Welcoming Remarks

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THE PURPOSE OF THIS CONFERENCE is to report on the work we have been conducting relevant to women's health issues, and to put this knowledge to use. Dr. Ruth L. Kirschstein will give us the overall Public Health Service (PHS) perspective. I will sketch the view from the Food and Drug Administration (FDA).

This is a particular pleasure for me, for in this undertaking, FDA is honoring a debt it incurred long ago. In 1906, it was the women of America, working through women's clubs and other organizations, who gave force and vigor to the drive to enact the first Pure Food and Drug Law. In 1938, when experience showed that the old law was inadequate to meet the changing needs of our society, women once again led the fight to give FDA the authority it needed to protect the health and safety of all Americans. The women's movement and the consumer's movement have come a long way since those days. So has FDA. Yet all Americans continue to benefit from the leadership of those pioneering women. While this conference and the ongoing work it represents can never fully repay the debt we owe them, I hope we can consider this a payment on the interest.

In the context of the PHS initiative that Dr. Kirschstein will describe, FDA established an Advisory Committee on Women's Health Issues in 1983, as a focal point for identifying areas of specific concern relative to the health of women. To quote its charter, "The Advisory Group is responsible for serving as an involved link with the members of the [FDA] Policy Board to assure that issues relating to women's health are considered in decisions made by the Agency in the implementation of its mission." That mission is to promote and protect the public health.

Yet FDA's commitment to addressing women's health needs is much older. A decade ago, FDA's Office of Consumer Affairs and other headquarters and field components started to work to set and meet priorities in this area. When the PHS task force was formed, FDA seized the opportunity to establish an internal advisory group. Associate Commissioner for Consumer Affairs Alexander Grant and Dr. Mary Ann Danello, my Special Assistant for Science, have ably chaired the FDA Advisory Group. Along with Patricia Kuntze of the Consumer Affairs staff, Dr. Danello has also served as liaison with the PHS task force. They have made an outstanding contribution to organizing this conference, and helped to make it a reality.

The FDA Advisory Committee on Women's Health Issues meets intermittently to assess research and identify new programs that are needed. It helps resolve potentially conflicting or controversial issues so as to keep our work on track. I am happy to say that it has done its job well.

The National Conference on Women's Health is intended to provide a forum for the presentation of the best medical and scientific information on the health needs of women. We have mobilized the public health community to establish a baseline of scientific data and its interpretation regarding women's health issues. Let us hope that the conference will produce a lasting network of information exchange—and concern.

We define a women'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. Given our mission of ensuring the safety and effectiveness of drugs and medical devices, the safety and nutritional quality of foods, and the safety of cosmetics and animal feeds, the relevance of FDA's activities is widespread. We can do a lot to improve the health of women, and we are keenly aware that neglect on our part can cause a lot of harm. Addressing these issues is the purpose of the Advisory Committee.

The first weapon against illness is knowledge, and FDA is conducting research on women's health in collaboration with other PHS agencies. We are investigating premenstrual syndrome with the National Institutes of Health, toxic shock syndrome with the Centers for Disease Control (CDC), and osteoporosis and nutrition and weight control with the National Center for Health Statistics (NCHS). Research of this type is ongoing throughout PHS, and we hope to learn much from it, as well as extend it

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into areas such as incontinence, which is proving to be an important issue.

In addition to research, FDA is also addressing women's health issues in many practical ways. Osteoporosis is a good example of a problem that has recently received much public attention. FDA is approaching the problem from several directions. As you may know, FDA has statutory responsibilities to ensure the safety and effectiveness of drugs and medical devices and the truthfulness of their labeling and advertising. Obviously these activities led us by several routes to osteoporosis, its treatment and prevention. We must not only learn about the nature of this common debilitating bone disease, but also assess the safety and effectiveness of products for alleviating it. We must consider the accuracy of claims that foods or other products will help women to treat or avoid it. And to be fully effective, we must communicate the substance of what we learn to American women as quickly as possible.

As part of this effort, FDA's Center for Food Safety and Applied Nutrition (CFSAN) has identified nutritional and other health measures that will be used to determine the prevalence of osteoporosis as part of the upcoming National Health and Nutrition Examination Survey. CFSAN is currently working with the NCHS, the responsible PHS agency, in planning and implementing the survey, which is scheduled to begin in mid-1988. By gathering the essential scientific and demographic data, we can launch an effective attack on osteoporosis. On the same issue, the NCHS has approached FDA's Center for Devices and Radiological Health (CDRH) to tap its electronic expertise. CDRH is serving as a consultant on the use of filmless diagnostic systems, which will be essential to the success of the osteoporosis survey. The survey ultimately will help to define the extent of the osteoporosis problem, and we hope it will yield clues that we can use to fight the disease.

At the same time, we seek to put our findings to use by communicating them to the public. Through public information and Consumer Education Programs on Issues Relating to Women carried out by our headquarters and field offices, we reach out in different but complementary ways to give the public correct information on health issues of concern to women and—equally important—to dispel any misinformation and to promote healthy behavior. In fact, this conference is a part of our overall outreach effort. I am proud of the excellent level of science that supports FDA's work; yet to take full advantage of it, we have to ensure that the public knows of its findings and puts them to use. These outreach programs are essential to doing just that.

Outreach in the area of nutrition is another key program. There has been renewed interest in expanded consumer communications with respect to diet and health. One particular area in which FDA has reviewed its regulatory policies is the use of health messages on food labels. In cooperation with consumers, health professionals, and industry, FDA is now developing a policy allowing appropriate food manufacturers to place responsible health messages on food labels. Such messages should be truthful and nonmisleading, and should emphasize health benefits in the context of total diet. Developing a policy to permit responsible messages without opening the door to fraudulent or misleading claims is difficult, but we hope to have a policy of great potential benefit to the public health in operation soon.

Toxic Shock Syndrome (TSS) is another area of special concern to women. TSS is a good example of how we use education, regulation, and science to address a health problem. We are all too familiar with its tragic effects on otherwise healthy young women. Consequently, the CDRH spearheaded a major Agency effort to design a poster format in a learning unit to teach young females how to protect themselves from TSS. The unit was distributed to secondary school students across the nation, health educators, medical professionals, and other appropriate groups. The Center also promulgated a regulation requiring TSS information in the labeling of menstrual tampon products to allow women to be better-informed consumers and to actively participate in their own protection. We are now addressing the issue of providing uniform tampon absorbency labeling. To establish performance standards for tampons, we are working with consumers, industry, and the American Society for Testing and Materials. Since we still do not know the nature of the association between tampons and TSS, we are supporting CDC's active surveillance project, which is being conducted in six areas of the United States. Last, but

certainly not least, we are active participants in the development of an international symposium (scheduled for November 1987 in Atlanta) to provide scientific data about TSS.

Health fraud—what has been called quackery—is the intentional selling of an unproven or worthless medical product for a profit. Such scams as "easy" weight loss, permanent pain relief, and cure-all devices persist, and their purveyors have grown more sophisticated despite good efforts by print and broadcast journalists to expose the tricks of their trade. FDA is working to monitor health fraud, to take regulatory actions against it where appropriate, and to help publicize the truth about such fraud. In the fall of 1985, FDA cosponsored a national conference on health fraud, and we have held several followup regional conferences since then. In December 1985, the legitimate health care industry joined FDA in a nationwide advertising campaign to "vaccinate" the public against medical frauds. I am confident that we are succeeding, but I also know that we need to maintain our vigilance in this area.

FDA is proud of its numerous practical initiatives relevant to women's health. Notable are the following programs:

• Nationwide Trends Breast Exposure Normalization Technique—a voluntary mammography quality control program conducted by State and other radiation control agencies. CDRH provides the essential technical training for reducing the measured mammographic exposures through better information and training for medical personnel.

• Relabeling of oral contraceptive and estrogen drug products to inform and protect consumers from needless risks is an important activity of FDA's Center for Drugs and Biologics. Typical is the revised labeling of estrogens to reflect the reduction in risks of cancer when low doses are prescribed for postmenopausal use. New indications for the use of these drugs include treatment of osteoporosis.

• The ongoing public information campaign to encourage women to consult health professionals before taking any drugs during pregnancy has been remarkably successful in informing the public. FDA has worked with other PHS agencies, and has enlisted professional and consumer groups as well as the media to caution women about the risks posed by medical products as well as by alcohol, drugs, and improper nutrition. The results are evident in healthy mothers with healthy babies. These efforts will continue.

• The Boston Collaborative Drug Study Program is a study of adverse drug reactions among women.

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Administered by Boston University with FDA support, these programs seek to quantify acute and long-term toxicity of drugs used in clinical medicine and surgery, to study factors which modify drug events, and to develop methodology for studying drug-induced illness. The best medicine is preventive, and the knowledge that these programs afford us will ultimately help many women avoid serious, preventable reactions.

These are just a few programs that are typical of FDA's commitment to addressing the pressing issues of women's health. At this conference, we will explore them and many others. We hope that we all will learn much at this conference, much that we can put to use in our respective fields. But that is not our only purpose. A true conference means we confer. The exchanges that take place will aid all participants as we chart a course for the future. I hope that we will have lively participation in the sessions and that we will constitute an effective continuing network of concern for women's health issues in the years to come, not just in the information presented, but in the ideas, associations, and contacts we form and strengthen at this conference which can develop into lasting benefits for women everywhere.