particular, who suffer from carpal tunnel syndrome and require treatment should make us all pause at the enormity of this condition, its disruption of the workplace (whether or not it is a work-related condition), and its cost to society. Certainly prevention must be researched, especially at present where the causative mechanism has not yet been fully delineated, but clearly we need to discern the cause of this condition at the cellular and physiologic level before we can truly impact our patients and our society.

The last issue concerning women's musculoskeletal health is arthritis of the basilar joint of the thumb. This is the joint which allows the greatest freedom of motion in the hand and the one responsible for placing the thumb in innumerable positions. Its stability allows fine and strong pinch. In short, it is the joint upon which the thumb depends and, as a consequence, upon which the hand depends. Eaton has pointed out that without a stable, pain-free basilar joint of the thumb, nearly every activity of daily living — brushing teeth, opening a car door, using a key, picking up a book — become difficult or impossible. Women suffer from osteoarthritis of this joint ten to 20 times more frequently than do men. It has been shown in post-mortem studies that approximately 50 percent of postmenopausal Caucasian women will show near-complete destruction of this joint. Another 25 percent will show significant deterioration of the joint cartilage (Pellegrini). It is, in fact, the most common site of premature joint degeneration in women (Kirk). It is thought that idiopathic hypermobility, a frequent finding in women, is probably the major factor in allowing wear and tear of this joint.

Fortunately, many women who are symptomatic can be treated conservatively with nonsteroidal anti-inflammatory medications, splinting, or intra-articular steroid injections. While not a big-ticket item, the shear volume of patients requiring this conservative treatment causes this condition to be a significant cost to society even before factoring in household activities and duties which can no longer be performed or hobbies which cannot be enjoyed because of pain. Surgically, it has been an area of significant research for hand surgeons, especially as it is the most common site needing surgical reconstruction in the upper extremity. Current solutions for the most part depend on soft tissue interposition between the arthritic bones rather than the total joint replacement more commonly seen in the hip and knee. The basilar joint of the thumb is very complex architecturally and it has been extremely difficult to develop a joint replacement which has been capable of withstanding the extraordinary stress and freedom of motion required of this joint. As with the other subjects I have discussed today, the major thrust has been in treatment of the underlying condition rather than prevention or better understanding the basis of the disorder. And, while this is a small joint, when diseased, the results can be far-reaching for that patient's life and lifestyle and can significantly limit their ability to remain independent.

To summarize, the hand and wrist play an extraordinary role in each and everyone's daily existence. The conditions which I have commented on today are but a few of the upper extremity musculoskeletal problems to which women are more susceptible and for which I hope you see fit to direct sufficient energy and resources to help us better understand and hopefully prevent these problems when we can and treat them effectively when we cannot.

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Gloria J. Nichols, B.S.P, M.Ed., Ph.D. *The University of Georgia*

New Priorities for Research on Women's Health in the Pharmaceutical Sciences

- Gender-related analysis of medications; specifically the pharmacokinetic differences in the absorption, distribution, metabolism, and elimination of drugs and changes that occur during pregnancy and different phases of a women's life span.

- Research on the considerations of the sociodemographic factors, such as gender, age, race, socioeconomic status, ethnicity, and cultural background, affecting quality-of-life measures and pharmacoeconomic studies in women and minorities.

- Epidemiological research on disease patterns, health-risk assessment profiles, and methodological developments in gender-related outcomes measurement. Health-risk assessment focuses on the characteristics of the targeted population that are linked to behavioral and environmental risks, and the health consequences of exposure to those risks. Research is particularly needed to explore factors that lead to and result from exposure to adverse effects of drug entities as potential risks in women.

- Research on the influence of hormonal factors on the course of specific diseases and disorders affecting women, along with the utility of using hormonal strategies as potential hormonal agents in treatment and patient management.

- Outcomes research studies that relate to the clinical manifestations, risk factors, disease course, and response in such disorders as osteoporosis, osteoarthritis, and fragility. Studies are needed on the markers of prognosis and followup on recent progress on biologic and genetic markers along with therapeutic management decisions to the disease potential.

- Ongoing research for new developments in AIDS research and drug development. This will include an overview of the epidemiology of the disease state and the outcomes research for evaluating effective drug therapy protocols; successful medical interventions; and optimal economic and therapeutic options for the practice setting.

- Research studies on the risk and benefits of hormone replacement therapy and new developments in terms of humanistic, economic, and quality-of-life parameters. Cross sectional, longitudinal, retrospective, and prospective studies are needed. Different populations at risk, compliance, and followup, and the presence of concomitant risk factors and duration of HRT should be considered.

- Cardiovascular disease research in women should include more demonstration projects on management strategies, including the use of group and educational programs for risk factor reduction, as well as indications for drug therapy and practice guidelines for hormone replacement therapy. Factors defining the high-risk patient (utilization of standardized guidelines), assessing and identifying women at high risk, and guidelines for utilization of therapeutic options need to be clarified.

- Research that examines the physiologic and pathophysiological differences that are responsible for cardiovascular disease and altered drug responses that occur in minority populations and women.

- Patient decisionmaking models and information systems, and computerized systems of online information services should be further developed, tested, and evaluated for accuracy of information; their impact on knowledge and confidence; and their usefulness in patient education and compliance management of drug therapy.

Catherine Noe *Arthritis Foundation*

Arthritis is the most prevalent chronic condition affecting women. Currently, 23 million women have arthritis and the number is expected to grow to 36 million by the year 2020. The cost of arthritis to our nation in lost wages, disability payments, hospitalizations, physician visits, and medications is close to $65 billion annually — representing over 1 percent of our Gross National Product.

Arthritis is a serious disabling condition which discriminates against women in overall prevalence. Women with rheumatoid arthritis outnumber men two to one. In the case of systemic lupus erythematosus and fibromyalgia, nine women have the disease to just one male. Given its enormous impact on women and its projected rate of growth in the future, arthritis must have a prominent place in the women's health agenda of the 21st century.

The economic, social, and psychological impact of arthritis on women is staggering. Arthritis is the leading cause of disability and the second leading cause of disability payments. Studies indicate that approximately half of patients who are working when diagnosed with rheumatoid arthritis become disabled within 10 years, suffering substantial earnings loss. Arthritis is the condition reported by women as the leading cause of physical limitations in activities of daily living. The impact of arthritis on psychological status has been noted in terms of depression, coping strategies, anxiety, cognitive changes, self-efficacy, and learned helplessness.

There are several research advances within the last 10 years which stand out for arthritis patients. The use of methotrexate as a safe and effective long-term treatment for rheumatoid arthritis has successfully controlled symptoms and reduced the need for steroids in adults and children. Advances in genetic research, Lyme disease recognition and treatment, and joint replacement technology are considered among the most important in improving the lives of arthritis patients.

For women, perhaps the most significant gap in arthritis research is the role of genetic makeup and hormones. Most researchers believe that the triggers for arthritis are in a woman's physiologic makeup. Could a woman's body structure, designed to bear children, be a contributing factor to the cause of osteoarthritis? Even more significantly, are hormones responsible for the autoimmune forms of arthritis, such as lupus and rheumatoid arthritis, that so predominately attack women? Is there a single arthritis gene or are a combination of genes involved? Finding the answers to these questions will provide critical clues to finding a cure for arthritis.

Of critical importance to the Arthritis Foundation is the use of comprehensive measurements to evaluate research outcomes in the lives of women. Outcomes measures that have meaning for women with a chronic disease, such as arthritis, must include a measurement of functional status and an assessment of their quality of life. These outcomes must be realistic and relevant to women's lives. They must be developed to apply for a period of decades rather than months, and they must place value in slowing the rate of decline in functional levels rather than maintaining functional status. It is imperative that good outcomes measures in women's health research in the 21st century are quantifiable, include the patient, and consider health status in terms of a woman's ability to function within roles of critical importance to her over the extended term of her life.

Nancy J. Norton, B.S. *International Foundation for Functional Gastrointestinal Disorders*

Dr. Pinn and members of the committee, I would like to thank you for the opportunity to speak before you today. My name is Nancy Norton. I am the president of the International Foundation for Functional Gastrointestinal Disorders and the current chairperson of the Digestive Disease National Coalition. As we move into the 21st century, there is a category of digestive diseases that historically has not been adequately addressed regarding research and patient care. I am referring to the functional gastrointestinal disorders; irritable bowel syndrome (IBS) being the most predominant. IBS is a complex of chronic disorders that malign the digestive system, affecting 20 percent of the population. Symptoms include chronic or recurrent abdominal pain, bloating, constipation, diarrhea, and fecal soiling. These common dysfunctions strike people from all walks of life and result in a significant toll of human suffering and disability. IBS represents one of the most common conditions encountered by gastroenterologists and general internists. It accounts for 20 to 50 percent of referrals to gastroenterology clinics.

Our focus today is on women's health. IBS predominantly affects women. Approximately 75 percent of indi-viduals with IBS in the community are female, with the incidence being reported as high as 90 percent in some medical centers. This is a major women's health issue.

In a recent U.S. Householder Survey of Functional Gastrointestinal Disorders, Prevalence, Sociodemography and Health Impact, Drossman reported individuals with IBS will miss 13.4 days of work annually, nearly three times the 4.9 national average.

IBS alone has recently been called a multi-billion dollar problem by the gastroenterology community. Survey data by Talley reflects that patients with IBS incurred a higher annual health care bill of $742 (1992 dollars) compared to $429 for those without the condition. This amounts to a total dollar amount of over $8 billion for the 35 million sufferers.

Reporting of multisystem medical complaints such as fatigue, headache, and backache occurs with increased frequency in patients with organic disease, and just as often in those with functional gastrointestinal disorders. Drossman reported that patients with a functional gastrointestinal disorder reported four times as many physician visits for nongastrointestinal as gastrointestinal visits.

Data also reveals that there is an increased risk of unnecessary extra-abdominal and abdominal surgery correlated by IBS patients. Hysterectomy or ovarian surgery has been reported in female patients with IBS as high as 47 to 55 percent, and has been performed more often in the IBS patient than in comparison groups. This misdiagnosed and misguided treatment may be due to a lack of knowledge and education that could prove dangerous for patients. Therefore, there is a pressing need to support educational programs for the public and health care providers.

There is a quiet desperation for those who suffer with IBS. For women this may mean resorting to frequent physician visits for relief, only to find physicians and other health care workers who neither fully understand this condition nor are able to treat them. In fact, some physicians may do unneeded diagnostic procedures and, when nothing is found, ignore or demean the legitimacy of their complaints.

We appear to have come to a place in medicine where we often hear that if the diagnosis isn't life threatening then our pain and suffering is somehow not legitimate and we are discounted as not having a serious enough problem to investigate and pay attention to.

Recently, it was reported to us that a woman who was a member of our organization, diagnosed with IBS, hemorrhaged to death after alleged excessive treatment for constipation.

As with any disease, accurate diagnosis and proper management is essential for those with IBS and other functional gastrointestinal disorders. Unnecessary surgery is costly and a waste of resources. But, beyond that, the consequences of misdiagnosis or mismanagement can lead to a serious and even grave threat to a person's health and well being.

We have yet to understand the precise mechanism of IBS. We need to continue scientific investigation to unravel the mysteries that explain the irritable bowel syndrome.

But, in addition, we need to study the patient with IBS in order to find proper treatment that reduces symptoms and improves quality of life, even before we have a complete understanding of the disorder. Like arthritis, this is a chronic condition and the patient who suffers should not be forgotten.

That involves clinical research and education. We need to educate the professional community, as well as the patient. We need to look at chronic disease management for the millions of people who are already affected. This includes developing a biopsychosocial understanding of the illness in order to develop behavioral and pharmacologic treatments.

To elaborate on some of the consequences of living with IBS, please allow me to share the experiences of some individuals who live with this disorder.

Imagine what your life would be like if every day, or even several times a week, you woke up and within an hour's time you have symptoms of a GI flu. You have severe abdominal cramping — to the point of being doubled over in pain — nausea, and diarrhea. You are unable to leave the bathroom for hours. You are now exhausted from what you have just been through. It is difficult to get yourself to work but you arrive on time because you have allowed yourself an extra hour or two in the morning just in case you needed it. You are hesitant to eat lunch or dinner because you know the symptoms could start all over again. Your life revolves around where is the next bathroom.

There is a quiet anxiety, an anticipatory response to perhaps what will be next. You may be depressed at times feeling that your life is out of control, or at the very least, your life is controlled by your bowel.

You live life from the edge of the room never willing to truly participate to the fullest for fear of having to find the quickest way out and to a bathroom. You feel a loss. There is lost potential.

Your disease is invisible to others but it effects every aspect of your life. Who would know your pain and the shame you feel except those who are closest to you. Even those you are most intimate with may not understand. You feel as if you are the only one, that you are alone.

It has been said the greatest fear is of uncertainty. For people living with IBS, uncertainty is a 24-hour challenge, it does not go away.

That challenge is met by millions of women and men every day. They are to be credited for their enormous personal strength of meeting the challenge of the day while continuing to put their faith and hope in the medical community to provide the best answers.

I would ask that, as we move forward with health care, we take into consideration the needs of these patients. Do not discount them.

You have an opportunity to fund research, education, and patient care on different levels for functional gastrointestinal disorders. We can no longer just concentrate on one aspect. The complexity of IBS symptoms range from basic science and physiology to research on medical and psychological treatment. We must investigate the entire picture. I would like to tell patients that there is a promise of a better future with the hope of resolution of their symptoms.

You can make that commitment to millions of people by the work you are doing today to set the agenda for women's health into the 21st century. Thank you.

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Nancy L. Parsley, D.P.M. *American Podiatric Medical Association*

I appreciate the privilege of participating in today's forum. The Office of Research on Women's Health is to be commended for the extensive efforts put forth in increasing awareness of women's health problems. By focusing attention on existing deficiencies in the research arena, the National Institutes of Health is fulfilling the important mission of stressing the need for quality research in an ever-changing health care environment. More important, forums such as this confirm that there is a significant lack of research directed at issues primarily affecting women. This event offers hope that more research dollars will soon be dedicated in areas previously ignored or underfunded.

It is a significant honor to have been invited to present testimony today on behalf of the American Podiatric Medical Association. As the primary providers of foot care, podiatrists are keenly aware of the need for more research directed at foot ailments. We recognize that foot disorders represent a tremendous cost to the health care system. Foot pain and foot disorders not only drain vital health care dollars in a direct way, but their wider socioeconomic impact includes lost productivity as well as potential compromises to one's quality of life.

My presentation will focus on a variety of issues related to foot health and the substantial need for further research. Foot ailments and foot needs specific to women are highlighted, but it is obvious that further research in specific areas such as diabetes and physical fitness would be beneficial to both sexes.

First, diabetes is a chronic disease afflicting approximately 16 million people in the United States, half of whom are unaware they have the disease. It is estimated that 15 percent of those with diabetes will develop an ulceration on the foot during their lifetime, and 20 percent of those ulcerations will lead to amputations. According to the American Diabetes Association, the annual incidence of nontraumatic lower extremity amputations among people with diabetes is approximately 54,000. Among African Americans, the amputation rate is 1$^1/_2$ to 2$^1/_2$ times that of whites, while Native Americans have rates as high as three or four times that of whites. Existing data suggests that amputation rates are higher in males than females, but anyone with the disease faces potentially devastating consequences.

Recently, new complications for women with diabetes have been discovered. Women with a long-term history of the disease, especially those who developed it at a young age, have been found to undergo menopause early, which increases their risk of cardiovascular disease. One suggestion for counteracting the effects of early menopause is the development of a regular exercise program. The importance of proper foot care in adhering to a physical fitness program cannot be underestimated. Most people don't realize the tremendous pressure that is put on their feet while exercising. For instance, when a 150-pound jogger runs 3 miles, the cumulative impact on each foot is more than 150 tons. In order to maintain good health, we must study and understand better what the long-term effects of exercise on the feet are, especially in the presence of complicating illnesses such as diabetes.

Consider further that diabetes is the fourth leading cause of death by disease in the United States with an estimated dollar cost of $92 billion annually, equally split between direct medical costs and indirect costs. Foot pathology exists as the most common diabetic complication requiring hospitalization with approximately 70 percent of all diabetics experiencing some form of neuropathy. There are over 40,000 lower extremity amputations in diabetics every year and between 41 and 70 percent of all diabetics with lower extremity amputations do not survive greater than 5 years postoperatively.

Greater concentration in the area of diabetes specifically involving the prevention of foot deformities and complications must be a research priority. Diabetes is not only limb and life threatening, it is particularly debilitating in other ways as well. It often ends careers, restricts social life, and compromises the independence that mobility affords. All of these effects need to be considered when weighing the overall effects of the disease.

Another area for focus involves the proper choice of footwear. I'm sure you've heard the saying that "when your feet hurt, your whole body hurts." For those of you in the audience today, consider your own feet at this very moment. If you can honestly say your feet don't hurt and you have no foot deformities, you're not only lucky, you're in the minority.

In 1990, the National Center for Health Statistics (NCHS) designed and conducted the National Health Interview Survey (NHIS), which has long been a useful source of information on the health status of the civilian noninstitutionalized population of the United States. Within the government, the Division of Medicine in the Health Resources and Services Administration recognized the need to learn more about foot care in general. Therefore, a special supplement dealing exclusively with the foot was added to the 1990 Survey. It concluded that foot problems were more commonly reported by females than males, and by Caucasians than blacks. Further, it found that the incidence of problems increases with age: persons 65 years or older display roughly twice the rate of foot problems as those between the ages of 18 and 44 years, with roughly one in every three elderly persons suffering from foot problems of one form or another. Factor in what is already known about the aging of the population and those statistics will be conservative, at best, in a few short years.

Further review of survey results demonstrates just how prevalent foot disorders are. A prevalence-to-incidence ratio of 83 percent was reported for corns and calluses; for bunions and arthritis of the toes, the ratio was in the vicinity of 90 percent. Bunions were found to be five times as common among females as males and arthritis of the toes was reported twice as often by females versus males. Additionally, other deformities of the toes or joint were also found to be twice as common among females as males. What accounts for these findings and how do we address them? This warrants further exploration.

In 1992, the APMA commissioned a survey on public attitudes towards foot care. The results of the survey revealed some disturbing trends. For instance, over half of the women interviewed admitted to experiencing foot pain. Nearly one-third reported wearing shoes that were uncomfortable but looked good. One-third of the women in the survey wore high heels despite the pain and the potential damage to their feet. In 1992, 35 percent of women believed that it was normal for feet to hurt sometimes while as many as 44 percent of women admitted to wearing good-looking shoes that didn't fit well.

What are the long-term effects of these attitudes and trends? Does the society in which we live and function create unrealistic demands on women in their selection of appropriate footwear? To what degree does foot pain, due to inappropriate shoe selection, contribute to lost productivity on the job? Is foot pain compromising one's quality of life by preventing an individual from participating in a physical fitness program or desired social activities? To what extent might foot pain create undue stress that affects one's mental health? We recognize a connection between foot health and overall health status, but to what degree can improved foot health improve physical as well as mental health? These questions deserve consideration in assessing research needs and priorities.

In 1994, Thompson and Coughlin discussed the effects of footwear on the foot. While the main purpose of footwear, protection of the foot, has remained virtually unchanged, the long-term effects of footwear continue to grow. It has been estimated that 43.1 million people in the United States have a foot problem. That's one in six.

Thirty-six percent, or 15.5 million of these individuals, has regarded their foot problem as serious enough to warrant medical attention. The authors acknowledge, however, that proving a causal relationship between high-fashion footwear and foot problems has been difficult. We know for a fact that the rate of foot problems in shoe-wearing societies is relatively high, while investigations in societies where shoes are not worn have reported a paucity of foot problems. Clearly, this suggests a relationship between shoes and the development of foot deformities and associated pain, but the need for further investigation in this area exists. More research would allow us to treat foot disorders more effectively while enhancing preventive efforts.

Another area specific to women's health that deserves further investigation involves the effects of pregnancy on the feet. A study by Vullo, et al. found that lower extremity pain is more likely to be developed by pregnant and postpartum women compared to nulliparous women. The authors recognize the effects of hormonally mediated changes through relaxing and the resulting ligamentous laxity, including ligaments of the foot and ankle. The onset of lower extremity pain in the second and third trimester of pregnancy suggests that biomechanical factors play a larger role compared to hormonal influences. The combined effects of these influences need to be studied further. We recognize that biomechanical factors associated with pregnancy and the postpartum period that contribute to lower extremity musculoskeletal dysfunction include changes in the center of gravity or gait pattern, weight gain, an increase in the amount of time spent in the side-lying position, and increased lower extremity demands related to infant care.

A separate study by Alvarez, et al. suggests an additional effect of pregnancy on the feet. The authors found that the mean volume of the feet increases by 57.2 milliliters between early and late pregnancy and decreases by only 8.42 milliliters between late pregnancy and 8 weeks postpartum. These changes were attributed to retention of fluid or to an increase in soft tissues. A better understanding of, and appreciation for, the effects of pregnancy on one's feet requires further study.

Consider also the role of women in sports. Since the advent of Title IX, women have consistently expanded their participation in sports at every level, not only at the collegiate and professional levels. As young children and adolescents, girls are encouraged to participate in sports-related activities. Women are demonstrating athletic prowess in areas previously considered to be the sole domain of men. The long-term effects of these changes in attitudes and patterns of physical fitness are yet to be sufficiently explored.

We recognize that available evidence indicates an inverse association between physical activity and chronic diseases. Aerobic exercise is the mode most frequently studied, and appears to confer positive changes, but other forms of exercise may prove to be equally beneficial. The appropriate duration, intensity, and frequency of the exercise have not been determined for any of these chronic health problems and must be considered before global recommendations can be made. The feet factor prominently in many forms of exercise and maintaining healthy feet is imperative to maintaining good health. But while the benefits of exercise are obvious, as discussed in the 1996 Report of the Surgeon General, more research is needed to determine the effects of a variety of factors on the risks of exercise-related injuries as well as how to make more judicious choices on how best to achieve the benefits of exercise while preventing injuries.

Clearly, the ramifications of increased concentration on physical fitness as it relates to women's health is worth further study. In particular, attention to lower extremity conditions are of primary importance for helping women maintain the ability to participate in such activities over the course of a lifetime.

Rheumatoid arthritis (RA) exists as another important area for investigation and research. Not only is the disease not well understood, but the prevalence in females is between 2:1 and 4:1 over males, depending upon the source. RA is incurable and its progression can lead to debilitating deformities which substantially affect a patient's quality of life. We know that the typical presentation of the disease occurs during the fourth to sixth decades of life, but symptoms can begin at any age. When the feet are involved, the presentation is most often in a symmetrical pattern.

A report by Smyth and Janson stresses that the frequency of involvement of the feet among 1,000 patients with rheumatoid arthritis was 91 percent in females and 85 percent in males. Furthermore, the authors discuss the existence of evidence that two host factors, gender and immune susceptibility, are major determinants in the development of the disease. Still, all efforts to discover a specific causative factor or triggering agent for the disease have been unsuccessful thus far. Until the disease is better understood, we must concentrate on managing the short- and long-term complications associated with the disease.

In the foot, we know that the metatarsophalangeal joints of the forefoot are the first and most common sites of involvement in RA. With progressive synovitis in these joints, patients experience pain and stiffness when walking. The great toe is involved and often drifts laterally, in a fashion similar to the lesser toes. It is estimated that 89 percent of patients with RA have forefoot involvement. Midfoot and hindfoot deformities also occur, but are not as visible on plain radiographs. Other imaging techniques such as computed tomography and magnetic resonance imaging may be useful in delineating abnormalities in the rheumatoid foot, but this exists as another area for further research and study.

It has also been reported that approximately 11 percent of patients with RA have tendon dysfunction. Rupture of the posterior tibial tendon secondary to rheumatoid arthritis may occur in the absence of bony destruction on radiographic study. Additional research is needed to better understand the effects of RA in general, and on the feet in particular.

Current treatment protocols vary widely, but most adhere to the belief that a more aggressive approach with the use of more potent drugs and modalities, earlier rather than later in the course of the disease, should be undertaken. The goals of treatment remain consistent, but promising advances in understanding the disease and enhanced forms of therapies are on the horizon. Due to research, we now better understand the function of the immune system and its key role in the pathophysiology of rheumatoid arthritis. The efficacy and use of immunosuppressive agents in the treatment of the disease is still under investigation, and should be encouraged.

Rheumatoid arthritis can be an all-encompassing disease affecting all dimensions of a woman's life, usually beginning with physical function. This results in loss of work, social, and recreational activities. On average, women incur 40 percent more chronic illnesses and live longer than men do. Therefore, they require more health care and supportive services as they age. Meeting the needs of an aging population, especially one with a variety of chronic conditions, is one of the most significant challenges we face.

There are additional considerations with an aging population that deserve attention. Since 1900, the life expectancy of the average American has increased by about 27 years. In 1900, there were 3 million Americans aged 65 or older. In 1995, this figure exceeded 33 million. In order to maintain useful, satisfying lives, people need to be able to move about. Mobility is a vital ingredient of the independence that older people, in particular, cherish. Therefore, dedication of research dollars and research efforts in maintaining foot health should be a priority.

The APMA believes the Office of Research on Women's Health can offer important leadership in the research arena. Between 1994 and 1996, approximately 10 percent of the total dollars dedicated to podiatric medical research came from the federal government. Only 10 percent. The APMA and the podiatric medical colleges contributed a combined amount of almost 50 percent of the total research dollars. Clearly, the wide disparity in research funding cannot continue if we are to address the specific needs of women in today's health care environment. If we are to fulfill our role in keeping America walking and maintaining foot health, we need to see noticeable increases in research dollars dedicated to these purposes. An investment of this type is guaranteed to have far-reaching and long-lasting benefits far into the future.

Kenneth A. Perkins, Ph.D. *University of Pittsburgh School of Medicine*

Need for New Directions in Research on Smoking Cessation in Women

Prevalence of tobacco smoking has declined gradually in the United States since publication of the first Surgeon General's Report on Smoking in 1964. However, smoking remains the single most important preventable cause of disease morbidity and mortality. Tobacco smoking accounts for at least 20 percent of all deaths, more than alcohol and other drugs, accidents, and AIDS combined. Moreover, this relatively modest decline in smoking has not been equal across all smokers but has been attenuated in women compared with men (see Perkins, 1996). For example, from 1965 to 1987, smoking prevalence in the United States declined 0.84 percent per year in men vs. 0.21 percent in women, a fourfold difference. Women are now more likely to die from lung cancer than breast cancer. Notably, sometime during the next decade, the United States is expected to become the first society in history in which women smokers outnumber men smokers.

Although the increasing initiation of smoking among female teens has likely contributed to the attenuated decline in smoking prevalence among women, for several decades there has been evidence that women are also less likely than men to successfully quit smoking. Rates of abstinence following formal treatment programs have generally remained stagnant over the past decade, and fewer than 10 percent of all smokers who try to quit are successful permanently. Results for women are even more discouraging. Some large-scale smoking cessation trials, especially those involving nicotine replacement therapy, suggest that women are less likely than men to initiate quitting and more likely to relapse if they do quit. Various explanations for the poorer success of smoking cessation efforts in women have been offered, including the greater reinforcing value in women of smoking's influence on body weight or food intake control, reduced availability of social support for cessation in women, and greater impact of advertising on promoting smoking in women vs. men.

One possible explanation that has not received attention is that men and women may differ in the extent to which they smoke for nicotine reinforcement, as opposed to smoking for other, non-nicotine factors (e.g., other sensory effects of smoke inhalation, conditioned responses to smoke stimuli, secondary social reinforcement). Recent research suggests that: nicotine self-administration (i.e., reinforcement) is less robust in women, women may reduce their smoking to a lesser degree following nicotine pre-loading, and women may be less sensitive to subjective/mood effects of nicotine. In contrast, women may be more responsive to non-nicotine stimuli of smoking. These findings are consistent with other research indicating that women are less able than men to detect interoceptive stimuli (physiological changes) as well as some findings that women may be less sensitive to other drugs, such as cocaine.

Since much of current smoking cessation efforts focus on nicotine replacement therapy via polacrilex (gum), transdermal patch, or other means, smokers who smoke less for nicotine reinforcement would be less likely to obtain therapeutic benefit from nicotine replacement strategies. Indeed, any smoking cessation treatment — whether behavioral or pharmacological in approach — would be less likely to be successful with this subgroup of smokers if it failed to adequately address or ameliorate possible non-nicotine factors influencing smoking. Perhaps, not surprising, a review of clinical research studies indicates that women are marginally or significantly less likely than men to quit smoking as a result of receiving nicotine replacement.

In summary, based on current research, it appears that the smoking behavior of women, relative to men, is reinforced less by nicotine intake and more by other non-nicotine factors. If confirmed, these sex differences would have important clinical implications; nicotine replacement may warrant a less important role in smoking cessation while interventions to counter non-nicotine aspects of smoking may need to be emphasized. Greater research on sex differences in nicotine effects and in new directions for smoking cessation treatment in women is sorely needed.

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Jann Primus, Ph.D. *Spelman College*

On behalf of Spelman College and our president, Dr. Audrey Forbes Manley, I would like to thank you for inviting Spelman to be part of this important event and for allowing me the opportunity to present testimony focusing on "Career Issues for Women Scientists: Overcoming Barriers and Achieving Success In Biomedical Careers."

As both a faculty member at and a graduate of an historically black college or university (HBCU), I would like to present my testimony in terms of the educational pipeline as a crucial gateway to either encourage entry or serve as a barrier for success. The pipleline is also *the* prime resource for supplying our nation with qualified researchers, physicians, and health-related professionals. It is within this historical context and contemporary focus that I have entitled my remarks "The Role of Historically Black Institutions in the Production of African Americans and Women in the Biomedical Research Enterprise."

The Challenge

Science is created, transmitted, and applied by people. It is fundamentally a human activity. If we are to continue to have good scientists, then human resources — and by this I mean the education and continued engagement of scientists, mathematicians, and scientifically literate citizens — is almost the only important question.

Yet, it is no secret that the U.S. educational enterprise is seriously underperforming. Distressing indicators include an alarmingly low level of scientific and technological literacy in the general population; a projected shortage of well-equipped scientists, mathematicians, and engineers; and severe inequities in the access of minorities and women to science and medical professional fields.

According to some of the most recent data:

- In 1984, minorities comprised 19.8 percent of the undergraduate population and 19.1 percent of the graduate population; by 1994, those figures had increased to 27.1 and 23.5 percent, respectively.
- In 1994, women comprised 51.2 percent of the U.S. population; we received 54.5 percent of all undergraduate degrees, but only 39.3 percent of Ph.D.s, few of which were in the "hard sciences."

The figures are equally distressing when we look at the professional workforce:

- In 1973, women were only 8.7 percent of all employed scientists and engineers; two decades later, we still represent only 21.6 percent of these professions.
- While women make up 56 percent of the U.S. population, only 21 percent of U.S. physicians are women.
- Even projecting to the Year 2010, only 30 percent of the physicians workforce will be women, based on the current rate of increase.

With respect to minorities. . .

- The data reveal that in 1973, we comprised only 8.3 percent of employed scientists and engineers.
- Two decades later, this figure had increased to only 17.5 percent.

There is a national crisis looming. All analyses of rates of participation of blacks and Hispanics confirm a picture of severe underrepresentation in science and mathematics at all levels of our system of education. Women and minorities are not only severely underrepresented in these areas, but also in the health professions.

The Success of HBCUs and Women's Colleges

In contrast to disturbing national trends, historically black, minority, and women's institutions have been the forerunner in recruiting, retaining, and successfully graduating women and minorities in the sciences at the baccalaureate level, and have been most successful in encouraging these underrepresented populations to enter professional schools and Ph.D. programs.

I point your attention to a 1990 report of the Association of American Medical Colleges (AAMC). When the faculties of Howard, Meharry, and Morehouse medical schools are excluded, African Americans and Latinos make up only .7 and 2.6 percent, respectively, of the basic science faculty.

What these schools have in common is a strong tradition of community. This is the crucial enabling factor in the success of historically black colleges and of other colleges that succeed with minority students. Community is what propels many minority graduates and graduates of women's colleges to successful careers. These settings warm the chilly climate for women and minorities so often noted at all levels of education in this country.

Private liberal arts women colleges — what the Carnegie Foundation for the Advancement of Teaching ranks as Baccalaureate I institutions — have been especially productive of women science and mathematics graduates and of women graduates who subsequently earn a doctorate in science or mathematics. Indeed these colleges produce a higher percentage of women science graduates than any other nonspecialized category of institution.

The high concentration of black science and mathematics graduates in the HBCUs stands in sharp contrast to the almost complete absence of black graduates in science and mathematics at the vast majority of the nation's colleges and universities — this despite the fact that nearly all colleges and universities have black students.

The existence of effective learning communities in HBCUs is an important factor in the success of students in science, but it is not the only factor. In HBCUs, professors expect that the students can and should achieve. They demand serious study and hard work, and they believe that deficiencies in background can be overcome. Promising students are encouraged to engage in research projects. As a result of high expectations held by the faculty, students see success in science and mathematics as attainable, and therefore they can achieve.

The Spelman Model

The success of HBCUs and women's institutions in successfully nurturing, preparing, and graduating skilled scientists and health professionals is especially evident at Spelman College.

Founded in 1881, Spelman has grown from its initial beginnings as a seminary for freed slaves to a pace-setting institution that enrolls 1,900 women from 45 states and 29 international countries; employs nearly 145 full-time faculty members; and offers a challenging liberal arts program that has prepared over six generations of African-American women to reach the highest levels of academic, community, and professional achievement.

Spelman's success in producing dynamic African-American women is most profoundly represented in the sciences. Before it was an issue of national concern, Spelman was building a strong science program with the goal of answering the needs of our nation and its business and educational communities. Today, fully one-third of the 1,900 women enrolled at Spelman consistently select mathematics, computer science, biology, physics, chemistry, biochemistry, or a dual degree program in engineering as a major and 30 percent graduate annually in these areas. Among a survey of the of the top 100 baccalaureate degree producers, Spelman ranked second for the number of undergraduate degrees awarded in mathematics to African-American graduates; fifth for the number of degrees awarded in the physical sciences; and seventh for the number of degrees awarded in the biological sciences.

The Association of American Medical Colleges ranks Spelman among the top ten schools with the most accepted black applicants to medical school. And in the period 1991-1995, the National Science Foundation ranked Spelman among the top 26 producers of African American's obtaining doctorates and second amongst historically black colleges and universities. Since 1988, the college has witnessed a 57 percent increase in the number of science majors entering graduate programs. Some of the graduate schools where Spelman women have gone on to pursue the Ph.D. include: Cornell University, Purdue University, Massachusetts Institute of Technology, Georgia Institute of Technology, University of Michigan, and the University of Wisconsin.

Because of the college's past success and capacity for future distinction, the National Science Foundation, along with NASA, designated Spelman a *Model Institution for Excellence (MIE)* in undergraduate science and mathematics education. Spelman is one of only six institutions nationwide to receive this distinction. The MIE program provides a guiding framework through which Spelman is positioning its science education and research programs to continue to fuel the pipeline with dynamic African-American women in science and health professions. Yet, the proof of Spelman's success is evidenced in both the *quantity* and *quality* of our graduates. Let me name just a few. . .

- Dr. Georgia Dwelle Rooks, the first Spelman alumna to graduate from medical school and founder of the first obstetrical hospital for black women in Atlanta.
- Dr. Carolyn Yancey, a pediatric rheumatologist and Associate Medical Director of the Cigna Corporation.
- Dr. Deborah Prothrow-Stith, an Assistant Dean at the Harvard University School of Public Health.

- Dr. Audrey Manley, recently appointed as Spelman's 8th president, trained as a neonatologist; and retiring as a two-star Navy admiral with the Public Health Service where she was Acting Surgeon General of these United States.

- And, I guess, I should mention myself.. . .as a 1981 graduate, the educational training I received at Spelman prepared me to succeed in gaining my Ph.D. from the Massachusetts Institute of Technology.

Research and research training are an integral part of the Spelman College science program. Contrary to popular misperceptions, faculty at HBCUs are active researchers. At Spelman, we attempt to instill early in our students this love and respect for research and investigation. Most faculty supervise an average of four undergraduate student researchers, many of whom collaborate with their faculty mentors on research articles and travel with faculty to make presentations at professional meetings and other gatherings of the science community.

Spelman College faculty are principal investigators on key biomedical research projects. For example,

- Professor Shelia McClure, in biology, is head of a $3.8 million center funded through the National Institutes of Health and the Spelman Center for Biomedical and Behavioral Research. Professor McClure's own research focuses on "The Characterization of Mammary Adenocarcinomas and Uterine Leiomyomas: A study with implications for understanding fibroid tumors."

- Dr. Mona Phillips, in sociology, is conducting research, in collaboration with clinicians at Emory University, on the "Indicators of Stress and Strain in African-American Women."

- Professor Pamela Scott-Johnson, psychology, is studying the "Structure Activity Relations in the Olfactory System," funded by the National Institutes of Health.

- And, Professor Pamela Gunter-Smith, who holds the Porter Professor of Physiology and is Chair of the Biology Department, is working under a grant from the Veteran's Administration to understand "Mechanisms of Epithelial Ion Transport," an area crucial to fighting kidney disease.

I would be remiss if I did not point out that the U.S. Department of Health and Human Services has been a strong supporter of Spelman:

- Just this year we received a $2.5 million grant from the Office of Minority Health to renovate our health facility so that we may establish a comprehensive program focused on research and education in African-American women's health.

- For the past 10 years, our faculty and students have gained needed dollars for research and research training under the Minority Biomedical Research Support (MBRS) Program.

- And in 1996, Spelman celebrated the 25th anniversary of our Health Careers Program, an initiative funded through the Health Careers Opportunity Program of Health and Human Services.

As Spelman prepares for the new millennium, we do so with a strong appreciation of the role science and technology will play in determining our nations ability to compete, and our responsibility to educate students who are equipped with the skills to meet these challenges.

A Prescription for the Future

If Spelman College typifies the atmosphere of excellence that resonates on the campuses of our nation's HBCUs, then we can not underestimate the critical role HBCUs, minority, and women's institutions will continue to play in providing our nation with dynamic future leaders in science and the health professions.

If we are to take demographic projections seriously, projections which state that minorities and women are the fastest growing segment of our society, then we must know that these two groups will increasingly emerge as the population that must be trained to assume roles as . . .

- . . . physicians to treat us when we're ill;
- . . . researchers to help prevent and cure disease;
- . . . educators to train our children, grandchildren, and great grandchildren; and
- . . . public officials to set a scientific policy agenda that is democratic, equitable, and sensitive to the needs of all our citizens.

In sum, minorities and women will increasingly emerge as a vital part of the human resources that our country depends upon to ensure its continued growth and well being.

Yet, despite Spelman's success, the college still recognizes that much work remains. Spelman has limited resources when compared with our majority institutional counterparts. The college's science facilities are cramped and outdated. Many of the students, while being some of the most sought-after African-American students in the nation, come from economically disadvantaged backgrounds. The college's faculty spend the majority of their time teaching and need enhanced research opportunities. In one aspect, the challenges Spelman faces are unique to the college's position as an undergraduate, liberal arts women's college that has moved to the national forefront in preparing minority women for careers in scientific fields. On the other hand, the challenges Spelman must face are very similar to the challenges confronting the many small colleges and universities that are doing the lion's share of training American students in these fields, particularly those that enroll large numbers of students from underrepresented backgrounds.

Let me end by pointing out that AAMC has established a goal of enrolling 3,000 underrepresented minority students in U.S. medical schools by the Year 2000. The trajectory of current trends clearly indicate that we will fail to achieve that goal.

NIH, with a $12.7 billion annual budget, can lead the way in the federal sector to reverse this trend. We need the establishment of additional programs specifically targeted toward enhancing the capacity of HBCUs, minority, and women's institutions. We need more of these programs, because they've only touched the tip of what we — African Americans, minorities, and women — can do.

- We want to branch out into RO1-level research.
- We want to become meaningful partners and principal investigators in the more than $12 billion in research that NIH funds each year through its 21 institutes.
- And, we want to be in earnest conversation with NIH and other federal agencies to help set the nation's scientific research policy agenda.

In this way, we can be assured that, as NIH continues to allocate what is currently a $1.8 billion budget for such line items as HIV/AIDS research, populations who can most benefit — African Americans, minorities, and women — are:

- included in clinical trials,
- have options for experimental drugs, and
- that faculty from minority institutions are significantly involved in performing the investigations.

We can also be assured that diseases and ailments that so disproportionately affect minorities and women — diabetes, hypertension, teenage pregnancy, low-birthweight babies, heart attacks, strokes, sickle cell anemia, and kidney failure — are given adequate attention and funding.

Yet, as I stated earlier, the genesis of any change must begin with an adequate human resource base. Expansion of that base must begin with those institutions of higher education that have proven successful in delivering quality, dynamic graduates. Historically black, minority, and women's institutions have proven a vital resource.

Our diversity is our strength.

The challenge, now, if for you to tap into what we have to offer. Thank you.

Bette A. Rank *American Foundation for Urologic Disease*

Summary of Women and Urologic Health

The mission of the Bladder Health Council (BHC) of the American Foundation for Urologic Disease (AFUD) is to provide research, education, and awareness to the general public, patients, and health care providers nationally about bladder diseases and conditions. These include urinary incontinence, cancer, urinary tract infections, and interstitial cystitis.

AFUD provides education programs and awareness campaigns to our constituents, working as a coalition with the NIH/NIDDK, Interstitial Cystitis Association, National Association for Continence, The Simon Foundation, and the Society of Urologic Nurses and Associates.

Approximately 13 million Americans over 65 are afflicted with urinary incontinence — 80 percent of whom are women. This condition affects all ages and people of every social and economic level. Approximately 800,000 elderly Americans, living at home, are beset severely enough to limit daily activities and to become socially isolated. Direct and indirect cost to society is $16.4 billion.

Urinary incontinence is one of the three major reasons for admittance to nursing homes, where an estimated 745,000 nursing home residents are incontinent. “The total economic impact of urinary incontinence among persons over the age of 65 was $8.2 billion or $2,409 per person. Based on inflation for the medical care sector, a revised estimate of $16.4 billion was reported in the 1996 Aging for Health Care Policy and Research (AHCPR) Clinical Guideline Update on Urinary Incontinence.”*

“The direct cost for routine care for urinary incontinence to older people was $10.2 billion. Incontinence can result in longer hospital stays. The total costs associated with adverse consequences were $12.4 billion. In sum, the direct costs of UI were estimated to be $23.6 billion.”*

Taking care of incontinence can sometimes cause the patient, spouse, or care giver to lose the potential to earn wages elsewhere. Indirect costs totaled $4.2 billion. Thus, the total cost of incontinence of persons over 65 was $27.8 billion, or $3,941 per person. If prevalence and cost per treatment remain constant, the predicted 5 percent increases in the aging population by the year 2000 will cause the total costs of UI to approach $29.3 billion.

In 1995, Bladder Health Week was launched to focus on urinary incontinence. As a part of that effort, a study on “Women and Incontinence” by Yankelovich Partners, found that:

- Majority of women wait at least 1 year before discussing their condition with relatives, friends, or their physician.
- Most are hesitant to talk about incontinence; they are too embarrassed.

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* National Association for Continence

- Many curtail daily activities, such as going to the store, taking walks, going on trips, and visiting friends.
- Generally, urinary incontinence is accepted as a part of growing older.
- Numerous women surveyed stated that they were unhappy with their current treatment and were willing to try other options.
- Additionally, women were not satisfied with the care that had been provided by their physician and would be willing to change physicians.

Increased education, research, and treatment of women about urinary incontinence, especially at an earlier age, could lead to improved quality of life and ultimately lower health care costs.

Urinary tract infection (UTI) is the number one urologic condition requiring approximately 1.6 million hospitalizations and 10 million physician visits each year, for a total cost of $4.4 billion. UTIs are an annoying problem. One in five women will visit their doctor at least once each year for relief from a UTI. Twenty-five percent of women who experience one infection will develop recurrent urinary tract infections; and 5 percent of these are infections caused by the same organism that caused the first infection. Young girls around 5 years of age may get a UTI; girls as they become sexually active; and pregnant women can develop pyelonephritis during their third trimester. More than 20 percent of women over the age of 65 will experience asymptomatic bacteriuria and need to be carefully monitored. Bacteria in the urine can cause infection and inflammation of the bladder. If the bacteria travel upward from the bladder and reach the kidneys, a kidney infection may develop. Kidney infections are less common, but often more serious than bladder infections.

As many as half a million people in the United States may suffer from interstitial cystitis (IC). Ninety percent of IC sufferers are women; the average age of onset is 40, with 25 percent of the cases under 30 years of age.

IC is a chronic inflammation of the bladder. The symptoms are pain and pressure in the bladder, urethra, and pelvic areas, as well as increased urinary urgency and frequency. People with IC experience urgency and frequency of urination — from 15 to 50 times a day, sometimes more, waking at night to urinate. They suffer with immense pain in the bladder, lower abdomen, and urethra. The pain experienced has been described to feel like paper cuts, razor blades, or acid in the bladder.

Cigarette smokers have an increased risk of developing bladder cancer, and exposure to certain chemicals in the workplace, has been associated with an increased risk. When found and treated in the early stages, even cancerous bladder tumors are not likely to spread and are not likely to be life threatening.

We encourage and support research and education of bladder diseases for women. Together we can make a difference toward improving the quality of life for millions of women.

Vicki Ratner, M.D. *Interstitial Cystitis Association*

The Interstitial Cystitis Association (ICA) is a not-for-profit, voluntary health organization dedicated to finding a cure for interstitial cystitis, a painful inflammatory bladder condition that affects predominantly women. The organization was established in 1984 to increase awareness of the condition, provide support for IC patients and their families, increase public and professional education, and to raise funds for IC research.

Dr. Pinn and Honorable Colleagues from the Office of Women's Health Research: Thank you for giving me the opportunity to present my testimony to you today. I would like to tell you about interstitial cystitis and to report to you about the developments over the last 5 years in the struggle to find a cure for this painful, debilitating disease. I am an orthopaedic surgeon and am the founder and president of the Interstitial Cystitis Association. I also have IC. While today I appear as a seemingly healthy person to anyone who meets me, that is because the effects of interstitial cystitis are not always visible to others. Without medication to control the pain, I would be unable to work, unable to travel, and unable to be here at this meeting today. I would be in constant, severe pain and would have to void every 15 to 20 minutes, day and night. I can assure you that my work, my family, and entire life have all been dramatically affected by the experience of IC. Today I hope to give you a better understanding of IC. I hope to give you an idea of how far we have come, and how far we have yet to go. But most importantly, I hope to give a voice to all those IC patients who are too ill to leave their homes.

This letter, which was published in the nationally syndicated Ann Landers column in 1987, is all too typical of IC patients, even today:

Dear Ann Landers:

After three years of non-stop pain, 40 to 60 bathroom trips a day, little sleep, lots of tests, 12 doctors, hundreds of allergy shots, diets, antibiotics, and six unnecessary operations, I have finally been diagnosed as having interstitial cystitis, a "rare" disease that doctors seldom look for and may turn out to be not so rare... Ann, please tell readers with undiagnosed bladder symptoms that there is help from the Interstitial Cystitis Association (ICA), P.O. Box 1553, Madison Square Station, New York, NY 10159.

– "Diagnosed in San Antonio."

Interstitial cystitis is a chronic inflammatory bladder condition. Its cause is unknown and, at present, there are no uniformly effective treatments. The symptoms are similar to an acute urinary tract infection, but urine cultures are negative and the symptoms do not respond to antibiotics. The symptoms, which can vary from mild to severe and unrelenting, include urgency and frequency of urination — up to 60 or more times in 24 hours — and pain in the bladder which IC patients have described as burning, like "electric shocks," like "razor blades in the bladder," or being so severe that it feels like the pelvis is on fire.

I developed IC symptoms while I was still in medical school. Like many IC sufferers, I went to doctor after doctor looking for a diagnosis, but was unable to obtain one. I was told to see a psychiatrist. It was also suggested that I quit medical school and get married. After seeing 14 doctors, ten of whom were urologists, I ultimately went to the library myself, found an article on IC that described my case, and brought it back to my doctors. They still were not convinced and told me that it was impossible because I was too young, and that IC was a rare, post-menopausal disease. I was told that I would just have to live with the pain and that nothing could be done, a recommendation that far too many IC patients still receive today. A cystoscopy was finally scheduled and the diagnosis of IC was made — 2 years after the onset of symptoms. It was a relief to finally have a name for my condition, but so little was known, and few treatments were available. In 1984 I founded the Interstitial Cystitis Association in order to find support for my own condition and to work toward better treatments and a cure.

Although IC was first described early in the 20th century, virtually nothing was done before 1984 to adequately address IC in terms of diagnosis, treatment, or research. It is only in the last 10 years that IC has been removed from the psychosomatic chapter in *Campbell's Urology*, the standard urologic textbook used at all medical schools. The following is a sample from that chapter. IC "may represent the end stage of a bladder that has been made irritable by emotional disturbance…. a pathway for the discharge of unconscious hatred." This was finally deleted from the text book in 1986, only 11 years ago. IC was considered, and still is considered by some urologists, as an "hysterical female condition." Unfortunately, this blatantly incorrect label still haunts IC victims with the sufferer taking on average $4^1/_2$ years to get a correct diagnosis and often having to see an average of five physicians before IC is diagnosed.

In many ways, IC could be described as a classic "woman's disease." Because statistically it affects women by a ratio of 10 to 1 over men, it could be argued that the largely male urological community has been slow to develop an interest in IC. Additionally, IC symptoms are varied and not uniformly present in all IC sufferers. Even the so-called "classic" symptoms, such as glomerulations on the bladder wall, do not necessarily appear in everyone, and the severity of the pain, frequency, and urgency associated with IC can vary from reasonably manageable to unbearable, making it hard to classify as well as diagnose. No specific marker or test has been developed for IC, and it is considered largely a diagnosis of exclusion.

Because of its relentless demands on the body, IC can cause dramatic changes in the lives of people who suffer from it, making it difficult to maintain a job, making travel impossible, and affecting everything from a person's sleep to their sex life. Many patients are house bound. Since patients may void up to 20 times or more at night, sleep deprivation may be severe and, as a result, depression is common. These changes result in psychological misery as well as physical pain. Because the typical IC patient is not diagnosed immediately and has to live with the symptoms as well as uncertainty about the condition, patients are not particularly trusting of medical authority. This is particularly the case when physicians blame the patients and tell them nothing is wrong, since all the tests are 'negative.' Obviously something is drastically wrong. The test to show this just has not been developed yet.

The personal toll that IC takes on the lives of its victims and their families is less easy to quantify than physi-cal symptoms, but this letter we received from the husband of an IC sufferer will give you some idea:

"Enclosed are three donations made in memory of my wife, Joanna. Joanna was diagnosed with IC on February 22, 1995, though she suspected the disease in December 1994, following a hysterectomy. Like many other sufferers, Joanna was told it was in her head after tests turned up nothing. A cystoscopy on February 22 revealed the disease. The extreme

pain and despair over chances for a cure caused her to end her life on April 8th. We hope that these donations help in some small way to find a cure and save others from this fate." [Joanna was 44 years old, was married for 23 years, and had a teenage son.]

Suicides still occur every year, because patients are left to live in severe pain and despair often without a diagnosis or adequate treatment for their pain. The most recent suicide was 2 months ago by a 33-year-old woman.

Since the founding of the Interstitial Cystitis Association (ICA) in 1984, much progress has been made in helping to create public awareness for the disease. One of the most important advances for us was NIDDK's Workshop on IC held in August 1987. It was a unique meeting because it included researchers from many different areas in medicine. At that meeting, the results of the first large-scale epidemiological study on IC were presented. This study was sponsored by the Urban Institute and NIDDK. Statistics derived from the study showed that:

- Approximately 450,000 people in the United States suffer from IC. We believe that this is a conservative estimate because there are thousands of patients with the diagnosis of urethral syndrome, trigonitis, or painful bladder syndrome who clearly fit the IC profile.
- It takes an average of 4½ years to get diagnosed.
- Thoughts of suicide are three to four times higher than that of the general population. A pilot study of 60 patients, done by the ICA 1 year prior to the formal epidemiological study, revealed a 12 percent suicide attempt rate.
- By combining additional medical expenses incurred by IC patients with lost wages because of disability, the study calculated the economic impact of this disease to be as high as $1.7 billion per year.
- The life satisfaction rating was lower than the average rating given by female kidney dialysis patients.
- Sixty-three percent of patients experience painful intercourse. Many are even unable to have intercourse. This can have a profound effect — not only on a patient's marriage or prospects of ever marrying — but on childbearing abilities as well.

The 1987 NIDDK Workshop set forth an agenda of research priorities, and we've made great progress. Since that time, six scientific conferences on IC have been held, the most recent one was last month. Dr. Lee Nyberg, Director of Urology at NIDDK, has been a strong supporter and advocate of IC research and has worked closely with us to develop a large community of researchers interested in IC. His efforts are restricted by limited funding. Increased NIH funding is critical if progress is to be made on this debilitating condition.

The following areas of research must be emphasized if an effective treatment, and ultimately a cure, is to be found for IC.

- Epidemiologic studies must be continued, their data further analyzed.

- Basic science research — further study of *inflammatory mediators* in the urine of patients with IC. A substance unique to IC, once isolated, could serve as a marker for this disease.

- Etiology of IC — still uncertain — further study into bladder urothelium, possible role of an infectious agent or immunologic process, etc.

- Neuroinflammatory pathways in IC — including the study of bladder sensory afferents, neurotransmitters, mast cells, unmeyelinated C fibers, substance P, etc., and development of agents directed exclusively at sensory afferents in the bladder.

- Pathology — subclassify the disease based on bladder biopsy characteristics.

- Further evaluation of possible *endocrinological, hormonal, and immunological* aspects of IC.

- Clinical trials of promising drugs.

- Further analysis of the *IC Database*, a 6-year project which will be completed in Spring, 1998.

- Developing better *educational resources and outreach programs to educate patients and members of the medical community*. One of the reasons that patients are not being diagnosed is that many physicians still believe the condition does not exist because they have been trained on inaccurate, outdated information.

- Encouraging researchers to work in this area and establishing research fellowships in this area.

In the last 10 years, great strides have been made toward understanding this disease. Government funding for IC research has grown substantially over the last decade. Prior to 1987 there was no federally funded research on IC. However, by FY 1996, NIDDK funding for IC research had grown to about $9 million.

ICA has a longstanding productive working relationship with NIDDK. Through the fundraising efforts of ICA, small pilot research grants are awarded each year for promising areas of research. Many recipients of these pilot research grants have gone on to receive NIH funding. The ICA and the NIDDK jointly sponsor Scientific Symposiums on IC, the most recent of which was held in Arlington, Virginia, last month. This was a large-scale international event including representatives of 14 countries other than the United States. Over 200 clinicians and researchers from around the world gathered to report on their findings. On the pharmaceutical front, Elmiron®, the first oral drug specifically for IC, was recently approved for distribution by the FDA. ICA's national spokesperson, LPGA Tour Player Terry-Jo Myers, has benefited tremendously from this medication, having won two major championships this past year after nearly 10 years of playing in severe pain.

Despite great progress, there is still so little known about the disease. Because IC is a diagnosis of exclusion, and because there is no marker or specific test for the disease, the definition of IC remains controversial. For this reason, IC research projects are not always deemed to be "safe risks" by the NIDDK study sections. *Only by gathering more data and by initiating more research will we be able to better define this disease, and then progress to its treatment and cure.*

Our need is great. But we are confident that with your help and with increased funding for IC research through the NIDDK, we will find an effective treatment and, ultimately, a cure for this disease.

Sally A. Rudicel, M.D. *American Foot and Ankle Society*

The Orthopaedic Health of Women: Foot and Ankle Issues

Foot and ankle complaints are a common source of pain and disability in the United States. It is estimated that 43 million people in this country have foot complaints yearly. Fifteen million of these people will eventually seek medical help, and the majority of these people will be women.

Forefoot pain is a very common complaint in all age groups. In this country, however, problems of the forefoot occur in women seven to eight times more commonly than men. In a study of 356 healthy women between the ages of 20 to 60, a stunning 80 percent complained of foot pain. This same study found that 88 percent of these women were wearing shoes too small for their feet, and that 76 percent of these women had some foot deformity.

The most common forefoot problems are bunions, bunionettes, hammer toes, and neuromas, all of which occur disproportionately in women. Studies in societies that do not wear shoes have shown that the incidence of bunions, while much smaller than in our society, is equal in both men and women. Michael Coughlin, M.D. has done a 15-year retrospective study of his foot practice and found that 80 to 90 percent of these forefoot problems occur in women. We now have very strong evidence that women's shoes are a major cause of these deformities.

These forefoot problems are a cause of pain and disability. As the deformities progress, surgery is often necessary. It has been estimated that 75 percent of forefoot surgery in this country is necessary because of constrictive shoewear. In 1995, approximately 285,000 bunionectomies, 300,000 hammertoes, 80,000 neuromas, and 130,000 bunionettes were surgically corrected in the United States. If 75 percent of these procedures were caused by constricting shoewear, the estimated surgical cost for forefoot problems is $2 billion. If time off from work is included, another $1.5 billion in expenses is added. These figures are staggering and do not even address the morbidity to the patients suffering from these problems. All of this for high-fashion footwear.

The American Orthopaedic Foot and Ankle Society and its Council on Women's Footwear has made major efforts to publicize this information and educate the public, the shoe retailers, and the shoe manufacturers. However, style and fashion dictate shoe wear. The consumer must be educated about this debilitating health problem. We also need to investigate more vigorous early preventative measures and look more critically at the benefits of surgery.

Education of appropriate shoe wear needs to begin in childhood, since we know that shoes have an effect on foot health. Mary Williams Clark, M.D. has been doing some studies of the pediatric population, looking at shoe trends and foot problems in this age group. In her study, nearly everyone under the age of 18 was wearing low top sneakers most of the time. However, some girls began wearing high heels as early as age 5, an age where they are not yet choosing their own shoes, and the incidence of high heel wearing began to rise by age 12. Fifteen percent of the girls in Dr. Clark's study population were wearing heels by age 12 years. Pointed toe flats were being worn as well, but the length of time in these and in heels was usually less than half of the day. Education of parents as well as children about shoes is necessary. We also need further studies about changing shoe trends and the effects on the feet in the long term.

In addition, some businesses have dress codes and requirements for women's shoes. We need to stress the health risk this imposes and work toward a change of such policies.

At the opposite end of the age spectrum, Carol Frey, M.D. has done some investigative work on the relationship of shoe wear to falls in the elderly. In this predominantly female population, falls are a huge source of morbidity. While a tie shoe is a safer shoe, Dr. Frey has found that even some athletic shoes may be a cause of falls. Large lugs which wrap around the toe area of running shoes were implicated in several cases of injury. Also, outer soles which are wearing down, even on appropriate tie shoes, may cause a problem. Dr. Frey has developed the Ten Points of Senior Shoe Safety to help educate the public. More effort in exploring this source of injury in the rapidly expanding elderly population may bring huge benefits both in the health of the elderly and in better use of financial resources.

Rheumatoid arthritis is another entity with a predilection toward women. Women are affected three times more often than men. About 17 percent of cases of rheumatoid arthritis begin in the foot, and the majority of patients will have foot problems during the course of their disease. The foot and ankle problems range from bunions, hammertoes, and metatarsalgia, which may be treated with orthotics and shoes, to severe, destructive joint disease that requires reconstructive surgery. Again, education and earlier intervention may prevent or lessen the formation of these severe deformities. More investigative work on the primary treatment of the disease may also prove helpful.

When the foot hurts, the entire body hurts, and activity is severely restricted. Foot pains and deformities are a common finding in all age groups as our studies show. Forefoot problems in particular, affect women seven to eight times more frequently than men. We need to look further into the causes of these problems, search for prevention, and educate our population at an earlier age. The Office of Research on Women's Health can help us in the AAOS and AOFAS to play a leadership role in this important aspect of health.

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Rosalie Sagraves, Pharm.D., F.C.C.P. *American Pharmaceutical Association*

Good afternoon. I am Dr. Rosalie Sagraves, dean of the University of Illinois at Chicago College of Pharmacy. I present this testimony as an elected officer of the American Pharmaceutical Association's (APhA) Academy of Pharmaceutical Research and Science and as one who, for many years, has been actively interested in research in the field of women's health, and specifically the importance of gender-related research to the practice of pharmacy.

As you work to develop strategies "that can result in an improved health status for all women" and to set an Agenda for Research, I would like to discuss some specific areas in which I believe the Office of Research on Women's Health can have a major impact. These include:

- gender differences in drug delivery;
- women as care givers;
- "real-world" research;
- population-based care;
- self care and over-the-counter medication use; and
- cost-effectiveness issues.

Gender Differences

For the researcher, gender-related pharmacokinetic and pharmacodynamic differences are one of the important issues that this workshop should address. The Food and Drug Administration (FDA) has been concerned for many years about the *failure* of research protocols to take into account the different ways in which men and women may absorb medications and the different rates at which those drugs are distributed, metabolized, or eliminated once absorbed. At an FDA public workshop on gender studies in product development 2 years ago, it was noted that gender-related events like menstruation, pregnancy, lactation, and menopause affect the pharmacokinetics/pharmacodynamics of many drugs, as may the use of oral contraceptives and hormone replacement. Yet the clinical literature primarily contains data combined for women and men. Additionally, there is a dearth of pharmacokinetic and pharmacodynamic studies addressing the use of medications by aging women. Studies tend to be age rather than gender specific, and focus on just a few drug categories. Papers presented at a symposium on “Gender-Related Health Issues” at the 1995 World Congress of Pharmacy and Pharmaceutical Sciences, demonstrated that these are universal problems. Marianne Haselgrave, director of the Commonwealth Medical Association, emphasized that gender analysis of health issues must be addressed along with life-cycle differences and human rights in order to improve women’s health. She singled out research on “self-inflicted poor health related to overindulgent lifestyles” as equal opportunities for women increase, as well as osteoporosis and other diseases of the elderly. Neil Cummings, a Canadian lawyer who has produced WHO documents relating to health care and law, noted that some research codes include a “necessity test,” i.e., the drug being tested will only be used in a pregnant or lactating population. The proceedings of the symposium have been published and are available at this workshop.

Despite the FDA’s best efforts to change the culture of pharmaceutical research, pharmaceutical companies remain reluctant to include women of childbearing age and the elderly (the majority of whom are women) in Phase II and III clinical studies. This workshop should produce strong recommendations that ORWH work with FDA in implementing the latter’s guidelines to ensure that women are included proportionately in future clinical studies, and that gender analysis be as complete as possible for labeling of commercially available products. Further, ORWH should work with the various institutes and offices within the National Institutes of Health to ensure that basic and clinical pharmacokinetic/pharmacodynamic studies are carried out for the drugs, to include studying the drug interactions between hormone replacement therapy and various medications, as well as oral contraceptives and medications. In the area of vitamins, which is part of preventive therapy, pharmacokinetic/pharmacodynamic proposals should examine possible gender differences.

Women as Care Givers

But what happens after a drug is approved? How are the safety and health of the patient protected when a medication is prescribed, whether it is new to the market or new only to the patient? These questions are particularly relevant to women because some studies have shown that their health problems are often not taken as seriously as those of men. This is true whether the problem is chest pain or the failure of a medication to work as anticipated. Further, women need access to a variety of health care professionals for more than their own health. They are also the primary care givers for their families. It is important that this series of workshops end with recommendations to provide the tools women need to fulfill this latter function adequately.

As a pharmacist, I know that women need the assurance that the medications they purchase for themselves, their children, their aging parents, and their husbands, are not only safe and effective, but that they know how to use them. Advice from a physician or nurse is often forgotten or muddled by the time a medicine is purchased. It is important that the pharmacist recognize this and ensure that the care giver leaves the pharmacy with the knowledge she needs to care for her charge. The Take Time To Care program, piloted by the FDA’s Office of Women’s Health, focuses on this need. In initiating the Chicago pilot program, FDA’s field personnel reached out to colleges, including my own, to include pharmacy in this initiative which develops programs for consumers about the proper use of medications. I applaud FDA for identifying prescription medication use as an important women’s health issue, and for taking the initiative to involve pharmacists and pharmacy students in educating women about their medicines and how to use them.

"Real-world" Research

An opportunity to expand women's involvement in clinical research is suggested by the success of demonstration projects in the community pharmacy practice setting. The American Pharmaceutical Association has created a Practice-based Research Network of pharmacy practitioners who have the skills and interest to perform research studies at their practice site under the aegis of principal investigators who may be either physicians or pharmaceutical scientists. In the first use of the Practice-based Research Network, more than 30 pharmacists are participating in a demonstration project in which they help patients with dyslipidemia not only to manage their medication but to modify diet and develop healthy lifestyles to lower their cholesterol and improve lipid levels. Preliminary data from this study — Project ImPACT: Hyperlipidemia — show that American's most accessible health professionals can make an impressive difference in improving the health of both men and women by monitoring drug therapy and by educating patients. Pharmaceutical manufacturers are exploring with APhA the possibility of using the Practice-based Research Network in a variety of Phase IV studies.

The skills used by the pharmacists in Project ImPACT: Hyperlipidemia illustrate a new method of pharmacy practice: pharmaceutical care. Pharmaceutical care builds on the fact that the pharmacist is the most accessible health professional. The pharmacy is just down the block, is open late, and no appointment is needed. The pharmacist is more knowledgeable about medications that any other health professional — how they work, how they interact with other drugs and with food, their side effects. Increasingly, the pharmacist is recognized for this knowledge and is using it as a member of a physician/pharmacist/patient triad to manage the patient's drug therapy. The recent discovery that certain weight-loss medications have major, previously unknown side effects is exemplary. Many pharmacists have well-established weight-management programs, often in conjunction with diabetes disease management programs, for their obese patients, the majority of whom are women. These in-place programs are now benefiting women who can no longer rely on an unsupervised drug regimen to help them lose weight. Patients are achieving better health with the assistance of health professionals who are easy to reach, eager to share their knowledge, and willing to take responsibility for improved outcomes. However, in most cases, these results have not been validated by rigorous studies. Research recommended by the Office of Research on Women's Health could remedy this, providing solid evidence that the cost to society of noncompliance and drug misadventures can be sharply decreased if pharmacy services are properly structured and supported.

Conferences and workshops such as this tend to emphasize the role of the medical profession in the kind of care I've just described. I would ask that your recommendations take note that other health professionals — pharmacists, nurses, physician assistants, etc. — are able to provide effective care in their respective areas of knowledge. This single recommendation, if broadly implemented, would go far in improving access to care and restraining the cost of health care, while continuing to recognize that the physician leads the team of well trained health care professionals.

It is equally important that both the care giver and the physician have confidence in the pharmacist. Additional research into the value of the team approach to health care is much needed. The issue of information exchange between professionals to smooth the continuum of care, particularly in light of emerging technologies, is an excellent example of an exciting area for additional research.

Population-based Care

We all know that research is expensive and underfunded in this time of reduced federal spending. Tightly controlled expenditures are also a common ingredient of health care delivery these days. This may be one reason why population-based care is being used more and more in health care settings. Similarly, research studies based on meta-analysis are becoming popular. This is of great value to improving women's health because much data *is* available if enough studies are combined. As women (and men, of course) live longer, these data become invaluable in reasoning from the general to the specific to improve individual health care. It is important that recommendations from this workshop focus on the usefulness of population-based studies for reasons other than reducing costs. Managed care organizations, in particular, must be encouraged to share their databases with researchers to make these studies possible.

Self Care

There are some areas of improving women's health status that do not need additional research but rather a different approach. The self-care movement is one example. In their role of care giver, as well for their own health needs, women are taking charge rather than relying on the experts. They read articles, both scholarly and popular; they watch health presentations on television; they listen to talk shows; they surf the Internet. And they read the labels on over-the-counter medications. A recent consumer survey conducted for APhA and *Prevention* magazine showed that as many as eight in ten of the nation's adults treat themselves before calling on a health care professional when suffering from common ills. Where do people seek information about how to choose and use medications? Eighty percent read the product label; 75 percent consult physicians; 70 percent ask their pharmacist. What can this conference do to ensure that they are gaining accurate information from reliable sources? I recommend that the development of guidelines to help the consumer judge the quality and reliability of available information be one outcome of your work.

Cost Effectiveness

Finally, the issue of economics must be confronted. Despite a moderating trend, the cost of health care continues to increase at a rate above inflation. More research about cost effectiveness and outcomes is essential. I encourage you to emphasize research on the fastest-growing group of health care users — the oldest old, who use the most resources on a per capita basis as they near the end of their lives. Most of these patients are women, and they would perhaps benefit most from decreasing unnecessary costs of health care. A recent study by Bootman in the *Archives of Internal Medicine* estimates that the cost of drug-related morbidity and mortality in nursing facilities could be nearly halved simply by utilizing the services of consultant pharmacists. An earlier study by Johnson and Bootman concluded that the cost of noncompliance and drug misadventures to the U.S. economy was nearly

$80 billion annually, and suggested that pharmacists taking a more active role in drug therapy management would sharply reduce this outlay. Focusing research on pharmacoeconomic issues clearly would do much more than merely cut costs. Outcomes and quality of life would be enhanced as well.

Thank you for the opportunity to offer the views of the profession of pharmacy and its clinical research arm. I have presented a large agenda, yet it is only a small part of what you will be asked to do over the next few days. I believe you will find that most of the presenters here are addressing the same issues; only the perspectives are different. I urge you to look for the similarities among the recommendations you receive, and consolidate them into a short research agenda with targeted goals. By so doing, you will benefit us all.

Charlotte (Barney) Sanborne, Ph.D.

Texas Woman's University

During the last decade, much attention has been given to women's wellness. Even with this current emphasis, recent statistics suggest that most American women are choosing not to participate in a wellness lifestyle. The NIH Office of Research on Women's Health postulates that inactivity and harmful behaviors lead females to be more vulnerable to disease, to experience more severe maladies than men, and to be impacted by health problems that are unique to women. In fact, women can significantly reduce the risk of both cardiovascular disease and osteoporosis with regular physical activity and proper nutrition. Despite this information, approximately 40 percent of American adults lead a sedentary lifestyle. These patterns begin in childhood and are especially prevalent in females. The National Children and Youth Fitness Study suggests that today's youth are fatter, less fit, and less healthy than 10 years ago. Specifically, there has been a 64 percent increase in obesity in elementary-school-aged children, thus 15 to 20 percent of American children may be classified as obese. Twenty-seven of every 28 of these adolescents will continue to be overweight throughout their lifetime. In fact, an earlier onset of obesity (by age 6) relates to an increased chance of obesity as an adult. Furthermore, the psychosocial ramifications, such as being ostracized by peers, may contribute to an overweight child's low self esteem and poor body image.

Although the principles necessary for a wellness lifestyle have been established, the ability to involve people in the process of participating in healthy lifestyles is a completely different concern. Early detection and preventative health strategies are the keys to avoiding a lifetime of medical treatments and financial burdens. For success, this process must focus on prevention and be multifaceted, ongoing, include all ages, and remove significant barriers to health care resources.

Prevention vs. Treatment Research

Health research has, historically, been rooted in a value system that favors understanding of treatment of disease over understanding of prevention. The requirements of diagnosis and treatment receive emphasis in the medical model over the larger picture of health maintenance throughout the life span. While this attitude is presently in a state of transition, it is still apparent in the health care policies and systems in the United States. Such a priority results in disease-specific focus for research. Once the focus becomes a specific disease, the search for understanding often narrows to a specific discipline or even a subspecialty within a discipline. Such a narrow perspective of health, coupled with the financial rewards and career advancement that may be associated with successful solutions to medical problems, invariably leads to lack of multidisciplinary collaboration.

Pragmatic Approaches to Curricular Research Design

Even if results of outcomes research prove to be conclusive, challenges still lie in the design of programs that can and will be implemented. For example, a successful school-based program must fit into existing curricular design regarding days and hours per week of health and fitness class time (if they are formally programmed at all). Prevention programs for women with multiple roles (family, career, etc.) must be compatible with existing life commitments. In addition to program design issues, further research in this area should include health beliefs, attitudes, and motivations to engage in health-promoting behaviors. Challenges are still evident, for example, in motivating young people to avoid unhealthy lifestyle choices that contribute to premature death or compromise quality of life in later years. Longitudinal research remains the most conclusive method for confirming behavior change and the complex factors contributing to sustained change.

Multidisciplinary Approaches to Research

An interdisciplinary approach integrating primary and specialty care has been proposed as the best way for medicine to focus on women as whole people. An interdisciplinary focus includes psychosocial factors as well as physical and biological factors. Research shows that health promotion programs, designed to address “leading health problems” within any given community, are often ineffective because no preliminary research was conducted to more clearly identify (a) psychosocial, environmental, and cultural influences upon those problems, and (b) factors related to the degree to which the targeted community is interested/concerned about the health problem and willing to embrace efforts to reduce incidence/prevalence. Any research related to the health of women should encompass a more comprehensive design which includes a broad, carefully-planned assessment of the influence of culture, other psychosocial factors, and the environment in which that community functions. Such designs should focus upon the community’s potential (i.e., capacity building factors) rather than only upon negative contributors.

Recognizing and addressing these multiple, inseparable influences on health requires new paradigms and harbors implications for our understanding of disease causation, therapeutic responses, healing, and the healer/patient relationship. Further investigation should explore the mechanisms and realities of truly crossing disciplines, not simply collaborating across subspecialties within a discipline. True multidisciplinary research will bring together professionals involved in all levels of care, from prevention to diagnosis to treatment to education, to insure a whole-person exploration of women’s health.

Public Policy Impact on Women’s Health

Another specific research area that needs to be addressed is the impact of public policy on women’s health. An example is the Welfare Reform Act of 1996 in which resources have been limited in an effort to decrease unwanted pregnancy. A potential problem is that very often the father of a teenage mother is an adult. The pregnancy is really a form of child abuse. This public policy punishes the victim and, at best, assumes the victim had some control. Research is needed to examine the impact of public policy on the health of not only the mother but also the far-reaching implications on the fetus, baby, and child.

Texas Woman's University

Texas Woman's University (TWU) is the nation's largest public university dedicated to the education and advancement of women. A teaching and research institution, the university emphasizes the liberal arts and specialized or professional studies. TWU is among the leading providers of health care professionals in the state and the nation. The College of Nursing is one of the largest in the United States. The School of Occupational Therapy is the largest in the nation and has the only graduate program in Texas and the only doctoral degree offered at a public university. The School of Physical Therapy has one of the leading programs in the United States and one of only four doctoral programs in the nation. Research is one of the missions of the University, along with instruction and public service. In addition, the library's Women's Collection is the largest depository for research material about women in the south and southwest, and it is one of only three major collections of its kind in the United States.

The Center for Research on Women's Health at Texas Woman's University is dedicated to the advancement of research, education, and advocacy concerning issues related to the physical, mental, and social health of women in all stages of their lives. The Center exists with the intent to lead in the development, dissemination, and implementation of knowledge about women's health and well being through ongoing multidisciplinary research programs. Numerous faculty and students, representing disciplines such as nutrition, textiles, biology, physical therapy, occupational therapy, nursing, kinesiology, women's studies, sociology, and health studies, have contributed their expertise to research and education efforts in the name of women's health. One example of the Center's groundbreaking endeavors involves the current planning, administration, and implementation of a longitudinal women's health study, the TWU Pioneer Project. The Pioneer Project is a longitudinal multidisciplinary study that will involve thousands of girls and women (ages 14 to 60 years) in the state of Texas. An initial assessment and yearly followup measurements will be obtained that will help explore the sociological, psychological, and physiological status of Pioneer Project participants.

Barbara Seaman *National Women's Health Network*

Consumer Participation in Government-funded Research

There is a worldwide movement, gaining momentum, to include greater consumer participation in the concept, design, execution, and (perhaps) analysis of medical research, especially where taxpayer funding is involved. As an editorial by Alessanda Liberati (Mario Negri Institute, Milan, Italy) in the *British Medical Journal*, August 31, 1997 observes:

> *"The quality and relevance of much clinical research falls short of patients' needs. . . Even among progressive scientists and health professionals, a paternalistic attitude still prevails. They do not believe that patients and consumers can improve the decisionmaking process . . . But successful efforts to shift the balance are becoming a reality, even in difficult areas such as oncology."*

Diane K. Seay *National Association for the Advancement of Women in Science*

The National Association for the Advancement of Women in Science (NAAWS) is a student organization chartered at the University of New Mexico (UNM). NAAWS was founded in the fall of 1994 in an effort to bring women scientists together with women science students. The organization provides an arena for scientists to share their work and the dynamics of career, school, and family. Gloria Sarto, M.D., Ph.D., Professor, Department of Obstetrics and Gynecology, and Andrea Allan, Ph.D., Assistant Professor, Department of Neuroscience, UNM, and Ellen Goldberg, Ph.D., President, Santa Fe Institute, are our advisors.

Shortly after our monthly meetings of NAAWS were initiated, a review of the literature substantiated our subjective realization that confidence and an interest in science is best fostered at an early age. Consequently, in the spring of 1995, the Girls and Mentors Manifesting Achievement (GAMMA) project was initiated. UNM women science students volunteered to mentor 5th and 7th grade rural school girls in small groups, generating and answering questions which follow the steps of scientific inquiry. Girls were selected from Los Lunas, New Mexico, a district that reflects the state of New Mexico in ethnicity. Intervention and control groups were set up. Initially, no female 5th graders agreed to participate stating that science was "boring" and "for boys." At that point, it was determined that intervention should include younger girls, and a tiered mentoring system for 3rd, 5th, and 7th graders was devised.

At the conclusion of each year, students visit various research laboratories of women scientists at UNM. A closing ceremony is hosted at the UNM president's home where girls are given the opportunity to discuss their projects in front of peers, mentors, and supporters from UNM.

A fourth intervention is planned for spring, 1998 which will involve approximately 50 rural school girls. The GAMMA project would like to make the following observations:

- Rural school girls need to be instructed in science by individuals who themselves have an interest in, and inquisitiveness for, math and science. All students should be encouraged to think about scientific ideas and concepts in a manner which facilitates their teaching someone else.

- Rural school girls need not only access to improved electronic methods for learning, but also training in the use of these methods by individuals who are themselves comfortable with their capabilities. For example, in one school district we found a new computer on the floor, unused, because its owner felt ill at ease with computers.

- Overall, awareness is heightened by such intervention methods regardless of whether the girls eventually take more science and math classes or choose math or science careers. Better methods to measure effectiveness of mentoring interventions need to be developed.

- Rural school girls need increased exposure to women in science. Invariably, the pre-intervention assessment, which included a task to “draw a scientist,” brought consistent images from the girls of men at work. Post-intervention drawings, on the other hand, showed more detail and more images of women scientists. We must continue to increase public awareness of women in science. While Bill Nye provides an exciting arena for scientific exploration on PBS, which encourages both girls and boys, he is still, “the science *guy*.”

- In order to generate an active rather than a passive interest in science and health issues for their future, rural school girls must be challenged to think and ask questions, and to develop critical thought processes and perspective.

NAAWS would like to propose that women Ph.D. graduates in science be given the opportunity to teach science in elementary, middle, and high schools in rural areas and to receive credit toward student loans just as physicians and nurses who choose to work in rural areas do. Additionally, course credit could be given for graduate students to teach science in rural schools. In these ways, an excitement for scientific inquiry would be fostered and maintained in the rural school setting.

Finally, we would like to challenge every woman scientist to acknowledge the influential part she plays in the lives of girls and women she encounters. Your example and encouragement make a difference.

Wesley Segawa *Emory University School of Nursing*

I, Wesley Segawa, will present testimony on the need for attention on cultural values, beliefs, and spiritual practices when conducting research or designing health care for women and families. I am an engineer by profession, from the Island of Hawaii, who has had the privilege of participating in federally funded projects by being named the engineer on record for the design and construction of the National Science Foundation’s Gemini Telescope Observatory at the Mauna Kea Science Reserve, Island of Hawaii. I am also past president of the East Hawaii Kiwanis International Service Organization. It was during my term as Kiwanis president that I became involved in learning about the issues involved in the recruitment and retention of women into health care. Our organization, along with other community businessmen and members of men’s service organizations, collaborated with researchers to build and evaluate a prenatal care program that was part of a two-phase research demonstration project targeting the improvement of birth outcomes. This project included ethnically diverse women from our rural island and other urban and rural Hawaiian communities on the Island of Oahu. As president of the advisory board to the Malama Na Wahine Hapai, or Caring for Pregnant Women, project in Hilo, Hawaii throughout the initial 5-year period, my board colleagues and I came to understand the importance of the promotion, respect and deference for, and integration of cultural/ethnic ways of knowing and healing into both the conduct of research and in helping women to participate in targeted health care programs available in their own communities.

Ethnic groupings are one of the strongest bonds that connect individuals, such as myself, to the larger island community. Each ethnic group has certain values, beliefs, symbolic meanings, and sense of spirituality that guide our family life, close interpersonal relationships, choices, and decisions. They also shape responses to the surrounding environment. For example, although sex roles are delineated in Japanese traditional families between the husband and wife, the actual authority for decisions regarding finances, childrearing, and health care lies with women, especially in rural farming and plantation communities. This is not readily apparent to the public, because this form of deference to the male partner is to uphold and not erode self esteem. When this cultural moré is not known by the researcher or health care provider, problems often develop during encounters as seemingly simple as obtaining consent to participate in a program.

With this in mind, it should not be surprising that standard modes for interfacing with, and then benefiting from, the standard medical system in the United States are not always straightforward. For Native Hawaiian people, researchers would need to understand the significance of “ohana” — extended family affiliation values wherein family group responsibilities supersede individual pursuits. Especially during resolution of problems and for coping, it is always about family. Therefore, health care recommendations such as individual psychotherapy may not be a culturally sensitive approach when a Hawaiian women is accustomed to the “hooponopono” process involving the entire family values of keeping relationships free of conflict. It is totally unacceptable to resolve conflicts openly or through Western-style confrontation. Japanese people speak of a similar sense of obligation, called “on,” that defines Japanese hierarchy. On is predicated on the concept of reciprocity, so that even if there exists a vertical leadership role hierarchy in a family or organization, confidence in a decision is extensively tested through a process of consensus. For this reason, reluctance to formulate an individual or unilateral decision when coaxed by a health care provider to do so, should be understood within this context when working with a Japanese woman.

These are but two examples of values and beliefs that would impact the inclination or interest in accessing a health care program that did not acknowledge the significance of culture in a real way. By this I mean not just being aware of various cultural attributes and customs, but making concerted efforts to find ways to incorporate this knowledge into the assessment of health problems and for shaping the interventions. What better way to show respect for a person’s sense of humanity and reflect sincerity for preserving an individual’s identity and dignity? It is clear to those of us who were observing and collecting data to evaluate the Malama program in our community, that women who entered and stayed with the program were those who were allowed time to listen to their “stories” when desired and provided with the opportunity to participate in developing their own action plan for health care.

For Native Hawaiian women who were enrolled in the Malama program and kept coming back to scheduled appointments, it was important, therefore, that nurses conducted preferred group sessions, rather than one-on-one, and incorporated cultural healers into the prenatal care visits to demonstrate such stress reduction strategies as "lomi-lomi" massage. The so-called "world" view of our people cannot be underestimated. If this is truly understood, doctors and nurses would know that when one of our Filipino women came into care, she may be less likely to maintain counseling or psychiatric-type services even if this was initially agreed to. This is because of difficulty in identifying emotional factors as the possible basis of a particular health problem. She may, instead report a dizziness, a touch of flu, spirits, or even a punishment from God, rather than acknowledge the occurrence of depression symptoms that are considered a sign of weakness. It would be important for health care providers to know that use of an authoritative explanation of what is wrong, what's to be done, for how long, and why would be viewed more positively by Filipino women versus an emphasis on Western approaches aimed at understanding concepts of communication, interpersonal relationships, and introspection which are considered too esoteric to be accepted.

While Hawaii's citizens are seemingly, for the most part, indoctrinated to the American system of health care; our most recent immigrants face even more difficulties in adapting or accepting the foreign model of health and health care. For example, I recently spoke to our local public health nurses about health care issues involving the many Marshall Islanders new to Hawaii. The nurses, although readily allowed into homes, were very concerned about lack of access and interest in obtaining additional health care by Marshall Islanders, particularly for children's immunizations and followup related to carrier status for communicable diseases such as tuberculosis and Hansen's disease, also known as leprosy. In this culture, the belief system is very strong that leprosy is a punishment for an evil deed. The challenge for the nurses assigned to work with the Marshall Islanders is to incorporate the meanings of this cultural belief into a culturally relevant intervention design.

I, and the other men living in the Hilo-Puna district of our island, learned several things during our participation in Malama activities. First, including members of the community with the same cultural backgrounds as the targeted recipients of the prenatal care program is essential to the success of the endeavor. Our concept of a Neighborhood Woman's Health Watch went beyond involving professionals and even semi-professionals in outreach efforts found in typical program recruitment efforts. Instead, Neighborhood Watch members understand the cultural expectations of childbearing and childrearing. Those members associated with the Malama project are responsible for guiding women in a process of role modeling for healthy behaviors and health care decision-making within the family to promote self esteem and gain recognition within the larger cultural community. They are also able to understand the stories that help women to describe their personal experience with both physiologic and psychologic symptoms of distress during pregnancy. Most importantly, they are often the bridge to standard health care systems that today's women still must contend with in the island communities.

We also learned that people are more likely to trust standard providers and researchers if encouraged to still follow beliefs that have meaning beyond the self, but also reflect the need to be connected to family and respected elders. This level of respect also extends to sacred parts of the environment, especially our active volcano located on the island of Hawaii. For example, when my neighbor's wife, who is Native Hawaiian, was pregnant, she was protected by the community in not going to watch the volcano. The local islanders wanted to assure the best outcome for her baby by encouraging distance from the volcano since it is believed that viewing the fountaining of the volcanic eruptions would result in the birth of a baby with a fiery birthmark. In deference to the cultural elders, she needed to follow this custom and maintain her distance until the baby was born.

Finally, as a man, I think that it's important not to leave men out of the equation of understanding the broader context of women's health. In the Malama project, we found that including males, either spouses, partners, brothers, or uncles, was important because an interpersonal relationship involves both partners. To omit one interrupts the system. It is important that the man's point of view is acknowledged within the context of roles, status, and health within a particular cultural group.

The advantage for men participating in the Malama project was also the opportunity to understand women's points of view. All we know about women is typically what we learned with our own families, and not much time was spent on explaining women's health issues or problems when I grew up. Understanding women's health becomes all the more complicated when multiethnic marriages are involved because of conflicts in cultural values. For this reason, I believe that men's relationships with the cultural healers and neighborhood watch members were also important to cultivate in our island communities.

Thank you for the opportunity to present my testimony at this public hearing. It is my intention in coming to Washington that this presentation would be purposeful in identifying the key factors involved in the promotion of current women's health care through the understanding of the role of culture. We need to keep in mind that men are eager to advocate and help develop polices for improving the health status of the important women in their lives.

On behalf of my colleagues and neighbors from Hawaii, I hope that efforts put forth by the Office of Research on Women's Health will continue to make the influences of ethnic and culturally diverse lifestyles a priority so that women in this era, and their daughters in the next, will be able to directly benefit from the results of this important work. Thank you for your attention.

Amanda Sherman *DES Action USA*

DES Action USA is a national nonprofit organization representing an estimated 10 million mothers, daughters, and sons exposed to the drug DES (diethylstilbestrol).

The purpose of DES Action USA is to provide education and support to those exposed to DES, to increase public awareness about DES so that individuals can discover if they are exposed, and to educate medical professionals so they can provide knowledgeable services to DES-exposed people. We also seek to keep public attention on the story of DES as a reminder of the need for vigilance in regard to health care practices.

DES Action USA and the DES Cancer Network are the only consumer groups to which DES-exposed Americans can turn for support, information, and education.

Testimony

Eight years ago we at DES Action USA were alarmed to hear about the impending cutoff of funding for DES research at the National Cancer Institute. Some of the comments which circulated included the sentiment that DES-related cancer affects a very small number of women, a finite population. We also heard that while cancer of the vagina or cervix is certainly a tragic diagnosis, the DES experience represented an anomaly of history, with few applications for the larger society.

We were disheartened, though not entirely surprised, to hear this line of reasoning. We realized that DES Action USA had to accelerate our work and include a campaign to raise awareness about the following points. One, that DES exposure has resulted in many disastrous health outcomes, some still under investigation, in addition to cancer. These outcomes have affected many more women and men than DES-related cancer. And two, that the DES experience contains essential lessons relevant to the entire population in terms of the particular hazards of fetal exposure to estrogen and the powerful potential of endocrine-disrupting chemicals. After all, those who have been exposed to DES have been the “canaries in the coal mine” for a number of very important health problems now coming to the fore.

With this in mind, DES Action USA launched a campaign that eventually not only restored and increased NCI funding, but also expanded research to include DES mothers and DES sons for the first time. In addition, NCI has also broadened the scope of their inquiry to look at many other adverse health effects besides DES-related cancer. We now seek to answer many outstanding questions, such as the possible effect of DES on such bodily systems as the skeletal and immune system, and on the grandchildren of the women who took DES while pregnant.

On behalf of nearly 10 million DES-exposed Americans, DES Action USA welcomes the opportunity to present this testimony and to contribute to the development of a women’s health research agenda. We thank Dr. Vivian Pinn and the Office of Women’s Health Research for their leadership in developing this agenda for women’s health research in the 21st century.

Following the discovery of DES-related cancer in 1971, DES was identified as the first known human transplacental carcinogen. One out of every 1,000 DES daughters will develop clear cell adenocarcinoma of the vagina or cervix. In addition to this cancer, DES also causes a variety of other grievous injuries, the full extent of which often remain latent for decades, until a DES daughter or son reaches childbearing age or beyond.

Of an estimated 2.4 million DES daughters, many have been born with reproductive-tract deformities which include cellular and/or structural malformations of the vagina, cervix, uterus, and Fallopian tubes. These abnormalities cause health problems ranging from infertility to serious difficulties with conception and childbearing.

DES daughters have five times the risk for ectopic pregnancy (a life-threatening condition), twice the risk for miscarriage or stillbirth, and three times the risk for premature labor and delivery. Many will never bear a child of their own.

DES daughters who do succeed in becoming pregnant require high-risk obstetric care and are often told by their physicians to spend most of their pregnancy in bed. Despite these precautions, many DES daughters deliver prematurely which, in turn, increases the risk of serious birth injuries, such as cerebral palsy, or even death among third generation DES babies.

Ironically, DES daughters are the most frequent consumers of infertility drugs and reproductive technologies, thus subjecting ourselves — and perhaps our own children — to yet another round of pharmacological experimentation. This is because the long-term effects of these medical interventions are unknown, and some infertility drugs are the chemical cousins to DES.

In addition, as the DES-exposed population ages, DES daughters and their physicians face another dilemma regarding the use of hormone replacement therapy (HRT). What are the risks of HRT for a population previously exposed to a potent synthetic estrogen prior to birth?

DES mothers, who unknowingly passed on a perilous medical legacy to their children, also inherited one for themselves. Studies point to an increased risk for breast cancer in DES mothers.

In April of 1992, the National Institutes of Health, led by Dr. Vivian Pinn through the Office of Research on Women's Health, sponsored the first research conference to identify the medical questions about DES that can only be answered by further scientific research.

Preliminary studies presented at the 1992 conference indicated that when DES crossed the mother's placenta it not only harmed the reproductive system of the fetus, but the endocrine, immune, cardiovascular, and skeletal systems as well. Also cited were animal studies indicating that DES-exposed offspring manifest adverse health effects throughout the entirety of their life span.

Researchers suspect that as DES daughters approach middle age they may encounter even greater risks for DES-related problems. What will be the long-term risks for this population as they age?

These are some of the key questions that must be included in the DES research agenda:

- Will DES daughters develop an increased rate of breast and reproductive tract cancers, as animal studies seem to suggest?
- Will there be a new peak of clear cell vaginal or cervical cancers? How many DES daughters will develop new cases? How many will suffer recurrences?
- What are the long-term effects of fertility drugs on a population already exposed to synthetic estrogen in utero?

- Should DES daughters be candidates for hormone replacement therapy during menopause?
- What are the effects of DES on the immune, endocrine, and cardiovascular systems?
- What are the risks for the third generation exposed to DES?

Further research is desperately needed for these questions and others to be answered. The fact is, no one yet knows the full extent of the damage DES may cause. But it is clear that DES does more than wreak havoc on the reproductive system. It does more than damage the immune system and cause cancer. It has become clear that in utero DES exposure in humans serves as an important model for our understanding of the potential destruction — yet to be fully realized — of endocrine-disrupting chemicals.

Therefore, we implore you, not only for the sake of the DES-exposed population, but for our collective scientific understanding, to learn the answers to all of the questions raised by DES.

On behalf of the affected population and the scientific community, it is my hope that research priorities will remain focused on the consequences of DES exposure. This workshop can certainly make that happen.

Thank you.

Eleanor G. Shore, M.D., M.P.H. *Harvard Medical School*

Program to Increase Representation of Women at all Ranks in Academic Medicine

One year ago, as Dean for Faculty Affairs at Harvard Medical School, I submitted public testimony about a new program to provide fellowship support for junior faculty at the most vulnerable point in their academic careers, i.e., when professional and personal responsibilities conflict. At that time, I documented the lack of adequate representation of women at the higher academic ranks both at Harvard Medical School and nationally. Today, I would like to give you a 1-year followup regarding the early effects of this program on the junior faculty who were recipients of these fellowships. As background I should explain that as part of the celebration of the 50th anniversary of the admission of women to Harvard Medical School, private funding from alumni(ae), friends, hospital departments, affiliated institutions, and women faculty was secured to provide partial support for ten junior faculty members each year for 5 years. The $25,000 awards are intended to buy protected time in which the recipients can do research, prepare grant proposals, write papers, or develop a new curriculum. Or, alternatively, if they are laboratory scientists, they can purchase the time of a research assistant. Men, as well as women, may apply if they can demonstrate similar levels of conflicting personal responsibilities and obstacles to their academic work.

Progress

As of this fall, ten junior faculty have completed their fellowships, and 11 more have begun theirs. More than 136 applications were submitted this year for the second round of fellowships. Each recipient is asked to complete a report at the end of the year's work. I would like to quote from one of the reports:

"I think the most important effect of the award on my career and personal life is that having a research assistant allowed me to apportion my time appropriately to the clinical care that I provide, the teaching that I do as a member of our faculty, and the continuation of my clinical research. What happened without a research assistant was that I spent my time doing the first two aforementioned activities, and wishing I could get the third activity done, but not getting very far. In terms of family life, receiving the award has allowed me to be more flexible with my hours and rely on another pair of hands to be at the Institute when family needs take precedence."

(This quote comes from the mother of twins.)

At a meeting this past October, three fellowship recipients appeared on a panel to discuss in more detail the effects of their fellowships on their academic careers. The most compelling feature of their individual accounts was their description of the leverage the fellowship awards had produced. Department heads regarded their academic aspirations more seriously, protected time for academic activities was extended beyond the year of the actual fellowship, new collaborations materialized, and more departmental support was forthcoming for their research.

We have been particularly pleased to see that there has been a spin-off effect from this effort. A separately funded set of fellowships for basic scientists in the Faculty of Medicine at Harvard was, after a careful examination of the Fiftieth Anniversary Program for Scholars in Medicine, announced with a particular emphasis on women applicants. Of the seven $50,000 fellowships offered in June 1997, four were awarded to women. Similarly, at an affiliated hospital in Boston, three fellowships were awarded to women with academic promise and these same obstacles to their academic careers.

Summary

It is our view that it is unconscionable to allow talented women (and men) to wither on the academic vine when a modest amount of support could maintain their academic careers and preserve their capacity to contribute to the research and teaching that are absolutely vital to the future of medicine.

While these fellowships have already had a leverage effect for the recipients, they touch only a small fraction of the women and men who need help at this particular phase of their careers. The same problem is certainly occurring in academic medical centers all over the country. A nationally funded, competitive fellowship program that acknowledges this time limited, but serious, problem when promising academic careers may be stifled without temporary support for academic activities, would go a long way toward strengthening the talent pool for future medical research and teaching. It would also help to diversify the senior faculty ranks by preventing the loss of junior women faculty who are well trained and motivated but temporarily in need of assistance to overcome the very real pressures created by the need to teach, do research, prepare manuscripts, submit grant proposals, and take care of patients at the same time they are beginning to assume greater family and other personal responsibilities. The country can not afford to lose this talent.

Amanda Spitler *American College of Rheumatology*

The American College of Rheumatology (ACR) is an organization of physicians, health professionals, and scientists that serves it members through programs of education, research, and advocacy that foster excellence in the care of people with arthritis, rheumatic, and musculoskeletal diseases. Many of these diseases — including rheumatoid arthritis, systemic lupus erythematosus, scleroderma, and Sjögren's syndrome, as well as osteoarthritis and osteoporosis — affect women disproportionately compared to men. The reasons for this disparity are not well understood, but there is evidence that the reasons are not just hormonal, but may reflect gender differences at the genome level via control of gene expression.

Last March, the Office of Research on Women's Health (ORWH) sponsored the Arthritis and Osteoporosis Seminar, which brought issues relating to gender differences in both arthritis and related rheumatic diseases and osteoporosis to the forefront. Significant gaps in knowledge currently exist, both with respect to women's health issues and gender differences, in disease that affect both sexes. In addition, better methods are needed in order to detect and to track the course of these diseases. These are chronic diseases, and therefore, these patients need a supportive network with input from education, physical therapy, and nursing, as well as from physicians. As the institute whose research mandate encompasses arthritis and related diseases and osteoporosis, the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) has taken a leadership role in supporting research in these areas, including research specifically focused on gender differential aspects. ACR is pleased to have the opportunity to provide our views to ORWH concerning the state of knowledge and future priorities in these women's health disease areas.

Osteoarthritis or degenerative joint disease, the most prevalent form of arthritis, ranges from mild to severe and can cause pain, stiffness, and tenderness in and around the joint. It commonly affects joints which contain cartilage, with the most commonly afflicted ones being the hands, feet, knees, and hips. Osteoarthritis, in most instances, causes the cartilage to fray and wear, and in extreme instances, completely disappear resulting in a loss of function of the joint. ACR estimates that osteoarthritis affects more than 16 million Americans, with women being three times more likely to develop the disease as compared to men. Contributory factors that encourage the onset of this disease may include age, injury, obesity, and genetics.

Currently, NIAMS and ORWH are supporting research on the effects of certain antibiotics, particularly doxycyline, on the progression of osteoarthritis. In every instance where doxycycline was used, researchers found that the cartilage breakdown was reduced. Furthermore, doxycycline at higher levels tended to stimulate cartilage growth which suggests that doxycycline could prove to be an effective treatment for patients with both osteoarthritis and rheumatoid arthritis.

Rheumatoid arthritis (RA), a less common variation of osteoarthritis, but by no means rare, occurs in about 1 percent of the population (over 2 million people). Similar to osteoarthritis, rheumatoid arthritis occurs in women about three times more often than men, and often attacks people in the very prime of life — between the ages of 20 to 45 years. While the disease can occur at almost any age, the peak incidence in women is between the ages of 40 and 60 years. The consequences of rheumatoid arthritis are far reaching as more than two million work days are being lost each year due to this disease. Additionally, total health care costs for individuals who are afflicted with rheumatoid arthritis average three times higher than for those who do not have the disease. In a joint with rheumatoid arthritis, the synovium, or joint lining, becomes inflamed, leading to the destruction of joint tissue (synovium and cartilage), which results in chronic pain and deformity. Pain and stiffness, weight loss, decreased appetite, and tender swollen joints, especially in the hands, wrists, shoulders, hips, knees, and feet, are common symptoms of rheumatoid arthritis. Possible causes may include a genetic susceptibility to the disease, combined with environmental factors such as bacteria or viruses.

Recently, researchers have been focusing their efforts on the viral and bacterial causes of this disease. They have uncovered evidence for the induction of rheumatoid arthritis by a protein fragment that is present in a bacterium. In laboratory experiments, NIAMS-supported scientists found that cells in joint fluid from patients with early RA had strong immune responses to a bacterial protein fragment, but cells in joint fluid from normal subjects did not. The abnormal reactivity of cells in the joint fluid of early RA patients could play a significant role in the development of the disease and may lead to new strategies for delaying its progression.

Additionally, researchers have made advancements in discovering the treatment for RA through the identification of the genes involved in its onset. Through a study of laboratory rats with collagen-induced arthritis (CIA), researchers found that the genetic basis of CIA bears a striking similarity to what is known about the genetics of RA in humans. The identification of specific genes may provide new insights into the biochemical pathways underlying this disease and may provide new targets for treatment or prevention.

Lupus, an inflammatory autoimmune disease characterized by excessive production of antibodies directed against the body's own tissue, has been shown to damage kidneys and other organs, attack brain cells causing convulsions and psychosis, and lead to phenomena that can cause clots in the lungs and stroke. Symptoms can range from mild to severe with the disease being highly variable; a patient can be in a period of remission and then suddenly go into a crisis. Lupus may cause weight loss, fever, fatigue, aching, and weakness and may involve different organ systems such as the central nervous system, the heart, lungs, kidneys, muscles, and joints. Less common than either osteoarthritis or rheumatoid arthritis, lupus affects about 130,000 individuals in the United States. Improved methods of diagnosis are uncovering more patients with a milder form of the disease. The disease affects women approximately nine times more often than men, strikes during their reproductive years, and can affect both older men and women. Its frequency is higher in African Americans and Hispanics, with African-American women experiencing more outbreaks than Caucasian women.

On November 6-8th of this year, several NIH institutes, the NIH Office of Research on Women's Health, and the Systemic Lupus Erythematosus Foundation sponsored a scientific workshop on "Novel Perspectives in SLE: From Basic Research to Clinical Application." Over 400 scientific professionals and members of the public interested in lupus research attended the 3-day conference. Research into the cause of lupus has focused primarily on the genetic susceptibility of individuals. Studies have been conducted where investigators examined three genes that are important for normal immunity. Their findings indicate that more than one gene may be involved in conferring susceptibility to lupus and emphasize the complexity inherent in identifying the genetic basis of the disease. Additionally, studies conducted by NIAMS-supported researchers have identified a gene associated with increased risk of lupus kidney disease in African Americans. Variations in the gene affect the ability of immune cells to remove potentially harmful molecules from the body. This finding is a significant step towards enabling physicians to predict who is at risk for lupus, its complications, and steps to take to minimize that risk.

Improved treatment of kidney manifestations of lupus has been demonstrated on a clinical level, using syclophosphamide for the prevention of kidney failure. Progress is also being made in animal models for lupus to identify an immunogenetic component at the molecular level. A gene on chromosome 1 has been linked with susceptibility to lupus in Caucasians, Asians, and African Americans. In addition, since lupus affects women of childbearing age, the role of pregnancy on the course of this diseases must be investigated. Questions include whether pregnancy modifies the course of the disease or changes disease outcome. A clinical trial known as SELENA (Safety of Estrogen in Lupus National Assessment), is being funded by NIAMS, ORWH, and the Office of Research on Minority Health. The results of the trial will provide scientific evidence concerning the safety of providing oral contraceptives and hormone replacement therapy (HRT) to women with systemic lupus erythematosus.

Scleroderma, also known as systemic sclerosis, is a condition that can affect many organs and tissues in the body, particularly the skin, arteries, kidneys, lungs, heart, gastrointestinal tract, muscles, and joints. It is characterized by inflammation and excessive accumulation of the structural protein collagen, which leads to thickening or hardening of tissue. Women are affected four times more often than men by this serious and sometimes life-threatening disease. Scleroderma means "hard skin," which is one of its most striking visible symptoms. The skin becomes tight and thick, affecting the fingers, hands, face, and extremities. The cause of scleroderma is unknown and often times it is a slow progressive disease which can be controlled in some cases. However, in rare instances, the disease may progress rapidly, causing death due to heart, kidney, or respiratory failure. Raynaud's phenomenon, which causes discoloration of the hands and feet upon exposure to cold, is the most common first symptom of scleroderma.

In addition, to facilitate and enhance both basic and clinical research on scleroderma, NIAMS awarded for the first time a grant for a Specialized Center of Research (SCOR) on Scleroderma, with support from ORWH. SCOR provides for a coordinated research effort that strongly emphasizes basic research and an interaction between basic and clinical investigations.

A group of NIAMS-supported researchers recently introduced a mutation into laboratory mice that is designed to block the normal collagen breakdown that is part of tissue remodeling. During the first 7 months, the mice experienced no abnormal symptoms. However, they then began to develop thickened skin and patchy hair loss due to skin fibrosis, resembling human scleroderma. The scientists subjected collagen taken from these mutant mice to a wide variety of tests; in so doing, they discovered a new cleavage site on the collagen molecule. They concluded that the newly discovered cleavage site permitted normal remodeling only during development and early postnatal life and that cleavage at the mutant site was necessary for subsequent remodeling of skin tissue. If similar mutations occur in humans with scleroderma, this mouse model should provide a powerful tool for further investigating the dermal fibrosis found in scleroderma.

Osteoporosis, characterized by low bone mass, has recently come to the forefront of women's health due to the disproportionate occurrence of the disease in women compared to men. Osteoporosis affects women four times more frequently than men, and postmenopausal women are among the most susceptible. With the onset of menopause comes estrogen loss, which has been shown to trigger rapid bone loss. This reduction in overall bone mass results in fractures occurring in the wrist, spine, and hip. About half of the people who break their hips end up in nursing homes, and in the year following the fracture, 20 percent will die. The lifetime risk of death due to hip fracture is comparable to the risk of death from breast cancer. Vertebral fracture can lead to deformity of the spine, chronic back pain, and a loss of height. Additional factors which cause the onset of osteoporosis include ethnicity — Caucasian and Asian women characteristically begin with a lower adult bone mass; high consumption of alcohol and caffeine; having a family history of osteoporosis; and taking certain drugs such as corticosteroid and thyroid medications over a long period of time.

Unlike the aforementioned diseases, osteoporosis is a disease which is entirely preventable. Adequate calcium consumption, weight-bearing exercise, and an overall healthy lifestyle are a few of the ways in which this disease can be prevented. Perhaps the most significant ally in the fight against this disease is estrogen replacement therapy. Since it is highly effective against osteoporosis as well as heart disease, taking estrogen at menopause may also protect the brain from Alzheimer's disease. Since women who take estrogen can reduce their fracture risk by 50 percent, osteoporosis need not be considered an inevitable part of aging. Rather, it is a highly diagnosable and treatable disease.

Researchers are continuing to study and search for improvements as to how to treat and prevent the onset of osteoporosis. The discovery of valuable new technologies concerning early detection continues to be ongoing. NIAMS-supported researchers have found that a quantitative ultrasound is a valuable technique for measuring bone mineral density. This technique is one that offers a faster, cheaper, and radiation-free alternative to other measurements of bone mineral density for the assessment of osteoporosis. Additionally, HRT has recently emerged as the cornerstone for the goal of prevention of this disease. A study conducted by NIAMS staff analyzed the cost savings due to the fracture-sparing effect of HRT. This analysis was based on NIAMS-supported research showing that HRT reduced the relative risk of osteoporosis fracture.

Finally, possible health impact of breast implants is an important issue which NIAMS has recently addressed. NIAMS organized a scientific workshop to examine and discuss the available data on the issue against a background of earlier studies that found no association between implants and well-defined rheumatic disease, and to address the "lingering question" as to whether there is an association between silicone breast implants and an atypical form of rheumatic disease.

A group of scientists and clinicians, who had not yet formulated an opinion on this issue, debated whether atypical forms of rheumatic diseases can be defined and whether there is reason to believe that a possible association may exist between atypical connective tissue disease and silicone breast implants. They acknowledged the need for the development of diagnostic criteria for atypical rheumatic disease and for additional basic research on the components of silicone as well as biological responses to silicone. In addition, NIAMS hopes to promote basic research on host responses to materials used in medical implants by participating in an NIH Request for Applications on tissue engineering, biomimetics, and medical implant science.

ACR is pleased to have the opportunity to provide our views to ORWH concerning the state of knowledge and new priorities in research on arthritis, related rheumatic diseases, and osteoporosis. We continue to support the efforts of ORWH in contributing to the NIH women's health research agenda.

Donna E. Stewart, M.D., D.Psych. *The Toronto Hospital*

Informed Medical Decisions Group in Women's Health

The Toronto Hospital, Ontario Cancer Institute, Princess Margaret Hospital (TTH, OCI, PMH) Women's Health Program focuses on seven priority areas: women and cancer, cardiovascular disease, neurosciences, organ transplantation, mental health/eating disorders, and reproductive health. The program focuses on research, education, and health care delivery and policy to adult women. The Joint Oncology Program, with the Ontario Cancer Institute and Princess Margaret Hospital, has added special strength to programs in cancer prevention, screening, diagnosis, treatment, and survivorship in women.

The Toronto Hospital is Canada's largest teaching hospital with over 1,200 beds, and the Ontario Cancer Institute and Toronto Hospital Research Institute constitute large reservoirs of expertise in basic science, and translational and clinical research. The hospital's past successes include the discovery of insulin, heparin, electron microscopy, heart pacemakers, artificial kidneys, artificial heart valves, coronary care units, and a long list of accomplishments in organ transplantation.

Research

In 1996, the TTH, OCI, PMH Women's Health Program at the University of Toronto obtained over $9 million in research grants supporting studies in women's health. Research projects range from basic biological sciences to clinical projects including the context of women's health, decisional science, psychosocial behavior, and quality-of-life concerns. Our methodology includes quantitative and qualitative methods, surveys, and analysis of databases. Our multidisciplinary and multispecialty team conducts research from bench to bedside.

Our Informed Medical Decision Group in Women's Health, with a core team from clinical epidemiology, health psychology, neurosciences, women's health, pharmacology, health administration, sociology, nursing, bioethics, obstetrics and gynecology, surgery, family medicine, internal medicine, anesthesia, and oncology, is central to our work. This group participates in quality-of-life studies, cost-effectiveness studies, the effects of drugs in pregnancy and lactation, drug side effects, health psychology, information needs, decisional sciences, choice and compliance, education, and postmenopausal health studies.

Current research grants involve women and cardiovascular disease and study gender differences in symptoms, presentation time, treatments, and outcomes in tertiary and community hospitals (Heart and Stroke Foundation of Canada). Cancer research involves gender differences in cancer information, decisional preferences, and quality of life (National Cancer Institute of Canada). We are currently the lead investigators in a national Canadian project looking at the implications on insurance of genetic testing for breast cancer (Canadian Breast Cancer Research Initiative). Studies in transplantation currently look at equal access to transplantation by women and whether women choose organ transplantation for the same reasons and frequency as men. Our neurosciences research includes projects on epilepsy in women and differences in cognition and choice. Autoimmune disease research, conducted through the Centre for Prognostic Studies in Rheumatologic Diseases at The Toronto Hospital, is studying the accelerated pace of arteriosclerotic disease in women with lupus erythematosis. Mental health research includes studies of depression, anxiety, eating disorders, and psychotropic drugs in women. Reproductive sciences research includes postmenopausal health and decisional determinants of prevention and treatment, advanced reproductive technology, and psychosocial screening for pregnant women at risk for adverse postpartum outcomes. The Women's Health Program's information needs and concerns surveys, and decision studies have resulted in consultations to a number of local, national, and international groups. Publications in widely cited journals (e.g., *New England Journal of Medicine*) have resulted in widespread impact.

Education

Education is vitally important to women involved in informed medical decisionmaking and self care. Equally important to the Women's Health Program is educating health care professionals and policymakers. The Women's Health Symposia Community Education Series won the prestigious 1996 Pharmaceutical Manufacturers of Canada Elan Award (with Ortho-Janssen) for excellence and innovation in promoting and advancing women's health. In November 1997, the program received the Commonwealth Award for Excellence in Women's Health — a competition with applications from across the British Commonwealth. This unique community series of women's health symposia, a partnership between community, hospital, university, and industry, was inaugurated to address identified needs of public health education and consumer-motivated research projects in women's health. Needs questionnaires identify the topics of greatest interest and importance to women, and ongoing evaluation shapes the format and content of symposia. The symposia have resulted in ten funded, women-identified, research projects which are currently ongoing. Improved clinical care and teaching in women's health are additional outcomes. Although this symposia series has been operating for only 3 years, it has had a major impact through dissemination by five women's health television documentaries, aired nationally and internationally, audio cassettes, transcribed proceedings, and over 300 media interviews resulting in television, radio, newspaper, and magazine articles.

We have also been active in health provider curriculum reform for women's health including participation in the National Academy for Women's Health Medical Education, the American Association for Medical Colleges initiative on professional development for women, and numerous international and national presentations on women's health to professional audiences.

Women's Health Services and Policy

Our advocacy for exemplary women's health services has resulted in consultations to a wide range of international, national, and local health providers, educators, researchers, and policy advisors. We are also involved in the analysis of existing databases to determine possible gender differences in cause, course, treatments, and outcomes for a variety of diseases and disorders.

Summary

It is our belief that through consumer and professional education about women's health, women and their health care providers will become more knowledgeable and responsive to women's special needs. Research in women's health will further inform us of women's gender differences, preferences, and best practices. Our informed decisionmaking group is central to the delivery of health information to women and advocacy for them to participate in their desired degree of informed medical decisionmaking.

Deborah Studen-Pavlovich, D.M.D. *American Association of Dental Schools*

My name is Deborah Studen-Pavlovich. I am a pediatric dentist and an associate professor at the University of Pittsburgh, School of Dental Medicine and the Enid Neidle Scholar-in-Residence at the Division of Women and Minority Affairs at the American Association of Dental Schools (AADS). I am pleased to present this testimony to the Office of Research on Women's Health (ORWH) and commend your efforts to expand opportunities for women in biomedical careers through the recruitment, re-entry, retention, support, and advancement of women scientists.

The AADS represents all of the nation's 55 dental schools as well as advanced education programs in dental schools and hospitals, and allied dental education programs. It is in these institutions where future dental practitioners, educators, and researchers are trained; significant dental care provided; and the majority of dental research conducted. The AADS is the one national organization that speaks exclusively on behalf of dental education. Identifying and representing women's issues is a priority for the association.

My remarks will focus on the needs of female dental researchers. I will first:

- Discuss the difference between dental and medical education.
- Discuss women's presence in dental school programs, in postgraduate clinical training and research training programs, and in faculty positions.
- And, finally, I will provide recommendations by AADS to support female dental scientists.

Differences Between Dental and Medical Education

Distinct differences exist between dental and medical education, and these differences have significant implications for the training of dentists.

Unlike medicine, no requirement exists for a dental school graduate to pursue postdoctoral or advanced education. Considering the rigorous dental school curriculum, and accumulated debt of dental graduates (average graduating debt was $81,688 in 1996[1]), it is surprising that despite such debt nearly 60 percent of recent graduates enroll in some form of advanced dental education. Annually, approximately 1,500 dentists begin a general dentist residency program and nearly an equal number begin clinical specialty programs.[2]

If dentists elect to enroll in a research training program, they pursue the program in a period equivalent to a medical residency. This is in contrast to physicians whose research training is a postresidency endeavor. Before the National Research Service Award (NRSA) program, postgraduate training centered around clinical specialty training. Legislation that limits NRSA training to 3 years of postdoctoral research experience is a significant problem for oral health research scientists. A dentist awarded a training grant seeking a Ph.D. requires more than 3 years, especially when concomitant clinical training is involved. Recruitment could be increased if the legislated limit were removed.

Additionally, dentists have a disincentive to pursue training as clinical investigators. Whereas, the physician receives a salary and benefits as a hospital resident and subspecialty fellow, the dentist's similar payment is limited largely to hospital-based training programs in oral surgery or oral pathology. Training in other specialty areas rarely offers compensation and may even require tuition payment.

Finally, even though the National Institutes of Health (NIH) comprises the largest single source of support for postdoctoral research training of physicians, a variety of private foundations, agencies, and corporate-related organizations fund the training of physician-scientists. However, the National Institute of Dental Research (NIDR) is the only funding source, through its NRSA programs and Dentist-Scientist Awards, that support oral health research or training specifically for oral health research. Continued support of training through NIDR is essential to continued improvement of oral health research scientists.

Women's Presence in Dentistry

Historically, women have been substantially underrepresented in the field of dentistry. In 1982, of all of the professionally active dentists, only 3 percent were women.[3] By 1995, the percentage rose to 12 percent.[3] A critical need for aggressive efforts to increase the number of women in dentistry exists. United States dental schools are working to increase the number of women entering the dental profession. Female enrollment at dental schools continues to grow with the total number of women exceeding 36 percent in 1996.[4] However, women are still a minority on almost every dental campus.

An increase in female enrollment in advanced dental programs is also occurring. Women accounted for 30 percent (1,433 women) of all the dentists in postgraduate training programs.[2] This increasing proportion of female dental postdoctoral students may make it possible for women to acquire a larger share of the faculty positions at U.S. dental schools.

The dilemma of underrepresentation is particularly severe among dental school faculty and administrators. Presently, no woman is the dean of a dental school in any of our 55 institutions. And historically, only one woman has ever held such a position. Only 6 percent of the department chairs are women.[5] From personal experience, this figure is often inflated.

Exact comparisons of data with other professions are not always consistent because data-reporting methods vary. Nevertheless, overall trends can be seen by the following statistics:

- Of the 178 law schools, 28 percent of the faculty are women, as are 40 percent of the associate professors, and 17 percent of the full professors.[6]
- In medicine, 20 percent of the associate professors and 10 percent of the full professors are women.[6]
- At the 55 U.S. dental schools, 15 percent of the associate professors and 5 percent of the full professors are women.[6] With regard to female faculty, dental schools are clearly lagging behind other professional institutions.

A database on dental educators, compiled by the AADS, provides the best available information on the oral health research labor force. This database includes all faculty appointments to U.S. dental educational institutions and is updated annually. It includes information on age, gender, race, academic rank, appointment status (full or part time), academic degrees held, and area of primary appointment. Analysis of this database showed that the average age of oral health research scientists increased from 47.3 to 49.1 years of age from 1986 to 1992.[7] During this same time, the percentage of these scientists who identified their primary appointments as clinical sciences decreased from 44 percent to 36 percent (comparative figure for all full-time faculty is 58 percent).[7] Finally, the portion of these scientists who entered and left was more than one-third of the total. These analyses indicate that oral health research scientists are a somewhat aging group who leave dental education and contribute to an acute shortage of dental educators and oral health researchers.

The most recent data for fiscal year 1993 (1992 for trainees) indicate that, overall, the success rate for competing research project grants (RO1 and FIRST awards) has been declining. The success rate for both women and men was 18 percent, although for renewal applications it was 40.2 percent for men and 38.4 percent for women.[8] In fiscal year 1993, 16.4 percent of research grant dollars went to women, compared with 10.2 percent in 1984.[8] However, total dollar amounts of competing and non-competing grant awards to women are significantly less than those for men. Of particular concern to AADS is the fact that the success rate for competing research projects is lowest for women at NIDR as compared with all other institutes at NIH.

Success rates for funded grants are higher among scientists with a dental degree and a Ph.D. Therefore, special initiatives are needed to allow women to enter these research training opportunities so they can approach the level of their male counterparts. An alarming shortage of research-trained, full-time female dental faculty exists at our dental schools. To alleviate these shortages, enhanced resources and cooperation and collaboration between institutions and NIH need to occur if we are to improve the oral health of the American people as mandated by Congress for the 21st century.

Recommendations

To meet current and anticipated needs from qualified female dental researchers in academic dentistry, our organization recommends the following:

- Stimulate interest in dental careers among young women through specific outreach programs, starting in the elementary school years with an increasing emphasis through high school and college.
- Establish research mentoring programs in magnet high schools for female teenagers to be linked with university oral health researchers. Some dental schools have initiated these types of programs, but NIH support for these efforts by identification of oral health researchers who would be interested in participating would only enhance these programs.
- Expand the clinical research fellowship program to train women dentists to research expertise level to investigate clinical areas such as epidemiology, behavioral medicine, and health services research. The NIH study sections are so focused on basic sciences that a new section needs to be formed that would focus on clinical areas of oral health research.
- Increase the number of positions in the 5-year Dentist-Scientist Award program and the NRSA training and fellowship programs to accommodate the increasing pool of women dental school graduates interested in research careers.

- Expand short-term research experiences (T-35 mechanism) to attract female dental students into research careers. Explore whether this mechanism can be extended to retraining and/or re-entry. Currently, this mechanism is limited to 4 percent of NRSA funds.
- Develop research grants for other advanced dental education programs such as pediatric dentistry, periodontology, orthodontics, or any of the other specialties (most grants cover oral and maxillofacial surgery and oral pathology positions). This should establish and strengthen research training capabilities in all of the specialty areas.
- Provide supplemental research opportunities at a critical career stage (for example, a career interruption to accommodate family responsibilities or relocation requirements). These supplements would be designed to support women dental scientists who had demonstrated excellent research potential, but interrupted their careers for family care responsibilities. Such grants would allow re-entry candidates to update their skills and advance toward becoming independent investigators.

The American Association of Dental Schools thanks you for this opportunity to provide testimony to the Office of Research on Women's Health. We encourage you to support programs for women to achieve career goals in dentistry and oral health research.

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Laura Lowe Tosi, M.D. *American Academy of Orthopaedic Surgeons*

The Orthopaedic Health of Women: Osteoarthritis, Osteoporosis, Sports Injuries, and Frozen Shoulder Syndrome

The American Academy of Orthopaedic Surgeons (AAOS) is pleased to have the opportunity to present testimony to the Office of Research on Women's Health (ORWH) Conference "Beyond Hunt Valley: Research on Women's Health for the 21st Century." Since its inception in 1988, ORWH has had a great impact on increasing the awareness of researchers and the public about the importance of women's health, the nature of women's health issues, and the need for more research. While we celebrate these achievements, we are reminded that our job is not done.

Women's health issues span a broad spectrum; a spectrum that includes disorders and conditions of the musculoskeletal system — the joints, bones, tendons, ligaments, and muscles of the body. The American Academy of Orthopaedic Surgeons provides education and practice management services for orthopaedic surgeons and allied health professionals. The Academy also serves as an advocate for improved patient care and informs the public about the science of orthopaedics.

AAOS is concerned with women's health issues not only because its physicians are committed to providing quality health care but also because several prevalent diseases of the musculoskeletal system are disorders occurring predominantly in women. Therefore, orthopaedic surgeons encounter women's health issues frequently. To provide their patients with the best possible care, they must be knowledgeable about the disorders and apply the latest research regarding etiology, pathogenesis, diagnostic techniques, and treatment regimens.

This testimony will address what is known, the gaps in knowledge, and suggested future research directions about four conditions, prominent both by virtue of their prevalence and cost to society, that occur predominantly in women. While arthritis and osteoporosis are conditions that manifest themselves mostly in older women, young women are not immune to musculoskeletal disorders. The conditions under which osteoporosis emerges are present in childhood when young girls are building their peak bone mass. Also, as young women participate to a greater extent in sports, more sports-related injuries are occurring. Although not as prevalent as arthritis, osteoporosis, and sports injuries, frozen shoulder syndrome remains one of the most common, yet least understood conditions affecting the glenohumeral joint. That just four areas within musculoskeletal disorders affect more than 40 million American women commands our attention.

Arthritis

Arthritic and arthralgic conditions, representing a group of 100 or so disorders of the tissues of the joint, are the most common and disabling conditions among women. They occur particularly after middle age and their prevalence increases with aging. Because of their increased prevalence in the older population, the aging of the population, and the greater longevity of women, these conditions currently have, and will increasingly have, a substantial impact on the practice of orthopaedics as we enter the new millennium.

Affecting 30 million Americans, osteoarthritis is the most common form of arthritis and the most frequently reported chronic condition among the elderly. Nearly half of America's elderly suffer from osteoarthritis and 70 percent of those over 65 years of age do as well. It is up to four times more common in women than men, a ratio that increases with age. Although several risk factors (age, female sex, trauma, exercise, obesity) have been associated with osteoarthritis, more information is needed and additional recently recognized risk factors (diet, biomechanical factors, ligamentous stress, neuromuscular function) warrant exploration. While these associations have been identified, the etiology of osteoarthritis is not yet fully understood.

The impact of these conditions on the American health care system is enormous. Estimated to have cost society $54.6 billion in 1988, one can be sure this figure is substantially larger in 1997. The costs arise from medical care, lost productivity, and disability, with $6 billion spent annually on nursing home care alone. Of course, these costs do not even address quality-of-life aspects, or the pain and functional limitations resulting from arthritis.

Many factors exert an influence on osteoarthritis. While it is known that genetic mutations are closely linked to certain types of osteoarthritis, neither their importance in common osteoarthritis nor the mutations' effects on cartilage matrix molecules and their ability to survive is known. Meniscal injury is a risk factor for osteoarthritis, yet the mechanisms are not understood. Whether the injury and its resulting instability are independent contributors to osteoarthritis remains to be determined.

Recommendation. Research is needed to better understand why arthritis is more common in women, what triggers it, the role that risk factors play in the progression of the conditions, and the different gender patterns in some diseases, such as anklyosing spondylitis.

Very early diagnosis of arthritis is important as evidence indicates, particularly for the knee, this can affect patients' ultimate activity levels and quality of life. For example, early diagnosis and weight reduction of 5.1 kg over 10 years in overweight patients reduced the risk of developing symptomatic disabling knee osteoarthritis by 50 percent. In addition, diagnostic patterns for women and men differ, with evidence for misdiagnosis and underdiagnosis in women.

As the disease progresses, pain associated with activity, variable degrees of inflammation, and activity limitations emerge, among other symptoms. There is also some evidence supporting gender differences; activity limitations are higher for women than for men.

Recommendations: Better understanding of why there are gender differences in the natural history of the disease are needed. Research should explore the biological and mechanical factors that influence the progression of osteoarthritis. Such investigations should encompass the cellular, tissue, and organ level, include all joint components, and use the latest technological advances in assessment.

With such a large number of patients demonstrating arthritic conditions, treatment emerges as an extremely important concern. We need to understand how to effectively treat arthritis early, not only to relieve symptoms, but also to slow progression of the disease. Since there is no cure, treatment of arthritis is aimed at controlling pain and maintaining function. Treatment programs include different approaches and may be used in combination. Drug therapy is used to reduce pain and swelling and there are promising drugs that modify joint tissues. New tissue engineering techniques may also be promising in the repair of articular cartilage. There is also some evidence that exercise that avoids impact and tortional loading, using appropriate impact absorbent footwear, can improve function.

The biological mechanisms of cartilage repair are not fully understood and how to stimulate repair needs further investigation. Akin to the biological mechanisms, the effects of mechanical abnormalities also need to be tested for their effectiveness in repairing osteoarthritic joints.

Surgical treatment for osteoarthritis encompasses a range of surgical procedures that may modify the joint (osteotomies), replace it, or stimulate repair. Joint replacements have become increasingly prevalent in the last 20 years. By 1994, nearly 490,000 were performed annually. However, the surgical procedures of choice remain unknown.

In addition, treatments for women and men may differ as may the outcomes of those treatments. Women treated surgically, benefited equally or better from the procedure than men, even though they had poorer functional status prior to surgery and had their surgery later. Why is this so? Do the answers lie, perhaps, in patient preferences, access to care, or physician practice patterns?

Recommendations: Research should address the possible early biological repair process in osteoarthritis with attention to the role of growth factors, among others, that would prevent late changes that lead to joint replacement. Researchers need to conduct prospective clinical trials for various surgical procedures designed to stimulate repair of osteoarthritic joints. Outcomes studies of various surgical treatments are also needed.

Osteoporosis (Metabolic Bone Disease)

Affecting primarily older persons, osteoporosis is a disease manifested by diminished bone mineral mass and highly associated with an increased susceptibility to fracture. As is the case with osteoarthritis, because of its prevalence in the older population, the aging of the population, and the greater longevity of women, osteoporosis has and will continue to have a substantial impact on the practice of orthopaedics.

Osteoporosis affects 25 million Americans; 80 percent of those affected are women. Fully 50 percent of women will suffer from osteoporosis in their lifetimes. Because of the diminished bone mineral mass and increased susceptibility to fracture, osteoporosis is implicated in 1.5 million fractures each year in the United States. One in two women and one in five men are at risk of developing osteoporotic fractures, with postmenopausal women being particularly vulnerable due to declining estrogen levels.

Based on medical bills and lost income, expenses related to osteoporosis and related fractures approach $10 billion annually. Due to our aging population, it is estimated that these costs will rise to $50 to $80 billion over the next 30 years. The costs associated with osteoporosis encompass not only health care expenses, but also costs in disability and mortality. Seventy percent of those suffering from osteoporosis do not return to previous pre-injury status, and many older patients, upon discharge from the hospital, are placed in long-term care facilities, from which many will never leave. Treatments for osteoporotic fractures are also extremely expensive, with the average cost of hip-fracture repair at $35,000 per person.

The overriding issue for exploration in osteoporosis is prevention. Prevention is the key to reducing the high prevalence of osteoporosis. Studies have indicated that a high peak bone mass reduces the risk of osteoporotic fractures later in life. Peak rate of bone growth and mineral accretion occur in girls between the ages of 11 and 14, and peak bone mass is achieved by age 30. Thus, we must begin osteoporosis prevention in childhood and continue to educate young adults, by stressing the importance of building peak bone mass with a calcium-rich diet.

Recommendations: Since recent retrospective studies indicate a positive correlation between milk consumption during adolescence and young adulthood and bone density in middle-aged and older women, lifelong prospective studies need to be conducted to determine the effects of childhood calcium intake on peak bone mass. Research is needed to understand how best to educate the public about prevention of osteoporosis and osteoporotic fractures (diet, exercise, etc.). We need to attain a better understanding of how to target young women, many of whom are misinformed about their likelihood of developing osteoporosis. Increased awareness of and education about an especially severe problem in young female athletes — the triad of osteoporosis, eating disorders, and amenorrhea — is also needed.

Although prevention is the key to reducing the incidence of osteoporosis in the future, women over 30 are faced with the reality that the critical age for building their bone bank has passed. While we can now diagnose osteoporosis accurately, we still have no cure. Research to date has indicated that some drug therapies can partially reverse osteoporosis and that treatments such as estrogen replacement therapy may be a reliable means of preventing osteoporosis in perimenopausal women. We can only slow, not halt, progressive loss of bone mass in affected individuals.

Recommendations: Additional research is needed to develop a better understanding of the effects of drugs that stabilize bone mass by limiting bone resorption or enhancing bone formation. Attempts to identify and analyze the incidence and reasons for falls leading to osteoporotic fractures need to be encouraged.

Different forms of osteoporosis have been identified, but little is known about their progression. Many risk factors have been identified in the occurrence of osteoporosis. Although some of these factors cannot be manipulated, such as aging and heredity, the majority of risk factors can be addressed (lack of weight-bearing exercise, excessive thyroid or cortisone hormone, smoking, excessive alcohol consumption, reduced estrogen levels, and low calcium intake).

Recommendations: Research is needed to better understand the different forms of osteoporosis, their courses of progression, and the impact of types of treatment programs on outcomes. Additionally, research is needed to address the questions of why osteoporosis is more common in the female Caucasian and Asian populations, what triggers it, and the role that risk factors play in its progression.

Very early diagnosis of osteoporosis is crucial in slowing the progression of the disease and recent technological developments have improved our abilities to diagnose osteoporosis accurately. Dual energy x-ray absorptiometry and CT scan densitometry permit early detection of osteoporosis before fractures occur and also provide a sensitive means of monitoring the effectiveness of various treatments.

Recommendation: Improved densitometry techniques to develop indications for earlier intervention would drastically improve patient quality of life.

As osteoporosis progresses, there is increased susceptibility to fractures resulting from relatively minor trauma. Common fracture sites include the spine, hip, wrist, ribs, and shoulder. With increasing numbers of osteoporotic fractures, treatment has become a major concern. Low-intensity ultrasound has been determined to speed healing of tibia fractures. Because this treatment seems to be more effective in older people and has been shown to reduce the need for secondary surgical treatments, it is particularly attractive.

Recommendations: The absolute and relative rates of bone formation and bone resorption may vary across individuals. Research needs to determine which treatment options are best for patients presenting with various combinations of these factors. Improved methods of bone fixation need to be developed. Use of mechanical and electromagnetic forces in stimulating increased bone mass needs to be explored. Research also needs to improve our understanding of drug effects that stabilize bone mass, by either improving bone formation or limiting bone resorption.

Sports Injuries (ACL Injury)

Throughout the past two decades, women's participation in sports has increased dramatically. With increased participation comes increased injury. Given that millions of Americans participate in organized sports, it is not surprising that 20 percent of all musculoskeletal injuries occur during sports activities. Annually, 33 million Americans suffer from trauma- and sports-related musculoskeletal injuries; 90 percent of them require medical attention.

The impact of these conditions on the American health care system is staggering, especially considering most could be prevented. Annually, it is estimated that 16 million of these injuries result in reduced activity, amounting to over 250 million reduced activity days per year, with an average of 7.6 disability days per injury. Annually 7.3 million musculoskeletal injuries result in a total of 71 million days of bed rest, and 77.6 million work days and 7.3 million school days lost. The grand total in terms of annual cost comes to more than $26 billion.

In the past 20 years, we have developed new technologies to assist in the treatment of musculoskeletal injuries, thereby reducing the length of time people are disabled by injuries and improving their overall outcomes. New devices, namely plates and rods, have been developed from new and improved metals with enhanced designs allowing for more accurate positioning and repositioning, while simultaneously permitting early ambulation and rehabilitation. Additionally, with the development of external fixators, patients have experienced an early return to function. Surgeons are now able to reattach completely severed limbs due to advancements in vascular microsurgery. Additionally, improvements in spine fracture stabilization have resulted in greater spine stability, with increased range of motion. Arthroscopic surgery has led to the ability to replace destroyed ligaments.

Recommendations: Continued research on devices and surgical technique improvements will enhance patient care and facilitate an earlier return to function. Future research needs to focus on attaining a better understanding of molecular signals that control repair and growth function in cells of the musculoskeletal system. Development of synthetic replacements for muscle, soft tissue, and bone damaged beyond repair, and enhanced ability to manipulate the body's immune system to increase successful transplantation of donated bone and ligaments are additional areas for future research.

The information presented thus far, relating to sports injuries, has focused on research that will improve treatments of injuries that affect both men and women equally. Generally, injury patterns between men and women are similar. With years of data, researchers have determined that injury patterns are generally sport specific, not gender specific. There are notable exceptions, however. Knee injuries and anterior cruciate ligament (ACL) injuries, spondylolisthesis, stress fractures in the pelvis and hip, pelvic floor dysfunction, patellofemoral problems, and bunions are injuries affecting women in greater numbers than men.

Recommendation: Research on relative influences of osseous anatomy, ligamentous laxity, and the effect of sex hormones on the aforementioned conditions needs to be conducted to help develop an understanding of why injury patterns differ between men and women.

Studies and data relating specifically to ACL injuries highlight them as problematic sports injuries for women, with, as yet, no conclusive evidence to explain the gender difference in prevalence. A 5-year analysis of soccer and basketball injuries in the NCAA demonstrated that female basketball players experienced four times as many ACL injuries as their male counterparts, and twice as many ACL injuries were experienced among female soccer players when compared to their male counterparts. Among skiers, the female knee injury rate was twice that for male skiers. In a review of medical records at the British Columbia Sports Medicine Clinic, 76 female and 151 male basketball injuries were identified. Seventy-two percent of female injuries involved the knee, of which 35 percent were ACL tears. Men sustained less than 3 percent of their injuries to the ACL.

One study explored the impact of estrogen levels on the cellular metabolism of the ACL as a possible explanation for the gender differences. According to this study, levels of estradiol had a significant dose-dependent effect on the fibroblasts of the ACL. It was determined that resulting structural and compositional changes may result in decreased strength of the ACL and increased female athlete ligament injury. The authors stressed the need for additional research into the causes of women's sports injuries to better address their underlying etiology.

Although there is a higher relative incidence of ACL injuries among female athletes, the majority of populations studied after ACL reconstruction are male dominated. Herein lies a fundamental problem in women's health research: exclusion of female subjects in research studies. No scientific basis exists for such exclusion.

Recommendations: Further research needs to explain the gender differences in the prevalence of ACL injuries. Researchers need to explore the basis for gender differences in treatment: what is effective, why outcomes in men and women differ when receiving the same treatment, and what mechanisms are underlying these differences. Findings will aid in the development of more effective treatment modalities.

Frozen Shoulder Syndrome

Although less prevalent than arthritis, osteoporosis, and sport injuries, frozen shoulder syndrome is one of the most common, yet least understood, disorders of shoulder motion. Frozen shoulder is a condition characterized by significant restriction of both active and passive shoulder motion that occurs in the absence of a known intrinsic shoulder disorder. Although frozen shoulder syndrome affects only 2 percent of the population, women are 70 percent more likely to develop the syndrome than their male counterparts. It predominantly affects women between the ages of 40 and 60. Frozen shoulder syndrome is characterized by a slow, progressive loss of glenohumeral motion due to steadily increasing, diffuse shoulder pain. Eventually patients experience stiffening due to lack of motion, followed by gradual improvement. As motion increases, there is a gradual restoration of function. The duration of the condition ranges from 18 to 24 months during which the patient experiences some degree of disability. The causes of this debilitating syndrome remain unknown.

Recommendations: Research needs to determine why gender differences exist in the prevalence of frozen shoulder syndrome. Is it menopause related or hormonally related? What is the vasculitic etiology? Further basic science studies on glenohumeral ligaments of the female shoulder will aid rehabilitative treatments.

Highlighting only four musculoskeletal disorders drives home the message: women's health issues are long on numbers, large in disability and suffering, and enormous in cost. To reduce suffering and disability we need to prevent these disorders when we can, diagnose them early to minimize their impact, and provide interventions to maximize functioning in patients who have them. We want our daughters and their daughters to travel a different road than we have. How do we get from here to there? Through research. With research agencies like ORWH, we can craft a research agenda that will pave the way. With collective input, expertise, and due diligence, we can create that new highway — the future is ours; carpe diem.

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Charlene Waldman *The Paget Foundation*

The Paget Foundation for Paget's disease of bone and related disorders is a voluntary health agency which provides information and programs for consumers and medical professionals for a number of bone disorders involving abnormal bone resorption. One of the disorders addressed by the foundation is primary hyperparathyroidism, a hormonal problem which occurs when one or more of the parathyroid glands produce too much parathyroid hormone. When this happens, the blood calcium becomes elevated. Bones may lose calcium, and too much calcium may be excreted by the kidneys.

In the U.S. population, 28 out of every 100,000 people can be expected to develop hyperparathyroidism each year. Women outnumber men by three to one, and the frequency of the condition increases with age.

Among women over age 60, new cases can be as high as two out of every 1,000 women or 2,000 out of every 1,000,000 annually.

A major complication of primary hyperparathyroidism is the weakening of bones due to loss of calcium, sometimes causing osteoporosis. Other complications include depression and kidney stones.

At present, the only known cure for this condition is surgical removal of the affected gland(s). Estrogen therapy may reduce some of the effects of the disease in women who have gone through menopause, but this treatment will not directly control the glandular overactivity. There are also some experimental drugs to control the elevated calcium, but these are not approved for routine use.

Clinical studies are needed to acquire information about the natural history of the disease, the incidence of fracture, and other complications including the neuropsychiatric manifestations. Also, greater insight into the relationship between the hyperparathyroid process and postmenopausal bone loss is essential. Information is also needed on the course of patients who undergo parathyroid surgery as well as those who are followed conservatively. Additional studies will help to more clearly refine currently accepted guidelines for surgery versus medical management for primary hyperparathyroidism. Also, research is needed to study possible medical therapies.

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Joanne A.P. Wilson, M.D., F.A.C.P. *American Gastroenterbiological Association*

I am Dr. Joanne Wilson, professor of medicine and associate chief of gastroenterology at Duke University Medical Center. I am pleased to be with you today to present testimony on behalf of the American Gastroenterological Association (AGA), a professional medical society representing over 8,900 clinicians, researchers, and educators specializing in digestive diseases. I greatly appreciate the opportunity to present the views of AGA on two issues of critical importance to the health of women throughout the world and to the advancement of medical research: first, research objectives related to digestive diseases in women; and second, the continuing need to strengthen efforts to recruit and retain women in biomedical research careers.

Research Objectives in Digestive Diseases

Gender-based differences have been established for a number of digestive diseases striking Americans. For many of these illnesses, major research questions remain and merit further study so we can improve current approaches to prevention and treatment strategies. I will focus my testimony on particular gastroenterological conditions for which gender differences should be explored further and a brief description of digestive disease-related research that should definitely be included in your agenda for women's health research for the 21st century; they should be strongly supported with NIH funding:

Colorectal cancer. Colorectal cancer is the second deadliest cancer in the United States and the third leading cause of cancer-related deaths in women, after lung and breast cancer. About 134,000 new cases of colorectal cancer will be diagnosed and about 55,000 people in the United States will die from this disease this year. For a 65-year-old woman, the risk of death from colorectal cancer is approximately equal to the risk of death from breast cancer. Yet, the research dollars devoted to colorectal cancer pales in comparison to those allocated to breast cancer research. Although the lifetime risk of colorectal cancer for women is 6 percent, there is a dramatic underappreciation among the public of the risk of colorectal cancer in women.

The last decade has witnessed major advances in prevention strategies for colorectal cancer. Prospective randomized controlled trials have shown that aggressive detection strategies result in a 30 percent decrease in colorectal cancer mortality. Case control studies have demonstrated that sigmoidoscopy to detect premalignant polyps reduces the risk of rectal cancer by as much as 80 percent.

Earlier this year, AGA joined with a consortium of GI societies in developing national practice guidelines on screening and surveillance for colorectal cancer. This interdisciplinary panel concluded that screening regimens, beginning at age 50 for persons at average risk of developing colorectal cancer and at age 40 for persons at increased risk of developing colorectal cancer due to personal or family medical history, are effective in identifying and preventing colorectal cancers. The American Cancer Society (ACS) also released similar screening guidelines this year. Both of these guidelines concluded that routine screening and surveillance of men and women are vital to saving lives, and are cost effective for the health care system.

Other potential preventative strategies have been identified for women through epidemiological research. Aspirin use has been shown to decrease the risk of colorectal cancer, through as yet unidentified mechanisms. Estrogen replacement therapy may be associated with up to a 50 percent decrease in colorectal cancer. The pathophysiological mechanisms of this have not been identified, and may shed important light on the effect that gender plays in colorectal cancer.

This year, Congress passed important legislation providing Medicare coverage of colorectal cancer screening. This action is a giant step toward providing greater access to screening for older women. Our next tasks should be to educate the public, physicians, and health plans on the importance of routine screening, and, equally important, to fund research on detection, clinical investigations, epidemiological studies, and studies on the effect of interventions (e.g., dietary; studies on the influence of reproductive hormones on the effectiveness of interventions), and progress of colorectal cancer in women.

Gallstones. In terms of health care costs, gallstone disease is the number one gastroenterological disease in the United States. About 10 percent of Americans have gallstone disease, and women are twice as likely to get gallstones as are men. This can be attributed in large part to the role of estrogens and progesterones during and following pregnancy and throughout women's lives. Despite this prevalence in women, the most extensive long-term study of the natural history of gallstones includes only men. The natural history of gallstones developing at the high-risk periods during and after pregnancy is not well described and is an area that demands additional research.

Approximately 500,000 cholecystectomies are performed in the United States each year, and for women, this is one of the most common surgical procedures. Research is necessary to identify: which symptoms are most likely to improve after cholecystectomy; methods for diagnosing whether abdominal pain is of biliary origin; and the outcomes, in terms of mortality and health care costs, of using advanced treatments for gallstone disease.

Functional bowel disorders. Irritable bowel syndrome and functional bowel disorders, which affect as much as 15 percent of the U.S. population, are twice as common in women as men. Affected individuals have chronic abdominal pain, changes in bowel habits, gas, and bloating. These disorders result in major health care costs and decreased productivity. Research on gastrointestinal motility has enhanced our understanding of the pathophysiology of these disorders. For example, functional bowel disorders can be associated with a history of physical and sexual abuse, with abused women experiencing a fourfold increased risk of pelvic pain. Additional research is needed with respect to:

- the effect of the menstrual cycle on functional bowel disorders;
- the relative impact of genetics, the environment, social factors on etiology;
- perpetuation of symptoms; and
- studies on various disease interventions, such as how seratonin receptor antagonists, antianxiolytics, and antimotility agents may improve the treatment of these disorders.

Helicobacter *Pylori* and the upper GI tract. The Helicobacter *pylori* bacterium is a relatively new discovery but it has already revolutionized and advanced treatment for a high-incidence, high-expense disease: peptic ulcer disease. An NIH consensus development conference concluded that the H. *pylori* bacterium causes peptic ulcers and that treatment with a combination therapy of acid-blocking drugs and antibiotics can eradicate ulcer disease in most patients. Further, there is considerable evidence that H. *pylori* infection plays a role in gastric cancer. Studies have shown that H. *pylori*-infected women are 15 to 18 times more likely to develop gastric cancer than infected men. Further research is needed regarding:

- the role of acid secretion (usually higher in men than women) in protecting against the development of gastric cancer; and
- clinical approaches to preventing gastric cancer in men, women, and children.

NSAIDs and peptic ulcer disease. The other known cause of peptic ulcer disease is ingestion of high dosages of non-steroidal, anti-inflammatory drugs (NSAIDs) such as aspirin and ibuprofen. Both men and women can experience NSAID side effects, but women consume more of these medications than men because of a higher incidence of degenerative arthritis and pelvic pain. Older women are particularly heavy users of NSAIDs and, therefore, at increased risk of GI ulcerations and GI bleeding. Further research is needed on the prevention of NSAIDs-induced peptic ulcer disease in men and women.

Primary biliary cirrhosis. There are a number of significant differences between men and women in terms of incidence and pathophysiology of liver disease. This is particularly striking with regard to primary biliary cirrhosis, which is nine times more common in women than men. For the thousands of women suffering from this disorder, current treatment is only marginally effective, and liver transplantation is likely. NIH is currently sponsoring a clinical trial of improved treatment, but it is clear that additional basic and clinical research is needed on the pathogenesis, immunology, and therapeutic approach to primary biliary cirrhosis.

Other liver diseases. Additional aspects of liver disease in women merit expanded study. Studies have shown that women develop cirrhosis with less alcohol ingestion than men. The risk for women developing end-stage liver disease occurs at half of the amount of alcohol intake that men require. Further, as the liver is an estrogen-responsive organ in both women and men, sex hormones clearly play a role in diseases of the liver. Finally, there is emerging evidence that livers from female donors for transplantation do not function as well in recipients as livers from male donors. With respect to liver disease, additional research is needed regarding:

- the impact of sex hormones on elements of the immune system and on the proliferation of liver cells;
- the factors responsible for differences between men and women in alcohol absorption and metabolism;
- the effects of estrogen and progesterone on the development of alcoholic liver disease;
- alcohol abuse in young women — perhaps as young as high school age — and the early development of liver disease; and
- liver function in transplant patients who receive livers from female donors.

Obesity and eating disorders. Obesity is extremely common, with about 25 percent of the adult population affected. Obesity is associated with an increase in mortality from all causes, largely mediated by its negative effects on the cardiovascular system including hypertension and diabetes. Because cycling weight up and down itself is associated with increased risk, such as developing gallstones, interventions that induce weight loss must be carefully examined to assess outcomes. The recent case of serious complications from combinations of seratonin agonists to depress the appetite highlights the need for rigorous evaluation in this often emotion-laden field.

Many research questions regarding GI disease in women merit further study. These areas I have chosen to highlight today are disorders of particularly high incidence in women, entail substantial health care expenditures, and result in high levels of morbidity and mortality.

Enhancing Biomedical Research Career Opportunities for Women

I would like to offer several recommendations for enhancing biomedical research career opportunities for women:

- First, NIH should expand small grant support for mentoring programs for women interested in beginning or retraining for research centers.
- Further, NIH should provide seed money for the initiation of special academic tracks for women interested in research careers. These should begin as early as medical school and certainly include residency training.
- Academic institutions should be encouraged to adopt “stop the clock” policies with regard to tenure and promotion of women faculty. This would extend the period of time that women would have to achieve tenure so that the professional “down-time” during leaves of absence would not be included. As your office has recommended, special research and training awards should be developed by academic institutions to help women re-enter biomedical careers after taking time off to raise their families.
- After years of productive research activity, investigators often move on to senior administrative positions as departmental chairs or deans through which they continue to foster research and influence the research activities of their institutions. Unfortunately, women do not succeed to these positions as early or as often as men. NIH should allow institutions to include in their indirect cost calculations expenses associated with programs to prepare women faculty members for these senior positions.

The American Gastroenterological Association greatly appreciates this opportunity to present testimony regarding GI research objectives of particular relevance to women’s health and to offer recommendations for enhancing biomedical research career opportunities for women. I commend Dr. Vivian Pinn and the Office of Research on Women’s Health for their outstanding leadership on these issues of critical importance to the health and lives of women of all ages.

Ruth E. York, Ph.D., R.N., F.A.A.N. *Association of Women’s Health, Obstetric and Neonatal Nurses*

Thank you for the opportunity to present testimony at this most important hearing. The Association of Women’s Health, Obstetric and Neonatal Nurses (AWHONN), an organization of 22,000 nurses and others committed to excellence in nursing practice for the health and health care of women and newborns, has a long-standing commitment to women’s health research and the use of that research in practice. This commitment is manifested in many diverse ways, including support for a Practice and Research Department, standards development and dissemination, evidence-based practice resources, a small research grants program, and widely distributed scientific and technical journals. In addition, the organization has committed resources to a research-based practice program in which a science-based protocol is developed and systematically evaluated by clinicians in multiple sites throughout the country and Canada. The most recent project, Continence for Women, is currently in the implementation stage at 37 diverse sites providing screening, evaluation, and treatment for women of all ages and ethnicities.

As an organization, we support and conduct research endeavors that strengthen the scientific basis of nursing practice. We believe that research which seeks to improve the health of women across their life span, such as prevention of adolescent pregnancy, improved reproductive health, and enhancement of postmenopausal well being, is necessary and vitally important.

Today, many women are single heads of households living below the federal poverty level, caring for children and elderly family members. With the loss of public assistance, women will need to hold one or more jobs outside the home and face the burden of insufficient child care resources. Current research in women's health does not provide information about how the health of women in today's society can be optimized. In addition, inadequate access to primary preventive services, underrepresentation of women in clinical research trials, underutilization of research findings to support clinical practice, and lack of information on the economic ramifications of women's health outcomes research are critical issues for all research conducted in women's health. Within the context of these issues, research on adolescent pregnancy, violence against women, substance abuse, breast cancer, menopause, and cardiovascular disease are but some of the health problems that remain vital concerns to women, their families, and society.

Prevention of adolescent pregnancy is another crucial area in need of continued research. As has been true in earlier years, it can be expected that 1,000,000 adolescents will become pregnant annually. To date, research has had little impact on providing the solutions to reducing the incidence of adolescent pregnancy. Clearly, unique and innovative research approaches are needed to address the issues of adolescent pregnancy and its multiple, negative-associated sequela.

Societal issues such as violence against women and substance abuse are areas that need to be explored to determine effective support and treatment for affected women. In the area of violence against women, delineating the factors which impede or facilitate women to resolve the abuse situation is critical and may vary for women of different ages, races, and ethnic groups. In the area of substance abuse, it is well documented that women have been managed similarly to men. However, research has shown that the effect of substance abuse is gender dependent. Therefore, comprehensive investigations are needed to develop and test appropriate, cost-effective management strategies for substance-abusing women and their families.

Among women who have cancer, breast cancer is a leading cause of death between the ages of 35 to 54. For all women, methods of early detection and prevention are critical. For the women diagnosed with breast cancer, research on treatment, sociocultural, and behavioral concerns is essential for them and their significant others. With the advent of genetic testing, new and important areas for research will greatly expand.

Menopause is a normal event in the lives of women, typically occurring at about 50 years of age. With a life expectancy of 82, women live one-third of their adult lives after menopause. Insufficient research has been conducted on clinical management of women's postmenopausal health concerns, such as use of hormone replacement therapy and other potential health-altering intervention modalities.

Cardiovascular diseases are the leading cause of death in women ages 55 and older. Yet, until recently, women have been underrepresented in studies of coronary heart disease. To date, it has generally been assumed that management of cardiovascular diseases is the same for men as it is for women. However, new evidence strongly suggests that interventions which are gender specific must be developed and tested.

In view of these facts, AWHONN supports:

- research that focuses on health promotion and maintenance, as well as,
- disease prevention, throughout women's life span;
- adequate representation of women in future studies of health problems;
- research on health problems that primarily affect women;
- research on diseases with social origins with emphasis on development of gender-specific interventions.

AWHONN is pleased to have this occasion to provide testimony to the Office of Research on Women's Health and help identify priorities for research on women's health for the 21st century. As a nurse representative of the 2.1 million predominantly female members of the nursing workforce, we applaud this important work. As a representative of more than 22,000 nurses whose practice is focused on women and newborns in the United States and Canada, and representing the professional nursing association whose mission is excellence in the health and health care for women and newborns, AWHONN welcomes all opportunities to provide recommendations for a revised research agenda for women's health.

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WORKSHOP AGENDA AND PARTICIPANT ROSTER

Putting It All Together: The Agenda for Research on Women's Health for the 21st Century

Bethesda Marriott
Bethesda, Maryland

November 17-19, 1997

AGENDA

MONDAY, NOVEMBER 17, 1997

11:00 a.m.-7:00 p.m. ***Conference Registration***

PUBLIC HEARING

1:00-6:00 p.m. ***Public Testimony: The Women's Health Task Force Research Agenda for the 21st Century***

TUESDAY, NOVEMBER 18, 1997

SCIENTIFIC WORKSHOP DAY 1

7:00 a.m.-6:30 p.m. ***Conference Registration***

7:00-8:00 a.m. ***Continental Breakfast***

8:00 a.m.-12:00 p.m. ***Opening Plenary Session***

8:00-9:00 a.m. ***Welcome and Opening Remarks***
Vivian W. Pinn, M.D.
Ruth L. Kirschstein, M.D.

Remarks
The Honorable Barbara A. Mikulski, U.S. Senate
The Honorable Constance A. Morella, U.S. House of Representatives

9:00-9:30 a.m. ***Overview: Beyond Hunt Valley: Research on Women's Health for the 21st Century***
Vivian W. Pinn, M.D.

9:45-10:00 a.m. ***Break***

10:00-11:00 a.m. ***Scientific Plenary Session I***
Genetics, Genomics, and Women's Health
Francis Collins, M.D., Ph.D.
Director, NHGRI

Panel Discussion: Legal and Ethical Issues
Karen Rothenberg, J.D.
John Fletcher, Ph.D.
Robert Murray, Ph.D.

11:00-11:45 a.m. ***Scientific Plenary Session II***
Heart Disease Research in Women: A Look Back and a View to the Future
Claude Lenfant, M.D., Director, NHLBI

Remarks: Research on Women: An Investigator's View
Julie Buring, Sc.D.

Charge to the Working Groups
Donna Dean, Ph.D.
Marianne Legato, M.D.

12:00-1:15 p.m. ***Lunch***
Speaker: The Cancer Program at the End of the 20th Century
Richard Klausner, M.D., Director, NCI

1:30-4:15 p.m. ***Breakout to Working Groups***
- ***Alcohol and Other Drug Use Disorders and Consequences***
- ***Bone and Musculoskeletal Disorders***
- ***Cancer***
- ***Cardiovascular and Pulmonary Disease***
- ***Career Issues for Women Scientists***
- ***Digestive Diseases***
- ***Immunity and Autoimmune Diseases***
- ***Mental Disorders***
- ***Neuroscience***
- ***Oral Health***
- ***Pharmacology***
- ***Reproductive Issues***
- ***Urologic and Kidney Conditions***

4:30-6:00 p.m. ***Scientific Plenary Session III***
Panel Discussion: Women's Health Research

Women and Research: Quo Vadis?
Antonia C. Novello, M.D., M.P.H.

Beyond Hunt Valley: Perspectives
Maureen Henderson, M.D., M.P.H.

Implications for Education and Public Policy
Barbara Ross-Lee, D.O.

Remarks
Audrey T. Haynes, Deputy Assistant to the President
White House Office for Women's Initiatives and Outreach

6:00-7:30 p.m. ***Networking Reception***
The Honorable Louise M. Slaughter, U.S. House of Representatives

WEDNESDAY, NOVEMBER 19, 1997

SCIENTIFIC WORKSHOP DAY 2

7:00-8:00 a.m. ***Continental Breakfast***
8:00-9:00 a.m. ***Scientific Plenary Session IV***
Speaker: Women in Biomedical Careers
Lydia Villa-Kamaroff, Ph.D.

Remarks: Women in Health — Towards a New Paradigm
Margaret Chesney, Ph.D.

9:00 a.m.-12:00 p.m. ***Concurrent Working Groups (continue)***

12:00 p.m. ***Lunch***
Remarks
The Honorable Louis Stokes, U.S. House of Representatives

Speaker: Putting It All Together
Byllye Avery, M.Ed.

1:15-3:00 p.m. ***Closing Plenary Session***
Working Group Reports
Working Group Cochairs
Task Force Cochairs

Discussion
Closing Remarks/Adjournment
Task Force Cochairs
Vivian W. Pinn, M.D.

3:15 p.m. ***Press Briefing***

BEYOND HUNT VALLEY:
RESEARCH ON WOMEN'S HEALTH FOR THE 21ST CENTURY

BETHESDA, MARYLAND
NOVEMBER 17-19, 1997

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