
Welcoming Remarks

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IT IS AN HONOR to be the general moderator for this important conference. At the Food and Drug Administration (FDA), I serve as Deputy Commissioner and Chief Operating Officer, vis-a-vis Commissioner Young's role as Chief Executive Officer. My role in this conference is also a practical one. Dr. Kirschstein and Dr. Young will articulate the vision and commitment of the Public Health Service (PHS) to the problems of women's health. My task is to address the specific mechanics. In effect, they steer the ship and chart its course, but it is my job to make sure all the machinery is orchestrated effectively and on schedule.

As a person concerned with the nuts and bolts of things, I would like to applaud Alexander Grant and his entire Consumer Affairs Staff, especially Patricia Kuntze, whose extremely hard work helped put this conference together. This conference could not have been brought to fruition without their, and especially Pat's, intelligent and steadfast efforts. Running a conference for over 700 people is no easy feat. It took more than 1 year of concentrated effort. We thank Pat and Alex for a job magnificently done.

FDA has been fortunate. It has employed many dedicated, highly professional staff over the years. It has been said that one does not so much work at FDA as belong to it, and my own experience and observations suggest that this is not much of an exaggeration. Fortunately, it is often a lasting arrangement. For instance, one of the great benefactors of women's health, Dr. Frances Kelsey, who 24 years ago almost single-handedly prevented the thalidomide tragedy from taking place in the United States, is still on the job with FDA today, protecting the public health. Many other employees too numerous to mention demonstrate that such talented people, who have exceptional dedication to women's health issues, continue to be the rule at FDA.

Now I would like very briefly to do two things: First, I would like to begin to define the scope of the women's health issues by citing a few lesser known facts, and second, I would like to sketch a picture for you of the kinds of things that FDA already is doing with respect to women's health by summarizing the areas in which we presently are involved.

The Scope of Women's Health Issues

We define a woman's health issue as any matter that affects the health of women exclusively, that impacts predominantly on women's health (at any age), or that affects women's health differently from that of men.

The members of this conference will explain what they have discovered through research and medical practice that will assist us all in improving women's health. The facts that follow illustrate that although women tend to live longer than men, they constitute such an important part of the population that public health issues which affect them are priorities for us all. Let me explain.

- Despite the heavy work women did at the turn of the century, they were still occasionally called the weaker sex. However, women continue to outlive men by several years. In fact, women in the United States live an average of about 8 years longer than men. Some argue that this is at least in part because they utilize more health services than men. If projections are correct, a woman can expect to live to 81 years in 2005 compared to a man's 73 years. By 2050, a woman may live to almost 84 years compared to a man's 75 years. Nonetheless, if poor health habits such as smoking increase among women, the evidence is clear that women could lose ground in their longevity.
- In 1982, the nation had an estimated 32,000 people at least 100 years old; of these, 19,000 (nearly 60 percent) were women.
- By 1980, women made up more than half—52 percent—of the total college student enrollment; 46 percent of all graduate students under 35 years of age in 1980 were women.
- More than 52 percent of all working-age women—46 million—were in the civilian labor force in 1981, with women now constituting 43 percent of the nation's entire labor force; and they are responsible for nearly 60 percent of its growth since 1970.
- Hypertension afflicts about 32 percent of all American women, and 38 percent of the men between 25 and 74 years of age. Obesity is a major contributor to the development of hypertension, which affects

one in six Americans, and more than one in four women between the ages of 20 and 74 are considered overweight in terms of being at risk for developing hypertension.

- Diabetes is the fifth leading cause of death in the United States. It occurs in twice as many women as men.
- Cancer is the leading cause of death among women aged 35 to 54 years. The number of deaths from lung cancer in women has risen an incredible 600 percent in the past 30 years—and has supplanted breast cancer as the leading cause of cancer deaths among U.S. women.
- Osteoporosis is a debilitating chronic disease affecting some 20 million Americans, especially older women. It is estimated that about 1.3 million fractures attributable to osteoporosis occur annually in people (mostly women) 45 years of age and older.

The bottom line is that besides the obvious contributions that women make to the quality and meaning of life, the health of women, as a group, is an enormously valuable cornerstone of our society. What improves women's health improves the public health, and vice versa. Women's health issues are an important priority for all thinking men and women.

FDA's Women's Health Program

As part of PHS, FDA's mission is to promote and to protect the public health. We do this partly by evaluating products such as drugs and medical devices *before* they go on the market, and by monitoring foods, drugs, medical devices, and other products involved in interstate commerce *after* they go to market. The sheer magnitude of this job comes home when you consider that FDA is responsible for ensuring every day the safety of products that account for some 25 cents of each consumer dollar spent in the United States.

The machinery that drives FDA's efforts to protect and promote the health of women is one of FDA's most valued assets. To give greater attention to the issues affecting women, FDA created an internal advisory group on women's health issues which is—as is this very conference—an important part of a larger effort.

FDA's scientific work on women's health issues is conducted through five centers. Each, in its own way, is responsible for addressing the women's health issues that concern us today. Dr. Young has outlined FDA's major involvement in combating osteoporosis and Toxic Shock Syndrome. I will summarize other FDA activities briefly.

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Center for Drugs and Biologics (CDB). Work especially relevant to women's health issues conducted by CDB:

- Creation and enforcement of guidelines for testing investigational drugs in elderly patients, primarily women, and
- Research (ongoing at the National Institutes of Health (NIH)) on premenstrual syndrome and review of drug applications in this area.

Center for Food Safety and Applied Nutrition (CFSAN). CFSAN is proceeding with research in many areas of women's health, including:

- Monitoring the impact of nutrition on women's health,
- Increasing knowledge of foodborne microbiological hazards, particularly those that impact on pregnancy and lactation, such as listeriosis; and
- Monitoring cosmetic products.

Center for Devices and Radiological Health (CDRH). Of particular importance for women's health is CDRH's work on:

- Improving mammography screening to provide information to improve the protocols of health care providers,
- Implementing a nationwide program to educate women of childbearing age about the risks of radiation exposure during pregnancy, and
- Developing criteria for assessing the safety and effectiveness of home use *in vitro* diagnostic devices.

National Center for Toxicological Research (NCTR). Current NCTR research important to women includes:

- Research on the prenatal induction of hypertension,

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- Research on the effect of prenatally administered caffeine on skeletal development and postnatal function,
- Research on the teratogenic potential of pulsed ultrasound, and
- Research on the role of estrogen as a tumor promoter.

Center for Veterinary Medicine (CVM). CVM has served women's health with critical work involving:

- Research on early identification of human risks associated with the use of DES in food animals, which led to the eventual withdrawal of approval for DES use in food-producing animals, and
- Research on lactation and transmission of drugs using data from animal models, and assisting in development of guidelines for human studies.

Thus, each of FDA's scientific Centers has found opportunities to contribute to the health of women, as have the many other parts of FDA I have not yet mentioned. For instance, the Office of Public Affairs keeps the public aware of developments with frequent features about women's health issues in *FDA Consumer* magazine and through other media, including press releases and talk papers on fast-breaking issues. The Office of Regulatory Affairs handles enforcement of food and drug regulations. The recent product tampering incidents demonstrate that they do a superb job in a crisis, but we must not neglect their routine enforcement (on products ranging from tampons to milk and soft cheese), which has taken so many ineffective or even hazardous products off the market. The Office of Consumer Affairs helped to organize a nationwide conference against health fraud in fall 1985, and followed it up with regional conferences. These have been particularly useful to alerting elderly women, who are some of the most frequent victims of quackery. Virtually

every component of the FDA is playing a role in protecting and promoting women's health through activities in the laboratory, in the media, and in the marketplace.

The entire PHS, including NIH and FDA, as Dr. Young and Dr. Kirschstein have noted, has been immersed in the health concerns that bring us together. The two-volume Report of the Public Health Service Task Force on Women's Health Issues shows how vigorous and substantive the PHS's work has been. I am hopeful that this conference will support and sustain the high level of this commitment and will point the way for us all to do more in supporting one another in achieving this common goal.

We have set four goals for this conference:

- To bring together the public health community to focus on major women's health issues,
- To present the best scientific and medical information by recognized experts in the area of women's health,
- To provide baseline information for the development of educational messages and programs within local communities, and
- To foster discussions and communications among Federal agencies and others who are working to respond effectively to women's health needs.

With everyone's cooperation, we can reach these goals in a way that will bring lasting benefits.