Oral History Interview with
Ruth B. Merkatz, PhD, RN, FAAN
Director of the Office of Women's Health
1994-1996

FDA Oral History Program

Final Edited Transcript

October 16, 2019

Table of Contents

Oral History Abstract

Ruth B. Merkatz, PhD, RN, FAAN, was the first Director of the FDA Office of Women's Health (1994-1996), and before that served as a Special Assistant on Women's Health Issues to Commissioner David Kessler (1991-1994). During her tenure at the FDA she not only stood up the Office of Women's Health and established its research program, but helped the agency to grapple with issues ranging from women's participation in clinical trials, gender differences in health, silicone breast implant safety, the Mammography Quality Standards Act, HIV/AIDS in women, contraceptive labeling, etc. After leaving FDA in late-1996, Dr. Merkatz served as Director of Women's Health at Pfizer, Inc. and later as the Director of Clinical Development in Reproductive Health at the Population Council.

Keywords

women's health; clinical trials; contraception; HIV/AIDS; mammography; gender differences in health; silicone breast implants

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Interviewer Biographies

Vanessa Burrows is an historian who holds a Ph.D. in the History of Public Health and Medicine from the City University of New York's Graduate Center (2015). She joined the FDA History Office in January 2017, where she focuses on the history of medical consumerism, regulatory policy and digital history. She has a background in documentary film, public history and higher education, and her prior work includes associate producer of the 2018 film *Power to Heal: Medicare and the Civil Rights Revolution*. Her research on the history of socially determined health inequities, dynamics of health literacy and the political economy of medical research has been published in the *Journal of American History* and the *Oxford Research Encyclopedia of Psychology*.

FDA Oral History Program Mission Statement

The principal goal of FDA's OHP is to supplement the textual record of the Agency's history to create a multi-dimensional record of the Agency's actions, policies, challenges, successes, and workplace culture. The OHP exists to preserve institutional memory, to facilitate scholarly and journalistic research, and to promote public awareness of the history of the FDA. Interview transcripts are made available for public research via the FDA website, and transcripts as well as audio recordings of the interviews are deposited in the archives of the National Library of Medicine. The collection includes interviews with former FDA employees, as well as members of industry, the academy and the legal and health professions with expertise in the history of food, drug and cosmetic law, policy, commerce and culture. These oral histories offer valuable first-person perspectives on the Agency's work and culture, and contribute otherwise undocumented information to the historical record.

Statement on Editing Practices

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Index

Interview Transcript

VB: This is an addition to the FDA Oral History Collection. I am Vanessa Burrows for the FDA History Office here with Ruth Merkatz, the first director of the FDA Office of Women's Health. It's October 16, 2019.

I'd like to just start off by asking you a little bit about your background, growing up, your education, and how you developed an interest in women's health that brought you to the FDA.

RM: Well, in terms of my background, I guess, I would say that I've always been involved in health care. My father was a physician, a general practitioner, and he had his office in the house. Although I had two brothers, he always called upon me to help him when patients came to the office off-hours or in the middle of the night or on weekends. So, I think I developed an interest in health when I was very young and saw what, the practice of medicine and dealing with health issues for families of different means was all about.

I actually then studied nursing as part of my liberal arts preparation at Cornell. And very early on in my nursing career, I did a lot of work caring for women patients, many of whom had breast cancer and had mastectomies back when there were very few options for women who may have wanted reconstruction or in terms of how they might deal with their body image. I then shifted into officially caring for women in the maternity cycle, providing obstetrical care. I was one of the early teachers, for prepared childbirth, and I, also, worked very closely with the moms in terms of breastfeeding back when breastfeeding was not very popular in the United States.

I also had an opportunity early in my career to care for women having in New York State who were seeking abortions. This is before *Roe v. Wade* was enacted into law, but New York State had already passed a law that enabled women to have a first trimester to have abortion. I was at a hospital where we actually set up a unit for women -- they came from all over the country to have abortions because they weren't able to have them in other parts of the United States. Actually, the very first paper I wrote dealt with the experience of setting up a unit in a hospital to provide safe abortion. I continued working in women's health here in New York City at the New York Hospital-Cornell.

And then as a family, we moved to Cleveland, Ohio mainly for my husband's work and some exciting opportunities he had to regionalize care of pregnant women and try to improve outcomes. I started doing graduate work in nursing at Case Western Reserve. I focused on women's health in my graduate work and had very forthright and very forward-thinking faculty who encouraged me in thinking out of the box, so to speak, about women's health. We actually wrote a book together, several of us. It was called *Nursing of Women in the Age of Liberation*, and we touched on subjects that most people would not have touched on at that particular time, e.g. feminist themes. We focused on theoretical aspects of caring for women as well as some of the challenges that women faced in health care.

So, I had very good schooling and was able to think quite broadly about some of the issues that women were facing in their health. While women's health seemed to focus mainly on reproductive health, there were many other aspects of health for women that needed attention whether it was cardiovascular disease, mental health disease. These were really important issues for women. But at the time, I focused on the care of women who were at high risk for poor pregnancy outcomes, and that, in fact, is what I did my thesis on.

And then having spent 10 years in the Midwest, we actually came back to New York where my husband was offered the chair of the department of obstetrics and gynecology at Albert Einstein in the Bronx. I began to work in the Bronx in the nursing department at the hospital. I don't know if you recall exactly date-wise, but certainly, I remember that when I came back, something had hit the Bronx that we didn't even talk about in the Midwest, and that was HIV. The Bronx was actually an epicenter of HIV in the United States. I actually cared for a woman who came into our special unit for high-risk pregnant women with a very bad case of pneumonia and a very bad case of vaginal herpes. I became very concerned about her, what was going on and after speaking with her at length about her lifestyle, I suspected -- even though it wasn't talked about -- suspected that she had HIV. I asked the physicians to please do an HIV test, and sure enough, this woman had HIV. So, that was my introduction to the world of HIV, which became a very important part of my nursing career in the 1980s and very important for my work when I landed at the FDA.

While I was continuing to active work in nursing, I was also working on doing a PhD in nursing research. I had started that in Cleveland, but I finished it here in New York. I did a lot with ethics as part of my doctoral study and worked on the bioethics committee at the hospital. It was there that I got to know Dr. David Kessler who was the medical director at the hospital where I was working. We tackled some very challenging cases together and with the other members of the committee; we worked together quite a bit in caring for patients at the hospital and I think sharing ways of thinking and approaches to health care.

Then just to fast-forward, as you know, Dr. Kessler became the head of the FDA, the commissioner of the FDA. He was appointed -- I believe it was -- in 1990; he went down to the FDA. And it just so happened that my husband who had been chairing the department of

obstetrics and gynecology at Einstein, planned on going to Washington for a year to do a sabbatical. He was going to be a Robert Wood Johnson Policy Fellow, and I decided that it was a great opportunity for me to go to Washington as well and actually planned to work at Georgetown University. They had a special research area on breastfeeding, and because I had always done a lot of work on breastfeeding, I thought that would be a very good research opportunity for me.

But then Dr. Kessler, because we had worked together very closely while he was the medical director at Einstein, contacted me and told me that women's health was very important at the FDA. It was really heating up in Washington, that there were many issues that were extremely important for the FDA that they were going to be grappling with -- for example, the issue of breast implants. He wondered whether I might be interested in coming down and meeting some of the people that he worked very closely with on his staff just as an exploratory interview to see whether there might be anything that I could work on or that would be a fit.

Since I was going down to Washington, and I thought it could be a wonderful opportunity, I interviewed with a number of people in the Office of the Commissioner. They explained to me that this was sort of unchartered territory for the FDA to have a special focus on women's health, but there were a lot of issues that were heating up -- as I mentioned, breast implants being front and center at that particular time. This is 1991. I must say I didn't have to think too hard. After I went down to the FDA to meet with some of the folks that interviewed me, I was very excited -- it was humbling in a way to think that someone with my beginnings in my Dad's office in a little town and a nursing background would be asked to come down and work directly in the Office of the Commissioner and try to work on issues of women's health.

And so, in September of 1991, I went down to the FDA, and originally, it was going to be for a year since my husband had to go back after his one-year sabbatical was up and so I originally thought I would just stay down there for a year. Well, I quickly learned that there was so much to do and there was opportunity for meaningful change in approaches to women's health. It didn't take me many months before I realized that in a year's time, there wasn't an awful lot that one could actually accomplished, but I would do my best.

The issue that I focused on almost exclusively when I first got down there was the issue of breast implants because they were getting ready to have some very important advisory committee meetings to review the four applications from companies that had their applications filed for review of the breast implants. More than four companies had filed for breast implant approval, for the FDA to give its approval, but only four were deemed fileable, i.e. had adequate information so that FDA could conduct a full review. I had a chance to review, myself, some of the documents that were part of the dossiers of the various companies and very much participated in the advisory committee meetings that became worldwide events. There were thousands of people that showed up for these hearings. It was broadcast all over the world, and it was quite an important event in women's health. It also, I think, really set the stage for the FDA realizing how important women's health was in and of itself.

Before the breast implant controversy erupted, there already was a focus on women's health. within the Department of Health and Human Services. There had been a committee that had started in the '80s. There had been very important reports that had come out describing women's health across the lifespan and some of the challenges that women faced in various periods of their life. And importantly, the Office of Women's Health Research was established at the NIH.

At the same time that David Kessler was appointed as the FDA Commissioner, Bernadine Healy became the head of the NIH. It was the first time a woman headed up the NIH. Dr. Healy and Dr. Kessler communicated with one another about women's health, and I actually had the privilege of meeting with Dr. Healy. Dr. Kessler brought me to a meeting with Dr. Healy where we talked about not only about what the NIH was doing but what we were going to be doing at FDA to be part of a real effort to raise awareness about issues in women's health.

The other thing that was going on at the same time -- and it was almost like a perfect storm in a way – besides breast implants, we had leaders in Congress like Barbara Mikulski who, I believe, marched on the NIH -- organized a march demanding that women be in clinical trials. So, this is when the issue of women in clinical trials starts and became a major focus for me and my work at FDA. The FDA, as you probably know, had a longstanding ban on the participation of women in the early phases of human clinical trials -- clinical trials being phase 1, phase 2, phase 3, the human trials. Phase 1 being the small trials that are primarily for safety, phase 2 being larger where they're looking at safety and efficacy and dose-finding and then, of course, the large phase 3 trials for further evidence of safety and efficacy before a new drug can be considered for approval for use and become commercially available.

To go back, the FDA has this long-standing ban that came about in 1977 as a result of concerns about exposing women who might become pregnant to any drugs that haven't been tested. And this comes about as a result of the thalidomide tragedy where the FDA was the hero in terms of preventing thalidomide from coming into the United States. So, the FDA, based on their good record keeping thalidomide out of the market, took it to the point of wanting to really protect -- quote "protect women" -- from exposure to any drugs that they didn't know very much about.

The NIH had gotten into quite a bit of political difficulty over the fact that they had conducted a very large study, with taxpayer dollars, on heart disease without including any women. That's what I think triggered Barbara Mikulski and other members of Congress to demand that the NIH put women into their clinical trials especially for trial on heart disease. No one talked about the fact that heart disease was the number one killer of women. They talked about heart disease in men; they didn't talk about heart disease in women. So, all of this was, as I said, almost the perfect storm. We had breast implants, then we had this issue of women in clinical trials. We had what was going on at NIH starting an Office of Women's Health Research. And the GAO from out of Congress did a study of women on clinical trials at the FDA, and their results also pointed to the fact that women were not being included to any great extent especially in the phase 1 and phase 2 clinical trials.

Then, to add to this perfect storm comes my experience with having worked in the Bronx the epicenter of HIV, women with HIV. Women with HIV were getting no attention whatsoever, and women with HIV were being excluded from the clinical trials, and women with HIV just like men with HIV were dying. The men with HIV were very well organized, and they had a lot of money. The women with HIV, for the most part, were very poor women who were getting contracting HIV through sharing needles and through sexual transmission. There was one group however, that was organized and headed by a very dynamic woman by the name of Terry McGovern -- this was the HIV Law Project -- and they started demanding that there be changes made in getting women into clinical trials. Shortly after I arrived, there was one meeting headed by another great woman, a real pioneer, and she was from the NIH. Her name was Ruth Kirschstein. But together with others from NIH and other Federal agencies including the

Department at HHS we started having meetings about how we were going to get women into clinical trials.

RM: Yes, from the department of HHS. I, of course, was reporting back to David Kessler, and I also worked very closely with Mary Pendergast who was the senior advisor to David. And together, we started to think about what we needed to do at the FDA to change the policy to get more women into clinical trials.

VB: Was there resistance?

RM: Oh yes, there was. You know change is always difficult no matter what it is, and... But I think we tried very hard to be strategic and mindful that bring about major change is not easy… change can be difficult, and you have to have very good reasons for making changes, not just make changes because, well, everybody else is doing it.

So, we organized a committee within the FDA, members from the Center for Drugs, the Center for Devices, and we started meeting with the committee to talk about what we needed to do. We had some outside groups involved as well and decided internally within the agency that we needed to abandon that 1977 policy of women not being able to be in the clinical trials in phase 1 and phase 2. Actually, I don't know if I have all the names of the people that were on the committee. But Bob Temple for example, was involved, very instrumental and made sure

that everything we did was grounded in science, which was one of the three cornerstones of the change we tried to bring about.

VB: I was going to ask --

RM: It was very important that we had the leadership of the Center for Drugs supportive …. we knew that it wasn't going to happen without the leadership of the Center for Drugs being supportive.

VB: It occurs to me that there was another turning point in '91, and I wonder if it had an impact on the agency's thinking about the '77 guidelines, and that was the UAW case against the Johnson Controls which led to the Pregnancy Discrimination Act?

RM: We had a conference, and that case was very important -- we discussed the legal issues and implications of the case a lot in addition to the ethical and the scientific/medical points of view. Those three, it was a triangle -- medical/scientific, legal and ethical -- we detailed these three perspectives in the article that was published in the *New England Journal of Medicine* in 1993. We also discussed these at conferences we had at FDA in conjunction with our sister agencies within HHS --

VB: Pregnancy Discrimination.

RM: The Act as interpreted by the Supreme Court in the *UAW v. Johnson Controls* was very much a factor in convincing everyone that that the restriction at FDA needed to be reconsidered. From a legal point of view, the Supreme Court determined that prohibiting the blanket exclusion of pregnant women from jobs they're qualified to perform solely because working conditions pose a potential risk to exposed fetuses constituted discrimination. Although the purposes of clinical trials are manifestly different from the purposes of employment, the court's emphasis on the woman's right to participate in decisions about fetal risk underscored the principles of autonomy and informed consent. So, it was both the ethics and the legal aspect of the case that were really, really important in the agency's decision to lift that restriction.

VB: So, you brought everybody together at the table and were able to formulate this really strong case for why it was time to reverse that policy?

RM: Right.

VB: Were there any people that needed further convincing that you needed --

RM: The hardest issue was from the scientific point of view. We were asked to provide examples of where the dosing of a drug needs to be different for women than for men based on what pharmacokinetic data, and cases like that were difficult to find. There wasn't very much information. So, I would say that the scientific argument was the hardest one at that point, especially at the agency. When it came to drugs for cardiac disease for example, where is it going to be different from men than it is for women in terms of how much the dose should be or what the effects will be? And those are still some challenges, but nevertheless, I think that when it comes to issues of safety, e.g. describing the side effects, the adverse events that occur with a drug, you must include women, and it's not just women. You need to have people with different phenotypes. That's why the agency now really stresses the importance of not only a balance in terms of sex but also by age and by race and also shy away from weight restrictions. Because there are some phenotypical aspects of race that are going to be important in the metabolism of drugs. And so using the issue of women, making sure that women were in clinical trials really raised the bar overall for representation of groups within the population of volunteers for clinical trials.

This issue is still a challenge the 1993 announcement that we're removing the ban and then came the guidance document was just the beginning…. making sure that when a new drug application is submitted to the agency, that the center that's reviewing that application really does its job in reviewing the data that the sponsor is supposed to submit on how the drug works by sex. And whether there actually have been enough women recruited into the clinical trials in order to have a valid analysis done is another important component. Removing the restriction was very important, and it was the beginning, but it was the beginning of really trying to have full disclosure of how drugs work in men and women as well as in the elderly for example.

Often, there are inclusion-exclusion criteria in the protocols for new drugs that have an age limit so that can make it very difficult sometimes to understand how a drug might work in someone who's elderly whose kidneys may not be functioning as well as someone who's much younger.

VB: Um-hm. In the course of all the discussions that you had that went into revising these guidelines, you mentioned early on that one of the things on your radar was women with HIV and how they were treated in general as men's HIV advocacy groups were really pushing FDA to revise treatment guidelines for investigation of new drugs and innovate new approval pathways and so forth. How do women benefit from this in the late '80s/90s when '77 guidelines excluded most from entering into the early phases of clinical trials?

RM: They didn't benefit initially -- while there was an expedited review of AZT, for example so that they didn't have to complete phase 3 clinical trials before it was approved, there hadn't been women in those AZT trials. For anyone diagnosed with HIV in the 80s, there were no approved therapies for women. If they were diagnosed with HIV, the only outcome would be death. They had no hope because they weren't able to get into any of the clinical trials. Finally, the women actually marched on the FDA. I was in the office when all of a sudden, I heard this noise outside, and I go to the window, and sure enough, they're marching. They were saying things to get them (FDA), to get women into the clinical trials, and it was, "Get the facts, call Ruth Merkatz." I'll never forget it.

We had also had a town hall before that where women with HIV, women activists were so angry and understandably angry at -- and it wasn't just FDA, it was all of us who were

involved in women's health in Washington at the time. I was on the podium; they started throwing rolls of toilet paper. I wasn't angry at them -- I empathized with them, but I was angry at the system. For me, it didn't require that kind of action to make me realize we had to do something because the facts were obvious, but still, it was very dramatic.

VB: Not to shift back and forth in time but when David Kessler asked if you'd be interested in this opportunity, was this on your radar? Did you realize that you were going to be leading the charge to...?

RM: No, absolutely not. I mean, I knew I was going to be involved in breast implants. When I was first invited down to the FDA to interview, I sat in on one early meeting on breast implants. It was a public meeting. I knew that there was a lot going on with HIV and trying to get new drugs approved, but, honestly, I wasn't aware of this whole issue of women in clinical trial., I think that was a reflection on how uninformed I was about how critical the actions of the FDA for women. But I think in general the public is very ill-informed about how drugs come to market. In fact, after I left FDA, I started going around to the different medical and nursing schools in New York talking about how drugs get approved and how we get the drugs, what's important to know about the drugs that we take for granted – that we use. In medical schools, for example, most physicians don't get this in their education. Nurses don't get it. Sometimes, they don't know that they're supposed to report serious adverse events or how to report.

Next week, I'm doing a webinar on the drug development process for family planning fellows. And it's something I want to continue to do because the important elements that go into development of new drugs aren't well known or understood.

VB: Yes, that's great. So, you knew you were going to be working on breast implants, and you had an inkling that there would be women and HIV issues, but what was it that really attracted you to the job? You said it was an amazing opportunity, what did you see in the job?

RM: Before I went into nursing, I was a government major in college, a subject I loved. I thought, "What a great opportunity to really see how the government works firsthand and to do it in relation to health to issues that I had been working on throughout my career; issues such as reproductive health, contraception, pregnancy, well-being, as well as breast and gynecologic cancers. I knew that that was something that would, certainly, be an important component of working on women's health at the FDA since they were in the business of reviewing and approving new methods of contraception whether it was a drug or a device. But I'll be honest; I myself wasn't fully aware of the way clinical trials were structured and their impact for women.

VB: Um-hm. You also mentioned the Physicians' Health Study and how that drew everyone's awareness to this problem and led to the GAO study and other reports. It also shone a light on the lack of data on women and cardiovascular disease. Did you anticipate that fleshing

out a research agenda and contributing to work on women and cardiovascular disease was going to be on your plate when you got to the FDA?

RM: No. I have to say that was not something I had focused on either before I went to the FDA because my career had been focused primarily around reproductive health. I wasn't that involved with the impact of cardiovascular disease for women at that point in my career. But I quickly became very involved with the issue of cardiovascular disease in women and other diseases as well.

I had the very good fortune of interacting with many different consumer advocacy groups at the FDA. For example, I worked closely with the group focused on seizure disorders, epilepsy, the issue of women with epilepsy and whether the drugs to treat epilepsy were being studied in those women. That became a big issue. We had two important conferences on inclusion of women in clinical trials for drugs in development. Women with epilepsy were always there to talk about how they needed to be represented in the clinical trials for drugs for epilepsy, and who would've thought about that? It wasn't just cardiovascular disease where men outnumbered by far the number of participants in the clinical trials, but there were other conditions as well.

VB: So, you had a variety of things and really important issues on your plate in the first two years that you were there. When did the proposal for the FDA to create an Office of Women's Health first come up? How did that idea germinate?

RM: Well, one thing that happened is -- as I think I mentioned -- I was just going to stay for a year when I went down to FDA. I was going to go back to NY with my husband. I remember talking to Dr. Kessler and saying, "A year is just an opener. We've just gotten started. I can't believe how many really important issues there are to focus on." The way I saw it and the way that other people saw it too, there's a little piece here and there were pieces all over the agency, but there wasn't a central focus to try to bring them together in a cohesive manner. I certainly may have mentioned it to Dr. Kessler that I thought an office would be good, but there was also a lot of discussion within the HSS Women's Health Coordinating Committee. They were going to create an Office of Women's Health in HSS. The office at the NIH was leading the pack, but through our coordinating committee I think all of the women's health

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representatives on the coordinating committee from the various DHHS agencies had the same "aha" if you will. In all the like agencies we concluded that we needed an Office of Women's Health to coordinate activities. to prioritize and bring people together to focus on women's issues that were different from men's. There are unique aspects in women's health that have important implications for the work of the agencies whether it was the FDA, CDC, HRSA or the overall HHS department. And so, ultimately, all the agencies created Offices of Women's Health.

But there was also an important group within Congress, the Women's Caucus. They were supportive of an Office of Women's Health. Barbara Mikulski, for example, who was such a champion of women's health, she was very supportive of creating an office of women's health and using Congressional funds. Because the Office of Women's Health at the FDA came

through legislative language -- and I think they were previously appropriated funds -- that they were able to utilize Congressional language to create an Office of Women's Health at the FDA.[1]

VB: So, it was through the budget process?

RM: Yes.

VB: I can't recall, but in the original or subsequent Women's Health Equity Act if there was a call for the creation of Offices of Women's Health?[2]

RM: What year was that?

VB: 1990 was the first one.

[1] The FDA Office of Women's Health was established as a delegation of HHS authority in July 1994 (see *Federal Register*, vol. 59, no. 144 (July 28, 1994): 38482).

[2] The Women's Health Equity Act of 1990 called for the creation of the National Institutes of Health Office of Women's Health Research and the Department of Health and Human Services Office of Women's Health. The bill did not pass, though it was resubmitted multiple times in subsequent Congresses. Many provisions of the Women's Health Equity Act were incorporated into other legislation.

RM: Honestly, I'd have to go back and look that up myself. I'm sorry; (laughter) I don't remember.

VB: I can give myself that homework. So, as the idea started spreading throughout HHS, by 1994, it was a reality at FDA. I suppose you had the hard work to figure out exactly how you're going to set up that office and who you're going to recruit to help you with it. I don't know if you recall how many FTEs you had or --?

RM: I sent you that picture. I think that was the office at the time. We were part of the Office of External Affairs even though the head of the office reported directly to the Commissioner

VB: Was that Sharon Smith Holston at the time?

RM: Yes. Sharon Smith Holston. Before that, Carol Scheman was in that post. Carol was there when I came down to the FDA and then when she left, Sharon Smith Holston stepped in.

VB: So, since you were under the Associate Commissioner for External Affairs, were you -- was your first title director, and then the associate commissioner came later or did -- as the office was created?

RM: I was never Associate Commissioner.

VB: Always Director?

RM: Yes…reporting directly to the commissioner but also working with the Office of External Affairs but reporting directly to the Commissioner.

VB: Okay. So, did you have ideal staff in mind who you wanted to recruit or...?

RM: You know, I had some people who started working with me before there was an office and I worked collaboratively with different folks across the council. I worked closely with Mary Pendergast, for example, and with the Office of Constituent Health Affairs, e.g. with Grant Bagley, Stuart Nightingale. Bruce Burlington was from CDRH. Linda Carter was there, [I believe] she was from the Office of New Drugs. Mary Gross who was my right hand, and I brought her into the office right away. She was so great organizing all these different conferences. We had Jane Henney who was Deputy Commissioner for Operations. Catherine Lorraine who was in the Office of the Commissioner (Office of Policy). Dianne Murphy from CDER, Terry Toigo from the Office of Special Health Issues, Carl Peck and Roger Williams, both from CDER and both recognized the importance of analyzing data for women and men.

VB: Yes.

RM: Elyse Summers, who then joined the OWH and was terrific. She had forward looking ideas and was smart, organized (we later wrote a chapter together for a nursing textbook on the drug development and regulations). Mike Taylor, in the Office of the Commissioner and -- worked closely with David Kessler. He was supportive of an Office of Women's Health. I also worked closely with Terry Toigo, the head of the Office of AIDS and Special Health Issues. especially around the issue of women with HIV and clinical trials.

VB: She briefly was acting director of OWH later on, after Susan Wood left.

RM: And there was Janet Woodcock from CDER and Nancy Yeates from the Office of the Commissioner (Office of Policy). Creating this working group was my way of making this change come about because I knew it wasn't going to be easy. We had to demonstrate the scientific necessity of including women in clinical trials. This was essential for gaining support from Bob Temple and other physicians and scientists in CDER.

VB: Was it hard to convince him?

RM: Oh. (laughs) But, he was the smartest, one of the smartest people I ever knew and great to work with.

VB: And if you could convince him, then he could convince everybody else for you. (laughs)

RM: Exactly, right.

VB: And you obviously did. I mean the transcript for the conference on Gender Studies in Product Development, he comes out swinging, you know?

RM: Yes. I mean I love working with someone who'll give you a very tough argument. He'll make you hone your own argument and make a solid case, and that's exactly what he did. He was terrific, one of the smartest people I've ever known. I have a great deal of respect for Bob.

VB: You said you brought Mary and Elyse into the office. Audrey Sheppard came on pretty early.

RM: Audrey came through Bill Clinton's office. She had great ideas, and started talking about working with consumers and ultimately created the Take Time to Care program that continues through today. Important initiative

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RM: But, as we organized with our small staff, I focused on the issue that brought us to the creation of the Office of Women's Health, the issue of women in clinical trials that appeared in the *New England Journal of Medicine* in 1993 and foreshadowed the Office of Women's Health, what it would be responsible for and what it would do. At the very end of the article, I wrote a short paragraph on testing drugs on pregnant women. And one of the first things I was able to do was to have this conference on drugs in pregnancy.

VB: Which is about four months after November 1994. It was just very shortly after you officially opened the office.

VB: So, was Marietta Anthony already in your office?

RM: Yes. I recruited Marietta who was a clear and focused thinker.

VB: Was Rachel Berman in your office?

RM: No. Rachel worked in CDER. But she was on the Clinical Trials in Women Committee and always brought a clear approach to the issues we were grappling with.

VB: You did a lot of speaking in your new role, didn't you? You had to go all over the place.

RM: I did a lot of speaking because I felt that it was really important to shed light on what had been a silent issue for very long. And the fact that I didn't even know about it and physicians didn't know about it, nurses didn't know about it -- nobody knew about it… it was a well-kept secret that women weren't being included in clinical trials to the extent men were and in the early phases of drug development when you learn so much about safety, efficacy, pharmacokinetics and dosing. Nobody knew about it. And so I traveled and tried to spread the message about why it was so important to include women in all phases of clinical trials. Perhaps one of my most important outreach events was when I gave the keynote address to the Menopause Society. I remember the audience, medical leaders in the care of women, being astonished to learn that women weren't included in the early phases of clinical trials and even for Phase 3 trials that their numbers were not commensurate with the incidence of certain diseases in women, e.g. CVD.

VB: And you got a lot of press coverage too. I mean, if you just do like a random search for your name in newspapers --

RM: Oh, really? I guess I didn't pay that much attention to the press coverage

VB: Yeah. It was really effective.

RM: Here is one conference that I organized, and when I looked at it over the weekend, because I was still trying to find stuff for you, this I actually did with my husband.

VB: What jumps out at me is this is '93, and the title is Women's Health Across the Lifespan. So, the idea from the beginning was that you had to have as representative a group of women as possible, right?

RM: And that women are different from men in all stages of their life, different physiologically in several important ways including the way they manifest their diseases and which diseases are really important for them -- that wasn't talked about either. It wasn't just that women weren't in the clinical trials. It was an important fact, for example that heart disease is the no. 1 killer of women, that depression is a woman's disease in many cases, and the issue of our bones, how they are affected.

VB: Nutrition?

RM: Not talked about very much either and yet an important part of the women's health movement.

VB: One of my core questions in this process and as someone who is involved in women's health work from very early on, we had a really powerful movement for women's health. It started in the late '60s, early '70s, and it took at least 20 years, 25 years to get that knowledge and that experience and that force to protect women's health inside the federal government. And pinning down the contingencies and the turning points and how that happened I think is really important. For instance, with clinical trials, there is a conference. I think it came out of the Office of the Assistant Secretary for Health in 1985. I think you mentioned it earlier, right?

RM: Yeah.

VB: And subsequent to that, NIH started on a policy level encouraging, even requiring the involvement of more women in clinical trials, but it wasn't enough, right?

RM: It needed bold action to make it happen.

VB: To make it happen. And it seems like one of those factors was having women in Congress that insisted on change?

RM: The Women's Caucus was very important, very important and people like Barbara Mikulski, Pat Schroder from Colorado, Nita Lowey from NY.

VB: And having people in government. Certainly, your role as a special advisor was a critical turning point that allowed that to grow into an Office of Women's Health having connections throughout all of the HHS offices, right?

RM: Yes. Actually, the infrastructure almost was there to bring people together. There were meetings that had started to try and figure out how they could make more happen. So, that it was the right time and I think the breast implant issue that exploded soon after I arrived at the FDA brought women's health into focus. It also raised the bar in terms of how vocal women could be.

The other issue that was going on was the breast cancer movement, and that was strong. I have some great slides; I don't know if I could still find them. But breast cancer awareness was another thing that was happening in the '90s. There were different marches and organizations and they helped to bring into focus issues of quality related to mammography. And ultimately

that led to the Mammography Quality Standards Act championed by Senators Barbara A. Mikulski and Ted Kennedy who co-sponsored the bill. It was alarming to learn how many mammography centers around the country were operating without tight standards or oversight and as a result women were not always diagnosed early in their disease. The mammography centers didn't have rigorous standards that they had to comply with.

VB: And patients didn't have any way of knowing what standards they should be looking for or how to judge the quality of the facility.

RM: Do you know how exciting and important it was to see that every center had to have a little -- like a degree on the wall for women to see that they had met the Mammography Quality Standards Act?

VB: Um-hm. So, one of the things -- and I'm pretty sure this came out of your office, I don't know what year it was, but the hotline that women could call to find out about screening mammography facilities.

RM: That was out of CDRH.

VB: That was CDRH?

RM: Yes. But our office collaborated with CDRH – they were terrific to work with, e.g. Lillian Yen, Florence Hou. Our office worked closed with CDRH who implemented the hot line.it was something we recommended, but we didn't have the funds to do that. I had a very small budget when we started and used those funds to encourage research.

VB: So, research in women's health was the goal from the beginning, right?

RM: Oh, right. I should have this written down somewhere. I don't know recall exactly what my first budget was, but it was small, and we used it for to fund research focused on sex-specific medicine.

VB: Did you have particular projects that you were hoping people would pitch?

RM: Well, certainly, on better ways to get women into clinical trials and get statistically robust data. If you had very small numbers of women compared to men, what was the best way to analyze the data, so it would be valid? That was my statistics background coming into play because I knew that you couldn't just enroll women without first thinking through a statical analysis plan. If they were going to enroll these women, you wanted the data to be usable. Tracking, keeping close tabs on tracking, how we were doing with getting women into the

clinical trials for the new drug applications that were coming in. This was such a key issue. Then we were also grappling with the issue of women and HIV.

VB: And the concerns in the 1990s about HRT and also about ovarian cancer --

RM: And the Women's Health Initiative, the very big study that the NIH was about to undertake?

VB: Yes.

RM: One of the first tasks that David Kessler gave me was to work with the Reproductive Drugs Division that, at the time, was headed by a fellow named Sol Sobel who's the loveliest gentleman. Oh, he was so kind and nice, and he had a crackerjack exec sec by the name of Phil Korfman. He passed away last year – what a wonderful guy. So, one of the first tasks that David gave me was to help them fill the vacancies for the reproductive health advisory committee. This was tricky because David had been appointed under the Bush administration. When I first joined FDA in '91, George Bush Sr. was the president, so it was a Republican administration, abortion was a controversial issue. So, they needed to have committee members that were not abortion providers or abortion activists. One of the first things I did was to help populate that advisory committee because I knew a lot of the ob-gyns through my husband. I think my husband knew just about every academic ob-gyn in the country. Through that work to

organize the advisory committee I became a close partner with the Division of Reproductive Health Drugs, which turned out to be very important. They were staunch allies, great supporters, and terrific to work with. And with that division there never was a dull day. There were some other things going on within that division during my time, including changing the label on oral contraceptives. It used to be that you had to have a physical exam in order to get a prescription for an oral contraception. We got rid of that. Then, we had the Norplant issue. At that time, there were all these disasters with Norplant (a subcutaneous contraceptive patch) because physicians hadn't been trained on how to remove the rods. They only knew how to put them in; they didn't know how to remove them.

It's ironic too because Norplant was developed by the Population Council, which is dedicated to research and development. We license products we develop to companies, and whatever we get back in royalties goes back into our research. So, we just had a new contraceptive approved last year that I was very involved in. I ran all the phase 3 trials for a new contraceptive. It was hard work, but always interesting and exciting.

VB: What was it?

RM: It's called Annovera™. It's a contraceptive vaginal ring or system and one ring is good for one year.

VB: Wow. That's a game changer.

RM: It's a game changer, exactly. That's what the USAID said and why they funded us to do this work. So, we were funded by USAID, NIH, World Health Organization to do all the work.

VB: Did you work at all with Population Council when you were at FDA? When was it the founded?

RM: In the Fifties. It has a great history. I didn't know that eventually I would come to work at the Pop Council and was only indirectly involved with the Council [while I was at the FDA. Mary Pendergast and Donna Shalala came to the Population Council and asked them to conduct the clinical trials in RU-486, which they did.

VB: And am I correct in saying this, the Population Council has the patent for RU-486, no?

RM: No. It was owned by Roussel-Uclaf, but we ran the clinical trials under the request of the FDA. Can you imagine the FDA now doing something like that?

VB: No.

RM: It was really a revolutionary decade in the ’90s. We knew RU-486 was going to be very important especially in states were surgical abortions are not permitted. And if they overturn *Roe v. Wade*, it’s going to be really important. What’s interesting if you look through the panels in this program [referring to conference program], these are the topics that I thought were important to discuss. This is in 1994. It includes a panel on RU-486.

VB: So, I had asked you if research was part -- was on your agenda from the beginning with the Office of Women’s Health, what about outreach? Did you envision that it’s always going to be part of the mission of the Office of Women’s Health?

RM: Yes. And that was part of the way the mission was written from the very beginning. But at that time, the Office of Consumer Affairs was very much in existence, so we had to tread lightly on how much we did versus what the Office of Consumer Affairs did. But Audrey brought in this other way of positioning it with the Take Time to Care program and that was a great success.

VB: In fact, it was a great tactic for getting information to women and for appealing to their role as caretakers. And it’s grown so much over time. So, I guess in that sense, you were blessed with a very active community?

RM: Everyone was so happy to be able to focus on this because everyone in the office was a "feminist" and a woman's health activist but also totally focused on making sure that science and ethics were at the heart of everything that we did. Elyse Summers went on to lead the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP), one of the key groups that reviews IRBs. I was blessed with very capable people.

[00:40:00]

[RECORDING PAUSED; NEW AUDIO FILE]

VB: So, when OWH came into existence, you had already been working with different people throughout the agency on so many different issues. How did the rest of the agency perceive the Office of Women's Health? Did they know how to interface with it?

RM: I think there are always going to be the supporters and the naysayers and people who were a little reluctant to change. We had a retreat actually to iron out the development of an Office of Women's Health.

VB: With just the office or other agency leadership, as well?

RM: No. Leadership within the agency. We had a retreat on opening up an office.

VB: How did that go?

RM: Well, I think, for the most part, it was fine. There were a few people who were skeptical I remember one comment was made that, "Well, these issues are very important, but they probably can be ironed out and then the office will sunset." I think that's in the transcript somewhere because I heard from Marsha Henderson that she read about that somewhere.

VB: She told me that too.

RM: I still remember, that at the outset several thought the office could sunset.

VB: That it would deal with the clinical trials' guidelines and then it would serve its purpose?

RM: Fulfill its mission and that would be the end of it.

VB: Lucky for us that it wasn't.

RM: And I think that there are still some of that from what I hear in talking to different people occasionally that it may still be an issue.

VB: I'm sure there's always tension over who should play what role and how to share power. But I think there are a lot of things OWH has done that are genuinely appreciated. But one thing that I don't think was originally part of the vision is to provide training to the other centers on how to view approvals or policymaking through the women's health lens. I think there's a lot of recognized added value in that.

RM: We actually started going around to the different divisions to talk about the issue of analyzing data for women and making sure that women were in the clinical trials. I remember I personally went around and sometimes got darts thrown at me. There were a couple of divisions that were tough in that regard. Others were very open and easy to work; others were tough, but that was OK. It made me, it made us as an office realize how important it was to have the science behind us every step of the way and to make improvement is science the underpinnings of everything we did.

VB: Was CDRH enthusiastic about the partnership with OWH?

RM: CDRH was very good to work with.

VB: They had a lot of really hard issues to deal with in that time period. I would imagine they would've been grateful for support on women's health issues.

RM: Well, they had breast implants.

VB: Yeah, and they still do.

RM: And that was just really tough.

[Referring to conference program] We organized this Gender Effects on Product Development conference -- this was a very, very important program. There was a meeting 10 years later to talk about issues of drugs in pregnancy. Sandra Kweder gave opening remarks, and in those opening remarks, she refers to this conference. There were sessions on study design and analysis, hormonal influences on metabolism, bioequivalence trials.

VB: Why does it resonate for you as such an important conference?

RM: Because the issue of drugs on pregnant women is still not resolved. It took them more than 20 years to make any changes to the way drugs are categorized in pregnancies -- the A, B, C, D.

VB: And in the 2000s OWH started working on -- maybe you were working on it before then just the internet hadn't become fully useful yet -- were the pregnancy registries.

RM: We had some pregnancy registries. That was just beginning. In fact, after I left FDA and went to work for Pfizer, we started a pregnancy registry for sertraline (ZOLOFT). But, yes, it was in its infancy at that point.

VB: Was that something that came out of this conference?

RM: The registries? I can't remember. Recommendations, yes. [Esther Rome was a staunch advocate and actively supportive our work to change pregnancy labeling in favor of more information about what we did and didn't know about how drugs work in pregnancy. There was so little research with pregnant women, an area in great need of research and data. Vivian Pinn.

VB: Susan Wood was involved in this conference too. It says '94. I think she was still on the Hill at that point.

RM: She was on the Hill. She ran the Women's Caucus on the Hill. That's how I came to know Susan because I testified on the hill about eight times, including several testimonies to the Women's Caucus.

VB: In four years? That's a lot.

RM: And, of course, clinical trials is one of the topics that we would have been speaking about. I have on my CV the topics that I testified about on the Hill.

In 1994 I led OWH's early efforts to examine emergency off-label use of oral contraceptives, which ended up as Plan B. No pharmaceutical company would come forward to submit and application. Usually, a pharmaceutical company is dying to get their drug approved. Not in this case, so Mary Pendergast and I went out and actively sought applications.

VB: What do you attribute all the resistance to?

RM: Plan B? It's the whole issue of likening it to abortion.

VB: One thing I find so peculiar about the Plan B controversy is when the prescription NDA was originally approved, it didn't -- not to say it wasn't controversial, but it did not draw the same level of scrutiny as the OTC application. Do you have any insight into why?

RM: I think timing was an issue and the political environment. It was during the time that Clinton was in office.

VB: The OTC was 2005, so it was under Bush II. And the prescription approval I think was '98 or '99, late '90s, so it was under the Bill Clinton era.

RM: [Referring to pamphlet] "FDA: Making a Difference in Women's Health," I don't know what year this is. July 1994.

VB: Can I share something with you? I don't know if you have this in here. This is the *FDA Consumer* article from the fall of 1994 that discusses cardiovascular disease and the sex differences.

RM: Marianne Legato? I worked with Marianne. And Nanette Wenger. We had all these bright, talented women involved in the work we were doing and involved in publishing the special edition of *FDA Consumer* on this topic.

So, when I went to Pfizer -- and I didn't have to do marketing of a drugs -- they gave me a budget to promote women's health, which was great. And consistent with Pfizer's product portfolio the first thing I focused on was cardiovascular disease, the number one killer of women but little talked about (Pfizer had NORVASC and then they acquired LIPITOR). We also focused on mental health and depression (Pfizer had ZOLOFT) . and then arthritis -- all major medical challenges for women. So, I focused on serious diseases that affect women, which Pfizer was proud to promote… we developed educational materials for women and their health care providers that could be distributed nationally.

VB: Did you draw on your experience at FDA when you moved to Pfizer or any point since?

RM: Absolutely. Pfizer didn't really understand what women's health was. Like so many, they, too, thought women's health was reproductive health. They were not into contraception or any of those therapeutic areas at the time. So, I said, "think about heart disease and think about your number one product in Pfizer, NORVASC." so, they loved it and we developed all these educational materials for the health care providers and for their patients that the reps could take into doctors' offices. It was a real win-win for them and an effective way to get health information to women.

And then I partnered with WomenHeart, the first advocacy organization on heart disease in women, and we started "Heart Parties" in which we partnered with communities to raise awareness of heart disease in women. There would be a race and or a walk, and there would be a party afterward; we did it in Dallas, Boston, and then in Wisconsin, and everyone loved it

VB: And that was in the ’90s?

RM: That was after I went to Pfizer in 1997. I was at Pfizer from ’97 to 2005 and we had the heart parties somewhere in that timeframe.

VB: Did you work on anything between FDA and Pfizer?

RM: No, I left the end of 1996. I still remember leaving because my husband was not well. He was diagnosed with cancer, was receiving chemotherapy and I couldn’t continue commuting. When I started at FDA in September of ’91, my husband was also in Washington doing a Sabbatical as a Robert Wood Johnson health policy scholar. But he had to return to his work at Einstein Medical School by December of ’92, so by 1996 I had been commuting five years. It was hard for him to be alone when he was ill (our kids were out of the house by that time).

VB: And he was teaching?

RM: Yes, he was still doing his job. He never lost a day of work even though he was receiving chemo.

VB: He's the kind of person that thrives on his work?

RM: Yes.

VB: So, you left FDA in late '96. And Audrey was your deputy, I guess, at that point?

RM: Right.

VB: Where did you leave things, and what were you hoping for the office when you left?

RM: Well, I certainly hoped that they would continue the work on clinical trials. We needed to have a final regulation on the inclusion of women, which came out in '98 as part of the Food and Drug Administration Modernization Act. I had worked with Bob Temple on writing that. We laid the groundwork for focusing on clinical trials. And I was hopeful that office could continue to collaborate with other offices and Centers and focus on breast implants, contraception, and HIV.

VB: I recall that in 1993, before OWH was founded, you helped change the labeling on contraceptives to include the STD disclaimer.

RM: Based on my clinical nursing experience, I realized that many women and their partners were unclear about how various contraceptives worked and the protection they provided. We conducted a small study on what women thought about their contraceptives; many thought contraceptives like oral contraceptives protected them against STDs.

VB: Oh, that's scary.

RM: There was no controversy about that change, no one in the agency opposed it]. Working with them made the change. That was the advantage of the old Parklawn Building, I think. It was very "heimish" if you will. My office was just around the corner to the Division of Reproductive Health Drugs. We were in each other's offices all the time and had a very collegial relationship. It was easy to collaborate and come up with new ideas.

[01:00:00]

RM: With this idea, we just made it happen.

VB: There was so much advocacy work around condom use in the early ’90s. Do you think that partly led to the misconception, that if you use any birth control it would protect you against STDs?

RM: Yes. But we just wanted to make sure that people didn’t think that if they took a pill, they were going to also be protected against HIV or other STDs. We had a collection of all these novelty condoms. We had collected hundreds of condoms in the office -- they were unbelievable, but women were using them, not realizing that many of them didn’t provide any protection.

VB: Oh, that’s terrible.

VB: While you were at the FDA, did you miss interacting with patients?

RM: I did, and maybe that’s why I worked closely with the various consumer groups. But, you know, I had worked with patients my whole career, so it was okay. This was so exciting to me to really learn firsthand how governmental checks and balances really work. I mean there were always things going on, you had to be careful that you didn’t get lost in the fray. Another big thing I was involved in was starting a group with Randy Wykoff, who was the Director of the AIDS Coordination Staff. We wanted to look at whether or not spermicides might protect against HIV, and we were particularly interested in nonoxynol-9. So, we had this task force

comprised of people from the FDA and NIH. I remember being on vacation and taking some calls when that task force was holding meetings. And that led to the study of nonoxynol-9 (conducted by Carol Trapnell at Johns Hopkins) and whether or not it provided any protection, and what they found, of course, is that not only did it not provide protection but it was a risk for transmission of HIV.

VB: I didn't realize that. Why does it increase risk?

RM: It can create some small abrasions of the epithelium of the vagina, which is a portal of entry for the virus. And because we knew then that we needed to develop a spermicide or something that could protect women from HIV transmission in addition to condom use. While effective its use is sporadic.

In fact, one of the major areas of focus of work at the Population Council when I joined that organization in 2005 was microbicides, which is still going on. When I started working at the Population Council, they were conducting a phase 3 trial in South Africa with carrageenan (Carraguard) to protect against vaginal transmission. It was not successful; it didn't show efficacy, but part of the problem with the method was that not all women in the trial used the product despite claiming they had. Adherence in clinical trials continues to be a huge issue and is an area that I have continued to work on with clinical and social science colleagues.

VB: I'm just curious. You mentioned the folic acid research?

RM: Yes.

VB: That is one particularly interesting area where foods and drugs have this sort of murky, shared territory. And I noticed that one of the first studies you funded out of the Office of Women's Health had looked at listeriosis.

RM: But it had to do with pregnancy, and pregnancy was always something I always focused on based on my clinical nursing experience. Which is why I think I wanted to do this conference so early on the issue of drugs in pregnancy. But listeriosis -- especially with immigrant populations -- was an issue and that's why we funded research on it.

VB: So, I was saying before, what were your hopes for the Office of Women's Health when you departed. And you said certainly that they continue the work with clinical trials. Was there anything else?

RM: To continue to work across the centers. Because there are always going to be issues in the centers that have a women's health focus whether it's reviewing a new device for contraception, certainly the breast implants or devices for any part of the body where there are anatomical differences, even in size, musculature. Devices have a lot of issues, all of the various

types of equipment that are used for men and women, which traditionally have been tested primarily in men.

I'll just give you an example, and this wasn't at the time that I was there but... In 2009, my mother who was quite elderly at the time was diagnosed with lung cancer out of the blue. We thought she had bad kidney disease, which she did. But she was having some trouble breathing, and I had to race her to the hospital. They tapped her chest, and she was filled with fluid and when they analyzed the fluid, it was lung cancer. So, they had to put in a chest tube, and I remember they had to go in twice. The chest tubes that they had were so long and so big, and my mother was very thin. They had to keep cutting her chest tubes. They didn't have a chest tube for her body build because the chest tubes were all built for men. Something as simple as that, and this is a CDRH issue. So, just like the drugs weren't being tested in women, the devices weren't being tested in women. For me that experience watching my mother hit home to me more than anything else, why drugs, devices, biologics must all be tested with women as well as with men.

VB: I can't remember the year that OWH funded research on customizing artificial heart valve development for women.

RM: Yeah, I can't remember that either but that was --.

VB: Obviously a long time coming.

RM: So, that's why in the Office of Women's Health, not that the centers can't do it but the centers may not be focused on it. It's not only doing it, it's focusing around the doing, what needs to happen, including, how to get the message out to the various constituents.

VB: The agency, I think, is pretty good about being consistent in consumer messages, but if you have information for an entire group of constituents that spans different product areas, it does make sense to have one place --

RM: Right.

VB: -- especially if they're half the population. But I do also see the value in having advisors on women's health in the centers as well as a complement to that.

RM: Yes, absolutely. And maybe they'll feel more comfortable with an in-house group as opposed to going to the Office of the Commissioner.

VB: Yes, it's more direct, it's more -- informal perhaps isn't the right word, but also constant, right?

RM: Constant.

VB: Instead of just we have to have a special meeting or -- and then we can't just walk down the hall --

RM: I harken back to the relationship I had with the reproductive division in the Center for Drugs before we had an Office of Women's Health where we were neighbors, and we were constantly talking to each other. And so there was a lot that we were able to do together because of that.

VB: Yeah. That creates opportunities that you just wouldn't have otherwise.

So, since leaving FDA, have you followed the Office of Women's Health?

RM: Yes. I've kept in touch with all the subsequent directors. We have our own little network between Audrey and Susan and Marsha Henderson.

VB: Do you have any wishes for the Office of Women's Health now 25 years down the line?

RM: There are still some of the same issues today that we confronted back then. Look at breast implants for example and this finding about the lymphoma. By the way, this -- I don't know if you ever saw these. I wrote two papers based on letters that we received from consumers about their breast implants. This was published in 1993. I was busy. We took the letters, and together with Jane McCarthy and Grant Bagley from the Office of Constituent Health Affairs we published two papers, "A Qualitative Analysis of Self-Reported Experiences among Women Encountering Difficulties with their [*sic*] Implants," and "A Descriptive Analysis of Physical Complaints from Women with Silicone Breast Implants." We had received thousands of letters, at the Agency about breast implants from both satisfied women and dissatisfied women also wrote letters. Some of them also testified at FDA advisory committee hearings. We did a qualitative review of those letters and published the findings.

VB: I imagine that there was a much higher volume of patient contact with the FDA about ruptured implants or about the controversy about the implants than many other products.

RM: Yeah, because it got so much press.

VB: And it becomes such an emotional issue for women -- for some women who view it as such an important part of their recovery and for others who view it as a very dangerous practice that shouldn't be permitted, and nevertheless so intimate that it's just difficult to talk about. From the professional community, did you get a response about these kinds of publications?

RM: Oh yes. There were pros and cons from the professional community as well.

VB: I suppose that's to be expected. Well, in closing, is there anything from this time that when you think back about it, that really stands out, any things you're particularly proud of or things that you wish you could've done that there just wasn't time for or opportunity for?

RM: Well, I have to say, overall, I was very, very grateful for the opportunity… it was a once-in-a-lifetime opportunity. Maybe it was a sign of the times. We were able to, I think, accomplish quite a bit. It's never enough in terms of what more we could've done. The fact that we didn't really deal with the issue of drugs in pregnancy, but there are so many ethical questions associated with testing drugs in pregnancy. We had a task force with the NICHD that looked at the whole issue of informed consent for doing clinical trials in pregnant women. Who signs the informed consent? The mother? The mother and father? What do you do if there's no involved father?

So, I would say that I'm grateful for the things that we were able to accomplish, but it was just like opening the door and tiptoeing. I'm also grateful that the agency is continuing, to focus attention on the issues that are unique to women. But as with everything else, it is tied up with politics and we don't always have control over that. But I hope that the advocacy community remains strong and is always there backing the OWH but looking critically at what it is or is not doing. And, certainly, whatever I was able to do, it was not me alone. It was

wonderful support and guidance from colleagues like Mary Pendergast, and David Kessler was terrific. He pushed me but in the right direction. He had good instincts about what was right at that particular time.

VB: And of all of the accomplishments under his time as commissioner, the Office of Women's Health have lasted and grown and is now congressionally mandated --

VB: Well, I could keep talking to you all afternoon, but I know you have other things to do. So, thank you so much.

RM: I hope it was helpful.

VB: It's very helpful and a really important history that I'm really glad we were able to capture.

END OF INTERVIEW

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EDUCATION

	DEGREE/YEAR
Cornell University, Ithaca, NY Cornell University—The New York Hospital School of Nursing New York, NY	BS, RN - 1961
Frances Payne Bolton School of Nursing, Case Western Reserve University Cleveland, Ohio	MS - 1977
Adelphi University, School of Nursing Garden City, Long Island, NY	PhD - 1989

PROFESSIONAL EMPLOYMENT

Surgical Staff Nurse The New York Hospital, New York, NY	1961 – 1962 1965 - 1966
Camp Nurse Camp HES, Bear Mountain, New York	1966
Nurse Instructor The New York Hospital, Lying-In Division, New York, NY	1966 - 1970
Clinical Nurse Specialist (Maternal/Child Health) (Clinical Care & Staff Education/Parent Education &Counseling; The New York Hospital, Lying-In Division, New York, NY	1970 - 1973
Nurse Clinician	1976 - 1982
Postpartum Nursing; University Hospitals of Cleveland MacDonald House, Cleveland, Ohio	
Assistant Director of Nursing: Nurse Clinician-Maternal/Child & &Women's Health/Nurse Researcher The Jack D. Weiler Hospital of the AECOM: MMC Albert Einstein College of Medicine	1982 - 1990
Director of Nursing (Acting) The Jack D. Weiler Hospital of the Albert Einstein College of Medicine/ Montefiore Medical Center (MMC), New York, NY	1990 – 1991
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U.S. Food and Drug Administration—Department of
Health and Human Services, Washington, DC

Director, Office of Women's Health 1994 - 1996
U.S. Food and Drug Administration—Department of
Health and Human Services, Washington, DC
(Established the Office & Mission- ongoing today)*

Director/Team Leader, Pfizer Women's Health; 1997 – 2005
Pfizer Pharmaceuticals Group, Pfizer Inc, New York, NY

Project Director, Contraceptive Development, Population Council 2005 - 2007

Director, Clinical Development, Reproductive Health 2007 - Present
Population Council

ACADEMIC APPOINTMENTS

Clinical Instructor 1976 - 1979
Maternity Nursing-University Hospitals of Cleveland
Frances Payne Bolton School of Nursing, Case Western Reserve University

Assistant Clinical Professor 1979 - 1983
Frances Payne Bolton School of Nursing
Case Western Reserve University, Cleveland, Ohio

Adjunct Lecturer 1982 - 1986
Lehman College of the City University of New York

Clinical Assistant Professor 1989 - 1995
Department of Obstetrics & Gynecology and Women's Health
Albert Einstein College of Medicine

Clinical Associate Professor 1995 - Present
Department of Obstetrics & Gynecology and Women's Health
Department of Epidemiology and Social Medicine
Albert Einstein College of Medicine

Adjunct Professor, Division of Nursing 1997 - 2000
New York University

Clinical Professor 2015-Present
Department of Obstetrics & Gynecology and Women's Health
Albert Einstein College of Medicine

POLITICAL APPOINTMENTS 2001 - Present
Westchester County Board of Health

PROFESSIONAL SOCIETY MEMBERSHIPS (Current)
American Academy of Nursing

American Nurses Association (New York State Chapter)
Association of Women's Health, Obstetric, and Neonatal Nurses
Association of Reproductive Health Professionals
Sigma Theta Tau (Alpha Upsilon Chapter)

LICENSURE

New York Nursing Registration ID # 157030-1 Current
Ohio Nursing Registration ID # 21-13-4921
Washington, DC License ID # 58611

DISTINCTIONS

Sigma Theta Tau 1965
National Nursing Honorary Society

Helen Bunge Award for Nursing Research: 1977
Frances Payne Bolton School of Nursing
Case Western Reserve University

Award for Excellence in Nursing: 1977
Frances Payne Bolton School of Nursing
Case Western Reserve University

Certificate of Recognition for Contributions to the Community: 1982
Federation for Community Planning, Cleveland, Ohio

Bolton Award for the Professional Member Making an
Outstanding Contribution to the Community: 1982
Junior League of Cleveland, Ohio

FDA Commissioner's Special Citation for Contributions to the May, 1992
Scientific and Policy Issues Associated with Breast Implants

FDA Commissioner's Special Citation for Exceptional Skill and May, 1993
Commitment in Successfully Changing FDA Policy to Allow Women
of Childbearing Potential to Participate in Early Phase Drug Trials

Distinguished Alumnus Award: May, 1994
Cornell University-The New York Hospital School of Nursing

FDA Commissioner's Special Group Citation May, 1995
for Outstanding Service to the National AIDS Drug
Development Task Force

FDA Commissioner's Special Group Citation for
Establishing the Mammography Information Service
May, 1995

Fellow of the American Academy of Nursing November, 1995

FDA Commissioner's Special Citation for Outstanding December, 1995

Leadership and Vision in Establishing the Office of Women's Health

Distinguished Alumnus Award — May, 1996
Adelphi University; School of Nursing

FDA Commissioner's Special Citation for — January, 1997
Outstanding Contributions to the Women's Health
Program of the FDA

Athena Award — February, 1999
Partnership for Women's Health
Columbia University

Honoree, International Health Awareness Network — March, 1999

Career Achievement Award: Assoc of Women's Health, Obstetrics — June, 2002
& Neonatal Nursing

Best in Class, Top Scientific Research - Internationals Family Planning Research
Conference, International Conference on Family Planning, — November 15, 2013
Addis Ababa, Ethiopia; Sponsored by B & M Gates Foundation & Johns Hopkins
University School of Public Health

Case Western Reserve Univ. Graduation Speaker- Frances Payne Bolton School
of Nursing — December 5, 2014

RESEARCH/GRANT SUPPORT

Long-term Follow-up of High Risk Mothers, Infants and Families. — 1978 – 1981
The Robert Wood Johnson Foundation

The Effects of Frequency and Duration of Early Breast-Feeding on — 1980 - 1983
Development of Nipple Soreness, Milk Output, Infant Serum Bilirubin,
and Infant Well-Being on the Longevity of Nursing.
University Hospitals of Cleveland Fund

Doctoral Dissertation: The Influence of Maternal Attachment and the — 1989
Capacity for Empathy on Perception of Social Support among Pregnant
Minority Women.
Grant Support - Sigma Theta Tau

Co- Principal Investigator & Technical Coordinator:
Development of a new contraceptive vaginal ring with Nestorone® &
Ethinyl estradiol (Phase 3 trial) USAID Cooperative Agreement;
PO-A-00-04-00019- Population Council Product Development;
9/05 – 6/31/09
7/09-6/14

Acceptability of a Contraceptive Vaginal Ring: Supplementary study within
RO1 project **3RO1HD047764-02S2,** Assessing & Improving the Measurement

of Sexual Behavior; NIH/NICHD. Co-Investigator 9/05– 5/12

Co-Principle Investigator: Delivering Contraceptive Vaginal Rings: Annual Program Statement No. SOL-OAA-13-000024: Agreement No. USAID-0AA-A-13-00075 Family Planning & Reproductive Health to Address Unmet Need 10/13-9/18

ADDITIONAL CERTIFICATION

American Society for Psychoprophylaxis in Obstetrics 1969 - 1991
New York, NY

The National Certification Board of Diabetes Educators 1986 – 2000
Certified Diabetes Educator (CDE)

BOARD AFFILIATIONS

The National Certification Board of Diabetes Educators 1986 – 2000
Certified Diabetes Educator (CDE)

President's Council of Cornell Women- Cornell University 1995 – Present

Friends of the Institute of Nursing Research 1999 - 2005

Jacobs Institute of Women's Health 1999 – 2005

Westchester County Board of Health 2002- Present

New York Hall of Science 2004 – 2007

Scientific Advisory Committee- International Partnership for 2006- Present

Rosalind Franklin Society, Founding Board Member 2007- Present

International Partnership for Microbicides (IPM) Scientific Advisory Board 2009-Present
Chair- IPM/USAID Project Advisory Committee (PAC) 2014- Present

PROFESSIONAL & COMMUNITY ACTIVITIES AND AFFILIATIONS

Editor, Cornell Alumni News (School of Nursing) 1965 – 1968

Member, New York State Democratic Party 1965 – 1973
1992- Present

Committee to Recreate St. Catherine's Park, 1968 - 1973
NYC Steering and Planning Committee

Chairperson, Women's Program, American Congress on 1971
Fertility and Sterility, New York City

New York Junior League 1973

Cleveland Junior League	1973 - 1982
Western Reserve Historical Society, Docent	1973 - 1974
"Friends to New Mothers"; Proposer and Advisor to new program for Maternal and Infant Care Project of Cleveland	1974 - 1976
Mercer School Parent Teachers Association; Parent Aide Shaker Heights, Ohio	1976 - 1978
Editorial Advisory Board, The Female Patient.	1976 - 1978
Chairperson, Committee for Early Detection and Prevention of Child Abuse/Neglect; Federation for Community Planning Cleveland, Ohio	1977 - 1982
Chairperson, Healthy Baby Month, Sponsored by Cleveland Chapter, March of Dimes	1977
Committee for Children at Risk, Member under Federation for Community Planning, Cleveland, Ohio	1978 - 1982
Co-Chairperson, Institute on Children at Risk: The Home, School and Community, Cleveland, Ohio	1978
Coach "Crash Course in Childhood" developed by Dr. Ray Helfer, Cleveland, Ohio	1978 - 1979
Co-Chairperson, Parenting Disorders in Pediatric Settings Sponsored by Cleveland Regional Perinatal Network and Cleveland Council on Children at Risk	1979
Chairperson, Volunteer Program to Provide Support to New Mothers: Mac Donald House University Hospitals of Cleveland	1980 - 1982
New York City Steering Committee on Breast-Feeding New York State Department of Health	1983 - 1991
Nominating Committee, Rye Neck Board of Education	1985 - 1988
Bronx Community Child Abuse Task Force	1985 - 1991
Advisory Board Member, Prevention Intervention Research Center (PIRC), Albert Einstein College of Medicine Bronx Breast Feeding Project	1986 - 1991
Human Rights Commission Member, Rye, New York.	1986 -1991
Co-Chairperson, Bioethics Committee Weiler Division/Montefiore Medical Center.	1987 - 1991

Nurse Consultant American International Perinatal Health, Inc. .	1989
Education Chairperson, Mid Hudson Valley Region New York State Perinatal Association	1989 - 1991
Editorial Advisory Board, Obstetrics and Gynecology	1989 – 1995
Member, Women's Health Coordinating Committee, U.S. Public Health Service	1991 - 1997
Member, Surgeon General's Committee for Women and Children with AIDS; U.S. Public Health Service	1991 – 1997
Editorial Advisory Board, Journal of Women's Health	1992 - Present
Member, Consumer Education Committee, NAACOG.	1992 - 1993
Member, Breast Implant Research Task Force, US Public Health Service	1992
Member, DHHS Inter-Agency Working Group on Breast and Gynecologic Cancer, US Public Health Service.	1993 - Present
Invited Member, President's Council of Cornell Women; (Chair -Special Task Force on Health of Cornell Students)	1995 - Present 1999-2001
Contributing Member-National Action Plan on Breast Cancer US Public Health Service.	1993 - 1995
Member, Planning Group under National Plan on Breast Cancer to Implement a Comprehensive Plan to Address the Needs of Individuals Carrying Breast Cancer Susceptibility Gene(s), US Public Health Service	1994
Editorial Advisory Board, American Journal of Public Health.	1994 - 1995
Program Chair, FDA Regulated Products and Pregnant Women; Arlington, VA	11/7 – 8/1994
Member, Human Subject Regulation Drafting Committee To Revise Subpart B, CFR, Part 46 Additional DHHS Protections Pertaining to Research for Pregnant Women, Human Fetuses Member, Human Subject Regulation Drafting Committee; US DHHS	1994-1995
Board Member- Jacobs Institute of Women's Health	1995-2003
Board Member, Friends of the National Institute of Nursing Research- NIH	2002-2006
Program Co-Chair, FDA Regulated Products and Pregnant	11/7-8/1994

Women, US FDA, Crystal City, VA

Program Co-Chair, Gender Studies in Product Development: Scientific Issues and Approaches; US FDA, Rockville, MD — 11/6-7/1995

Invited Participant, "Beyond Hunt Valley: Research in Women's Health for the 21st Century, Scientific Meeting Sponsored by the Office of Research on Women's Health of the National Institutes of Health; Philadelphia, Pa., Santa Fe, NM, Bethesda, MD — 9/25-26/96

Volunteer, HIV Law Project, NYC — 1998 - 2003

Special Task Force on Nursing Shortage, City University of NY — 2001

Institute of Medicine Reviewer: Exploring the Biological Contributions To Health: Does Sex Matter? — 2001

Institute of Medicine Committee Member: New Frontiers in Contraception: A Blueprint for Action — 2003 - 2004

EINSTEIN AND POPULATION COUNCIL TEACHING ACTIVITIES

Conference Director: *Autumn in New York* — 11/14-15, 1993
"Women's Health Across the Lifespan"
Department of Obstetrics & Gynecology
Albert Einstein College of Medicine
Bronx, NY

Participant/Speaker: *Autumn in New York* — 11/15-16/2003
"A Commitment to Equity in Women's and Perinatal Health: Closing the Gaps"
Department of Obstetrics & Gynecology and Women's Health
Albert Einstein College of Medicine
Bronx, NY

Journey to Uganda- Grand Rounds Lecture* (sparked Departmental Interest among Faculty and students to embark upon teaching and service in selected SSA countries — 10/11/ 2005

Organizing Committee: *Autumn in New York* — 11/10-12/2006
"Women's Health: A Global Perspective In Honor of Allan Rosenfield, MD"
Department of Obstetrics & Gynecology and Women's Health
Albert Einstein College of Medicine
Bronx, NY

Director, Mentor — 2009-present
Population Council's Family Planning Teaching/Learning Program offered semi-annually to Selected Family Planning Fellows training under US Family Planning Fellowship Program
Mentored 10 Family Planning Fellows

Bixby Fellowship Mentor (Population Council) Mentor to Dr. Yongmei Huang 10/10-8/13
(International Peace Maternity and Child Health Hospital: Shanghai Institute of
Family Planning Technical Instruction

Program Committee: *Autumn in New York* 11/19/2013
"Local and Global Health Issues of Adolescent Girls"
Department of Obstetrics & Gynecology and Women's Health
Albert Einstein College of Medicine
Bronx, NY

Fellowship Director for Research 2014-present
Family Planning Fellowship
Department of Obstetrics and Gynecology & Women's Health
Albert Einstein College of Medicine (Assisted in preparation of Einstein fellowship application and site
Visit in 2014; Fellowship status awarded to Dept. of Obs and GYN & Women's Health
July 2014.

Mentored Dr. Carol Sales Vieira- FP fellowship at Population Council; Sept 2016-Jan 2018
Sponsored by Medical School of Ribeirao Preto, University of Sao Paulo, Brazil

ORIGINAL COMMUNICATIONS IN REVIEWED JOURNALS

1. Smith E, Veolitze M, **Merkatz R**. Social aspects of abortion counseling for patients undergoing elective abortion. ClinObstet Gynecol 1971 Mar; 14(1): 204-16**.**

2. **Merkatz R,** Smith E, Seitz R. Preoperative teaching for gynecologic patients. Am J Nurs 1974 June; 74(6) 1072-4.

3. **Merkatz RB**. Budd K. Merkatz IR. Psychological and social implications of scientific care for pregnant diabetic women. Sem in Perinatol 1978 October; 11(4):373-81.

4. DeCarvalho M. , Robertson S. Klaus M. **Merkatz RB.** The effects of frequency and duration of breast feeding on serum bilirubin, weight gain and milk output. Ped Res. 1981. 15. 530; doi 0.1203/00006450-198104001-00552

5. DeCarvalho M. Klaus MH. **Merkatz RB**. The effects of frequency of breast-feeding on serum bilirubin concentration. Am J Dis Child 1982 Aug; 136: (8):737-8.

6. Pittard WB. **Merkatz R.** Fletcher BD. Radioactive excretion in human milk following administration of technetium TC-99m macroaggregated albumin. Pediatrics, 1982 Aug; 70(2):231-4.

7. DeCarvalho M. Robertson S. **Merkatz RB.** Klaus MH. Milk intake and frequency of feeding in breast-fed infants. Early Hum Dev 1982 Nov; 7(2):155-63.

8. Anderson D. Williams F. **Merkatz RB.** Schulman P. Kerr D. Pittard W. Length of gestation and nutritional components of human milk. Am J Clin Nutr 1983 May; 37(5):810-14.

9. Langer O. Levy J. Brustman L. Anyaegbunam A. **Merkatz RB**. Divon M: Glycemic Control in GDM - How tight is tight enough: Sga vs lga. Am J Obstet Gynecol 1989 Sep; 161(3): 646-53.

10. **Merkatz RB** & Merkatz IR: The contribution of the nurse and the machine in home uterine monitoring systems. Am J Obstet Gynecol 1991 May; 164(5Pt1):1159-1162.

11. Mikhail MS. Freda MC. **Merkatz RB.** Polizzotto R. Mazloon E. Merkatz IR. The effect of fetal movement counting on maternal attachment to fetus. Am J Obstet Gynecol 1991 October; 165(4Pt1):998-991.

12. **Merkatz RB** & Couig MP. Helping America take its medicine. Am J Nurs 1992 June; 92(6):59-62.

13. **Merkatz RB**. Bagley GP. McCarthy EJ. A qualitative analysis of self reported experiences among women encountering difficulties with silicone breast implants. J Wom Health 1993 Summer; 2(2):105-9.

14. McCarthy EJ. **Merkatz RB**. Bagley GP. A descriptive analysis of physical complaints from women with silicone breast implants. J Wom Health 1993 Summer; 2(2): 111-15.

15. **Merkatz RB**. Temple R. Sobel S. Feiden K. Kessler DA. Women in clinical trials of new drugs and biologics: A change in FDA policy. N Engl J Med. 1993 July; 329(4):292-296.

16. Kessler DA. **Merkatz RB**. Shapiro R. A call for higher standards for breast implants. JAMA 1993 Dec 1; 270(21):2607-8.

17. **Merkatz RB**. FDA: Making a difference in women's health. J Am Med Wom Assoc 1994 July/Aug; 49(4)117-120.

18. **Merkatz RB**. White Junod S. Historical background of changes in FDA policy on the study and evaluation of drugs in women. Acad Med 1994 Sept; 69(9):703-707.

19. Sherman LA. Temple R. **Merkatz RB**. Women in clinical trials: An FDA perspective. Science. Aug 11, 1995; 269:793-5.

20. **Merkatz RB.** Inclusion of women in clinical trials: A Historical overview of scientific, ethical, and legal issues. JOGNN. 1998 Jan/Feb; 27(1): 001-7

21. **Merkatz RB.** Female Sexuality: Scientific Advances- Editorial. JWH. May 2002; 11(4): 331-3

22. **Merkatz RB.** FDA's Office of Women's Health- Will it Endure. JWH August 2007; 16(6):818-826.

23. **Merkatz RB,** Tokay B, Sitruk-Ware RL. Methods for female contraception: A model for innovation in drug delivery systems. Clin Pharmacology & Therapeutics. May 2009 85 (5): 553-7.

24. Huang YM, **Merkatz R,** Kang JZ, Roberts K, Hu XY, Di Donato F, Sitruk-Ware R, Cheng LN. Postpartum unintended pregnancy and contraception practice among rural-to-urban migrant women in Shanghai. Contraception. 2012 Dec; 86(6):731-8.

25. RamaRao S, Clark H, **Merkatz R**, Sussman H, Sitruk-Ware R. Progesterone vaginal ring: introducing a contraceptive to meet the needs of breastfeeding women. Contraception 2013 Nov; 88(5), 591-8). doi: 10.1016/j.contraception.2013.05.004. Epub 2013 May 16

26. Huang YM, **Merkatz R,** Zu, Zuu, Roberts K, F, Sitruk-Ware R, Cheng LN. The free perinatal/postpartum contraceptive services project for migrant women in Shanghai: Effects on the incidence of unintended pregnancy. Contraception 2014 June; 89 (6) 521-7.

27. **Merkatz RM,** Plagianos M**,** Hoskin E, M, Hewett P, Mensch B. Contraception**.** Acceptability of the Nestorone®/Ethinyl Estradiol Contraceptive Vaginal Ring; Development of a Model; Implications for Introduction. Contraception. 90 (5) 2014, 514–21.

28. Huang Y. Jensen JT, , Brache V, Cochon L, Williams A, Miranda MJ , Croxatto H, Kumar N, Sussman H, Hoskin E, Plagianos M, Roberts R, **Merkatz R.** Blithe D, Sitruk-Ware R.. A randomized study on pharmacodynamic effects of vaginal rings delivering the progesterone receptor modulator ulipristal acetate: research for a novel estrogen-free, method of contraception. Contraception. 90 (6) 2014, 559-622.

29. Brache V, **Merkatz R**, Kumar N, Jesam C, Sussman H, Hoskin E, Roberts K, Alami M, Taylor D, Jorge A, Croxatto H, Lorange E, Mishell DR, Sitruk-Ware R. A dose-finding, cross-over study to evaluate the effect of a Nestorone®/Estradiol transdermal gel delivery on ovulation suppression in normal ovulating women. CONTRACEPTION Epub 2015 May 29

30. Huang T, **Merkatz RB,** Hillier SL, Roberts K, Blithe DL, Sitruk-Ware R, Creinin, MD. Effects of a One Year Reusable Contraceptive Vaginal Ring on Vaginal Microflora and the Risk of Vaginal Infection: An Open-Label Prospective Evaluation. PLOS ONE. Aug 14, 2015, DOI 10.1371, journal pone 0134460.

31. Archer DF, Thomas MA, Conard J, **Merkatz RB**, Creasy GW, Roberts K, Plagianos M, Blithe D, Sitruk-Ware R. Impact on Hepatic Estrogen-Sensitive Proteins by a One-Year Contraceptive Vaginal Ring Delivering Nestorone® and Ethinyl Estradiol. Contraception. 2015 doi:10.1016/j 15.09.008.

32. Sitruk-Ware R, Ramarao S, **Merkatz R,** Townsend J. Risk of Pregnancy in Breastfeeding Mothers: Role of the Progesterone Vaginal Ring on Birth Spacing. 2016. EMJ Repro Health. 2(1): 66-72

33. Stifani BM, Plagianos B, Sales Vieira C, **Merkatz RB** Factors associated with non-adherence to instructions for using the Nestorone®/ethinyl estradiol contraceptive vaginal ring. Contraception 2018 May;97(5):415- 421. doi: 10.1016/j.contraception.2017.12.011

34. Simmons K, Kumar N, Plagianos M, Roberts K, Hoskin E, Alami M, Creasy G, Variano B, **Merkatz R.E**ffects of concurrent vaginal miconazole treatment on the absorption and exposure of Nestorone® (segesterone acetate) and ethinyl estradiol delivered from a contraceptive vaginal ring: A randomized, crossover drug-drug interaction study. Published online: October 30, 2017. http://doi.org/10.1016/j.contraception. 2017.10.010

35. Archer DF, **Merkatz RB,** Bahamondes L, Westhoff CL, Darney P, Apter D, Jensen JT, Brache V, Nelson AL, Banks E, Bartfai G, Portman DJ, Plagianos M, Dart C, Kumar N, Creasy GW, Sitruk-Ware R, Blithe DL. Efficacy of the 1-Year (13-Cycle) Segesterone Acetate/Ethinyl Estradiol Contraceptive Vaginal System: Results from Phase 3 Trials, Published online June20, 2019, http://dx.doi.org/10.1016/S2214-109X(19)30265-7

36. Murphy DJ, McCoy CF, Plagianos. M, RamaRao S, **Merkatz R**, Clark H, Boyd P, Variano. Malcom RK. Post-use ring weight and residual drug content as potential objective measures of user adherence to a contraceptive progesterone vaginal ring. 24-JUN-2019 DOI information: 10.1016/j.

Contraception.2019.06.013

37. Vieira CS, Fraser I, Plagianos M, Burke AE, Westhoff CL, Jensen JT, Brache V, Bahamondes L, **Merkatz RB**, Sitruk-Ware R, Blithe DL. Bleeding profile associated with

1-year use of the segesterone acetate/ethinyl estradiol contraceptive vaginal system: pooled analysis from phase 3 trials. In Press. Contraception

ADDITIONAL PUBLICATIONS

1. **Merkatz, Ruth B**. Breast-Feeding Information. The New York Hospital. Unpublished Patient Information, 1972.

2. **Merkatz, Ruth B**. Behavioral responses of hospitalized high risk maternity patients. Unpublished Masters' Thesis, Case Western Reserve University, Cleveland, Ohio, 1976.

5. **Merkatz, Ruth B**.; Lytle, Nancy. Nursing of women in the age of liberation. Dubuque, Iowa: Wm. C. Brown; 1977. Chapter 7, Modern trends in parenting.

6. ***Merkatz, Ruth B.** et al. Parenting disorders: Identification and Intervention with families at risk. Cleveland: Federation for Community Planning & The Cleveland Regional Perinatal Network; Nov. 1977. * **City of Cleveland Merit Award.**

7. **Merkatz RB**. Prolonged hospitalization of pregnant women: The effects on the family. Birth 1978; 5(4):204-206.

8. **Merkatz, Ruth B**. Proceedings of Centennial Celebration of Cornell University, New York: The New York Hospital School of Nursing; 1978. Behavioral responses of hospitalized high risk maternity patients.

9. ****Merkatz, Ruth B**. Budd, Karen. Merkatz Irwin R.; In Merkatz, Irwin R. Adam, Peter AJ. (Eds) The Diabetic Pregnancy: A Perinatal Perspective. New York: Grune and Stratton; 1979. Chapter 7, Psychological and Social Implications of Scientific Care for Pregnant Diabetic Women. ** **Annual Book of the Year Award, American Journal of Nursing, 1979.**

10. **Merkatz Ruth B**. et al. Parenting disorders: Identification and intervention with families at risk. Cleveland: Federation for Community Planning. (expanded edition) Nov. 1980.

11. **Merkatz Ruth B** & Budd K. in Smith ED (Ed.). Teaching and the obstetrical and gynecologic patient. New York: Appleton-Century-Crofts, 1981. Chapter 4, The high risk patient: A new challenge in maternity nursing.

10. Merkatz, Irwin R. **Merkatz, Ruth B.** The Proceedings of Second Annual Women's Health Day. University Hospitals of Cleveland, April 1981. Healthy Pregnancy and Parenthood in the 80's.

11. **Merkatz, Ruth B.** & DeFlorville, Wendy. Mothers' Guide to Breast-Feeding. Cleveland: Maternity Nursing Department, University Hospitals of Cleveland; 1978. Revised, 1981.

12. **Merkatz, Ruth B**; Kennell, John H. Klaus, Marshall H. Parent-infant bonding. St. Louis: C.V. Mosby, 1982. Critical Comments.

13. **Merkatz, Ruth B**.; Smalkowski, S.F. Readings in public policy and health care. Garden City, NY: Adelphi University, Summer, 1984. Ethical dilemmas in reproductive health following Roe v. Wade.

14. **Merkatz, Ruth B**. et al; Breastfeeding guidelines for the hospital. New York: New York City Steering Committee for the Promotion of Breastfeeding, June, 1984.

15. **Merkatz, Ruth B**. The Influence of maternal attachment and the capacity for empathy on perception of social support among pregnant minority women. Doctoral Dissertation, Adelphi Univ. UMI Dissertation Abstracts International, No. 3266, University Microfilms, Ann Arbor, MI, 1989.

16. **Merkatz, Ruth B**.; Cherry, Sheldon H. Merkatz, Irwin R. Medical, surgical and gynecologic complications of pregnancy. 4th ed. Baltimore: Williams & Wilkins; 1991. Chapter 14, Psychosocial issues in high risk pregnancy.

17. **Merkatz RB**. Gel-filled breast implants: an update. Contemp Ob/Gyn 1992 June; 61-75.

18. **Merkatz RB** & Couig, MP. Women's health: FDA nears decision on breast implants. Am J Nurs 1992 Jan; 92(1): 11-12.

19. **Merkatz RB**. & Couig MP. From FDA Nurses. Am J Nurs Nov, 1992:74-80; Feb, 1993: June, 1993: 72-76.

20. **Merkatz RB**. Letter: The breast implant controversy. N Engl J Med, 1993 Jun 18; 326(25):1695-6.

21. **Merkatz RB.** Women in clinical trials of new drugs and biologics: A change in FDA policy. Food Drug Law J, 1993 Summer; 48(2): 292-96.

22. Couig MP & **Merkatz RB.** From FDA Nurses. MEDWatch: The New Medical Products Reporting Program, Am J Nurs August, 1993, 65-8.

23. **Merkatz RB**. From FDA Nurses: Progress Notes on Women's Health notes on women's health, Am J Nurs November, 1993, 75-80.

24. Kessler DA. **Merkatz RB.** Temple R. Reply: FDA policy on women in drug trials. N Engl J Med 1993 Dec 9; 329(24):1815-6.

25. Kessler DA. **Merkatz RB**. Shapiro R. A call for higher standards for breast implants. JAMA 1993 Dec 1; 270(21):2607-8.

26. **Merkatz RB.** Summers EI. Toigo TA. FDA: Making a difference for women and HIV/AIDS. JAMWA 1995 50(3):108:121.

27. Merkatz IR. & **Merkatz RB**. (Eds). Social interventions in Perinatology. Sem Perinatol 1995 19(4):241-340.

28. **Merkatz RB**. Helping women control their lives. MCN 1996 21(1):39-40.

29. **Merkatz RB.** FDA moves ahead with policies on studying drugs' effects on women. Reg Affairs Focus. 1996(10):20-21.

30. **Merkatz RB.** Gender analysis in peer reviewed journals: A call to publishers. JWH 1996 5(6):525-7.

31. **Merkatz RB**, Clary CM, Harrison W. Women and Mental Health Research Methodology: In Kornstein SG, Clayton AH (Eds) Womens' Mental Health. Guilford Publications, Inc. New York. 2001 (Copyright 2002).

32. Institute of Medicine: New Frontiers in Contraceptive Research: a Blueprint for Actio. Sharyl J. Nass & Jerome F. Strauss III, Editors. **Committee Member**- 2004.

33. **Merkatz RB,** Summers E. Nursing's Influence on Drug Development and Safety. In Mason, DJ, Leavitt, JK, Chaffeen MW (Eds.). (2011). Policy and politics in nursing and health care. Philadelphia, PA. Elsevier.

34. Roberts K, **Merkatz RB**, Sales Vieira C. Letter to the Editor- N Engl J Med, March29, 2018; 378: 1263-1266, DOI 10 .1045/NEJMc1800054

ABSTRACTS

1. Anderson D., Kerr, D., Pittard, W., Schulman, P., **Merkatz, R.,** et al. Comparative Nutrient Composition of Human Milk. Pediatric Research, April, 1981, Vol. 15, p. 507.

2. **Merkatz R**, Villeneuve M, O'Kane G: Psychological Characteristics of Pregnant Diabetic Women. American Diabetes Assoc. Jan. 1986.

3. Mikhail, M.S., Freda, M., Polizzotto R., Mazloom E., **Merkatz R.B.,** and Merkatz I.R. Does Fetal Movement Counting Increase Maternal Fetal Attachment? Society of Perinatal Obstetricians. 1991;164: p. 232.

4. **Merkatz, R.**Sitruk-Ware, R. Sivin,I. Mensch,B. Hewett,P. Cooney,M. Hoskin,E. Development and Acceptability of the NES/EE CVR: A Year-Long, User Controlled Contraceptive Method. International Conference on Family Planning. Munyonyo, Uganda, Nov. 2009.

5. **Merkatz, R.** Sussman, H. Sivin, I. Mensch,B. Hewett,P. Cooney,M. Sitruk-Ware,R. Phase III Investigators. Preliminary results from a phase III study on the nestorone®/ethinyl estradiol contraceptive vaginal ring: A new, long acting (one year) user controlled contraceptive method. 11th Congress of the European Society of Contraception and Reproductive Health, The Hague, May 2010.

6. **Merkatz, R.** Sitruk-Ware, R. Mishell, D. Brache, V. Taylor, D, Jesam Gaiete, C. A dose-finding, cross-over study to evaluate the effect of a transdermal Nestorone®- Estradiol (NES/E2) gel on ovulation suppression and assess acceptability in healthy ovulating women. 66th Annual Meeting of the American Society for Reproductive Medicine, Denver, CO, October 25, 2010.

7. **Merkatz, R.** Fisher, A. Cooney, M. Huang, Y. Hoskin, E. Mensch, B. and Investigators from 12 Clinical Sites. Acceptability of the Nestorone®/Ethinyl Estradiol Contraceptive Vaginal. Ring. North American Forum on Family Planning, Washington, DC. October 24, 2011.

8. Townsend, J. Sitruk-Ware, R. **Merkatz, R.** Gabelnick, HL. Glasier, A Translating Contraception Research to Product Delivery; Better semi long-acting methods: Acceptability of new contraceptives in development. International Conference on Family Planning, Dakar, Senegal, Nov 30, 2011.

9. **Merkatz, R.** Mishell, D. Holger, K. Brache, V. Jesam C. Hoskin, E. Sitruk-Ware, R. A Phase II, Dose-Finding, Crossover Study to Evaluate the Effect of a Transdermal Nestorone®/Estradiol (NES/E2 Gel on Ovulation Suppression and Assess Acceptability in Healthy Ovulating Women. International Conference on Family Planning, Dakar, Senegal, Nov 30, 2011.

10. **Merkatz, R.** Family Planning for the Postpartum Lactating Mother. International Conference on Reproductive Health with Emphasis on Strategies for Family Planning and the 22nd Annual Meeting of the Indian Society for the Study of Reproduction & Fertility. February 19-21, 2012.

11. **Merkatz R**, K. Roberts, H. Sussman, E. Hoskin, R. Sitruk-Ware, D. Apter, I. Bahamondes, E. Banks, G.Bartfai, V. Brache, H. Croxatto, P. Darney, I. Frasier, K. Gemzell Danielsson, M. Gilliam, M.Miranda, D. Mishell, A. Nicosia, D. Portman, J. Steinauer, and E. Weisberg. Efficacy, Safety & Acceptability of a New Contraceptive Vaginal Ring Delivering Nestorone® 150 µg & Ethinyl Estradiol 15µg daily: Results from a Multi-Center Open Label Phase 3 Clinical Trial. First global conference on contraception, reproductive & sexual health Copenhagen, Denmark, May 22, 2013.

12. **Merkatz, R.** Plagianos, M. An Acceptability Model for the Nestorone®/Ethinyl Estradiol Contraceptive Vaginal Ring. International Conference on Family Planning, Addis Ababa, Ethiopia, Nov 15, 2013 (Awarded Best in Class, Scientific Research.

13. Manning J, VanBirglen F, Bukusi R, **Merkatz R**. From Bench to Bedside Bench to Bedside: Public, Private, Regional and Donor Perspectives on the Challenges and Opportunities for Introducing New Contraceptives- A Preformed Panel: Donaldson R (Moderator) - 2013 International Conference on Family Planning- Ethiopia.

14. **Merkatz R,** Townsend, J, Sailer J, Creasy G, Sussman H, Kumar N, Variano B, RamaRao S,Sitruk-Ware R. Development of the Nestorone®/Ethinyl Estradiol Contraceptive Vaginal Ring (NES/EE CVR); Challenges, Opportunities and Obligations for the Public Sector. Poster Presentation- European Society for contraception. Lisbon, May 29-31, 2014.

15. Creasy G, Brache V, Croxatto H, Mishell D, Kumar N, Roberts K, **Merkatz R**, Sitruk-Ware R. User controlled long acting reversible contraception: the pharmacokinetic profile of the Nestorone®/Ethinyl Estradiol Contraceptive Vaginal Ring. European Society for contraception. Lisbon, May 29-31, 2014.

16. **Merkatz R**, Huang Y, Hillier S, Blithe D, Roberts K, Creinin M. Effects of a one year reusable contraceptive vaginal ring on vaginal flora and vaginal infection: A prospective evaluation. European Society for Contraception. Lisbon, May 29-31, 2014.

17. **Merkatz R.** Townsend, J, Sailer J, Creasy G, Sussman H, Kumar N, Variano B, RamaRao S,Sitruk-Ware R. Development of the Nestorone®/Ethinyl Etradiol Contraceptive Vaginal Ring (NES/EE CVR); Challenges, Opportunities and Obligations for the Public Sector. Poster Presentation- European Society for contraception. Lisbon. May 29-31, 2014.

18. Mishell, D, Kumar, N, **Merkatz, R**, Creasy, G, Roberts, K, Sitruk-Ware, R. Maximum Concentration and Exposure to Ethinyl Estradiol from the Nestorone®/Ethinyl Estradiol Contraceptive Vaginal Ring (NES/EE CVR) Poster accepted for presentation @ Society for Reproductive Investigation 62nd Annual Scientific Meeting San Francisco, March 25-28 2015.

19. **Merkatz R**. Efficacy, Safety and Acceptability of a New Contraceptive Vaginal Ring Delivering Nestorone® 150 µg & Ethinyl Estradiol; Results form an Open Label Phase 3 Clinical Trial. Figo Meeting. XXI FIGO World Congress of Gynecology & Obstetrics from October 4 - 9, 2015.Vancouver, Canada. Global Obstetrics & Gynecology.

20. **Merkatz R**. Acceptability of the Nestorone®/Ethinyl Estradiol Contraceptive Vaginal Ring; Development of a Model: Implications for Introduction. XXI FIGO World Congress of Gynecology & Obstetrics from October 4 - 9, 2015.Vancouver, Canada. Global Obstetrics & Gynecology.

22. . Plagianos M, Stifani B, Sales-Vieira C, **Merkatz R**. Sales-Vieira C. Acceptability & Adherence To Use Of The Nestorone®/Ethinylestradiol Contraceptive Vaginal Ring: Comparison of Audio Computer-Assisted Self-Interviews and Face To Face Interviews, ASRM, Denver, Sept.2018

23 **Merkatz R**, Roy M. Plagianos M, Hazra A, Sales Vieira C, Rijo N, Sitruk Ware R. Reports of Acceptability by Women Using Novel Contraceptive Vagina. Rings in Diverse Settings. 15th ESC Congress, Budapest, Hungary, May 9-12 2018.

24. **Merkatz R**. Creasy B, Blithe D, Archer D, Gemzell K; Sitruk-Ware R. Clinical Trial Results for the Segesterone Acetate (SA/EE) Contraceptive Vaginal Ring: A New Long-Acting Contraceptive Under a Woman's Control. International Conf on Family Planning, Kigali, Rwanda, Nov 2018

25. Plagianos M, **Merkatz R,** Do women really tell us what they think of new contraceptives? What we can learn from various interviewing techniques.

26. Westhoff C, Darney P, Jensen JT, Bahamondes L, Apter L, **Merkatz RB.** Efficacy of the 1- Year Segesterone Acetate/Ethinyl Estradiol Contraceptive Vaginal System. American College of Obstetrics and Gynecology (**ACOG),** May 3-6, 2019, Nashville, TN.

27 **Merkatz RB**, Magnani M, Sussman H, Creasy GW, Sitruk-Ware R. Efficacy and Safety of a 1-Year Segesterone Acetate/Ethinyl Estradiol Contraceptive Vaginal System. American Academy of Nurse Practitioners (A**ANP),** Jun 18-23, 2019 Indianapolis, IN

28. **Merkatz RB**, Magnani M, Sussman H, Creasy GW, Sitruk-Ware R. Efficacy and Safety of a 1-Year Segesterone Acetate/Ethinyl Estradiol Contraceptive Vaginal System. Association of Women's Health, Obstetrical and Neonatal Nurses (AWHONN), Jun 8- 12, 2019, Atlanta, GA

29. Archer DF, Sitruk-Ware R, Mirkin S, Brache V, **Merkatz RB**. Low Systemic Levels of Segesterone Acetate are Required to Inhibit Ovulation in Women. Endocrine Society, Mar 23-26, 2019, New Orleans, LA

30. Archer DF, Thomas MA, Sitruk-Ware R, Liu J, Bernick B, Mirkin S, **Merkatz RB**, Kumar N, Blithe DL. A Novel 1-Year Contraceptive Vaginal System Delivering Segesterone Acetate and Ethinyl Estradiol: Effects on Lipids and other Hepatic Proteins. Endocrine Society, Mar 23-26, 2019, New Orleans, LA.

PRESENTATIONS: Historical Selections of Oral Presentations Prior to 1990

1. Preoperative Counseling of the Gynecologic Patient. The Nurses Association of the American College of Obstetrics and Gynecology, Annual Convention, New York City, 1972.

2. Predictors of Child Abuse. Case Western Reserve University Medical School, December 1977 sponsored by the Council on Children at Risk and the Cleveland Regional Perinatal Network. December, 1977.

3. Hospital Policies That Promote Breast-Feeding Success: A Research Approach. Bronx Lebanon Hospital, Department of Obstetrics, July 8, 1983.

4. The Nurses' Role in Supporting the Breast-Feeding Family During the Pregnancy Cycle. Lincoln Hospital, Department of Nursing, September 28, 1984.

5. Increasing the Incidence of Breast Feeding in the U.S.; National Conference of Child Health sponsored by Bureau Maternal/Child Health, Washington, DC, October 14, 1983.

6. Nursing Care Policies That Promote Successful Breast Feeding in the Hospital Setting. Mt. Sinai Hospital, Department of Obstetrical Nursing, New York, New York, April 25, 1984.

7. A Comprehensive Health Professional's Approach to Promoting Breast Feeding. New York City Conference sponsored by Steering Committee to Promote Breast Feeding New York, New York, June 4, 1984.

8. Mothering Behaviors and Child Development Outcomes: A Longitudinal Study Comparing High Risk and Low Risk Mothers. Research Day, Hospital of the Albert Einstein College of Medicine, Bronx, New York, June 14, 1984.

9. Medical Factors Associated with Preterm Birth. March of Dimes Annual Nursing Conference, New York City, March 6, 1987.

10. Psychological and Social Factors in the Management of Diabetes in Pregnancy: Critical Issues in Diabetes in Pregnancy, The Albert Einstein College of Medicine, Department of Obstetrics and Gynecology, November, 1987.

11. Nurses Working in Government. Guest Lecture in Honor of Nurse Recognition Week, Flushing Hospital, May 11, 1993.

Selected Oral Presentations/Teaching Lectures 1990-Present

12. The Effects of Maternal Attachment and the Capacity for Empathy on Social Support. The Society of Psychosomatic Obstetrics & Gynecology, New York City, March 29, 1990.

13. Avoiding Moral Distress in Caring for the Dying Oncology Patient. Oncology Nursing Society, Hudson Valley Chapter, February 7, 1990.

14. Utilizing the POPRAS Record; A Guide to Prenatal Care. New York City Hospitals Seminars for Perinatal Nurses, sponsored by the March of Dimes, New York Chapter, June 7, 1990.

15. Development of a Model for Social Support among Black and Hispanic Pregnant Women. Sigma Theta Tau, Alpha Upsilon Chapter, January, 1991.

16. A Women's Health Initiative at FDA. Washington, DC. Annual Meeting of FDA Public Affairs Specialists, October, 1991.

17. A Model for the Development of Social Support among Black and Hispanic Pregnant Women. Sigma Theta Tau International Conference, Orlando, Florida, November, 1991.

18. **Keynote Address:** Participation of Women with AIDS in Clinical Trials. Annual Meeting, Community Groups for Women and Aids, Washington DC. January, 1992.

19. Research Initiatives in Women's Health. University of Michigan School of Nursing, Ann Arbor, Michigan. March 19, 1992.

20. **Keynote Address:** The Challenge of Promoting Women's Health. Women's Health Conference, Texas Medical Center, Houston; Sponsored by FDA, USHHS, & Texas Agricultural Extension Service, March 20, 1992.

21. **Keynote Address:** An FDA Agenda for Women's Health. North American Menopause Society. Cleveland, Ohio, September 16, 1992.

22. **Keynote Address:** Women in Clinical Trials; An Overview. Keynote Address, Conference sponsored by USFDA and Food, Drug and Law Institute on Women in Clinical Trials of FDA-Regulated Products-Who Participates and Who Decides, Washington, DC, October 5, 1992.

23. FDA Approval of Depo-Provera. CBS Morning Show, October 30, 1992.

24. The Role of the FDA in Safeguarding Patient Care. Grand Rounds, Department of Obstetrics and Gynecology at the Albert Einstein College of Medicine, December 22, 1992.

25. FDA Calls for Changes in Contraceptive Labeling. CBS Morning Show, April 9, 1993.

26. Participation of Women in Clinical Trials of New Drugs. Pharmaceutical Manufacturers Association, Newark, NJ, April 16, 1993.

27. Nurses Working in Government. Guest Lecture in Honor of Nurse Recognition Week, Flushing Hospital, May 11, 1993.

28. Plenary Address: Women's Issues-Lessons Learned from the Breast Implant Story. Public Health Service, Commissioned Officers Association Annual Meeting, Scottsdale, AZ., May 24, 1993.

29. Women in Clinical Trials: The FDA's Historical Concern and Its Recent Developments. NIH Conference on Women and Minorities in Clinical Research, Georgetown University, Washington, DC, June 28, 1993.

30. FDA's New Policies on Women in Clinical Trials. Hearing on Recruitment and Retention of Women into Clinical Trials; Office for Research on Women's Health, NIH, Bethesda, MD, July 13, 1993.

31. The Mammography Quality Standards Act (MQSA): Consumer Concerns. FDA Conference, Implementing the MQSA of 1992: Roles in Improving Mammography Services, September 21, 1993, Reston, VA.

32. **Keynote Address:** Women's Health: An Historical Perspective. Keynote Address, Women's Health across the Lifespan, Annual Autumn in NY Conference sponsored by the Department of Obstetrics & Gynecology, Albert Einstein College of Medicine, November 14, 1993.

33. Participation of Women in Clinical Trials; Lecture to the Department of Epidemiology and Social Medicine; Albert Einstein College of Medicine; February 7, 1994.

34. Women's Health Comes of Age; FDA Seminar presented at the Annual Meeting of the American College of Obstetricians and Gynecologists, Orlando, FL. May 11, 1994.

35. Recent FDA and NIH Perspectives on Women's Participation/Access into Clinical Research vs. Scientific Objectives. Association of Clinical Pharmacology Units; 6th Annual Meeting, Chicago, Ill. October 7, 1994.

36. **Keynote Address:** Promoting Health in Women with Turner's Syndrome. Keynote Address; Annual Meeting, Turners Syndrome Society. San Diego, CA, October 9, 1994.

37. Testing FDA Medical Products in Pregnant Women: Is it Time to Change?

Introductory Address. Conference on FDA Regulated Products in Pregnant Women. Sponsored by the Office of Women's Health, US Food and Drug Administration, Crystal City, VA. November 7-8, 1994.

38. Eighteen Months since the New Gender Guideline. Speech to the Corporate Advisory Council of the Society for the Advancement of Women's Health Research, Washington, DC, January 19, 1995.

39. Women's Health: Its Role in the Women's Movement. Linnea Henderson Nursing Lectureship, Kent State University, Kent, Ohio, April 6, 1995.

40. Women and Drug Research Trials, Women's Wellness Conference to the New York State Legislature, sponsored by the American College of Obstetricians and Gynecologists, NY State, Albany, NY, May 22, 1995.

41. Women's Health at the FDA: A New Era- Speech to the Jacob's Institute of Women's Health, July 3, 1995.

42. Including Women in Clinical Trials. Luncheon Speech to Ohio Congress on Women's Health sponsored by Ohio Department of Health and Ohio State University. Columbus, Ohio, September 10, 1995.

43. Current Issues in Clinical Trials for Pharmaceuticals: 19th Annual Conference Regulatory Affairs Professional Society, Washington, DC, October 12, 1995.

44. Clinical Trials: Inclusion of Women. Sixth International Congress on Ethics in Medicine, New York Academy of Medicine, New York City, October 24, 1995.

45. Clinical Research and Products Liability Issues: Including Women with Childbearing Potential in Drug Trials. New York State Bar Association, New York City, October 30, 1995.

46. Historical Review of Women's Participation in Clinical Trials: Opening Remarks at FDA sponsored workshop on Gender Studies in Product Development: Scientific Issues and Approaches. Rockville, MD, November 6, 1995.

47. Inclusion of Women in Clinical Trials: New Developments Since the 1993 FDA Guideline; National Institutes of Health, Bethesda, MD, February 22, 1996.

48. Scientific Aspects of Including Women in Clinical Trials: Drugs Directorate of Canada, Ottawa, Canada, April 2, 1996.

49. Celebrating Nursing: Our Past, Present and Future: Montefiore Medical Center, Bronx, NY, May 9, 1996.

50. Women's Health Advances through Clinical Trials: Third Annual Women's Health Conference, Society for the Advancement of Women's Health Research, Washington, DC. June 18, 1996.

51. Women and HIV: Impact on Policies for Participation of Women in Clinical Trials. Duke University School of Law Conference on HIV Law & Policy: Ensuring Gender-Equitable Reform, Durham, NC, February 21, 1997.

52. Are any Drugs Safe for Use in Pregnancy? Annual March of Dimes Nursing Conference, New York City February 27, 1997.

53. Women's Health Comes of Age, US Public Health Service Nursing Research Conference, Bethesda, MD March 21, 1997.

54. Are any Drugs Safe for Use in Pregnancy: Status of Current Information, World Conference in Perinatology, Rome, Italy May 8-9, 1997.

55. Continuing Controversy on Mammography for Women Ages 40-49 Years, The National Council on Women's Health, Lenox Hill Hospital, New York, NY, June 12, 1997.

56. Cancers in Women: A Reassessment on Focus, 5th Annual Congress on Women's Health, Washington, DC. June 25, 1997.

57. The Art of Women's Health: Women's Healthcare and Wellness Conference, Washington, DC. September 10, 1997.

58. Recruitment and Retention of Minorities and Women in Cancer Clinical Trials, University of Illinois, Chicago, IL September 19, 1997.

59. Addressing Women's Health Issues in a Managed Care Environment; IPA Association of America, Washington, DC, October 20, 1997.

60. Women's Health Leadership Conference; Blue Cross and Blue Shield Association, Communicating Success to Women, Boston, MA, October 31, 1997.

61. Why Women's Health Matters, Women for Healthcare Education Reform and Equity (WHERE) First Anniversary Celebration, Seattle, WA, November 3, 1997.

62. Report to the Commission on Women-Commonwealth Foundation Conference, Washington, DC; November 12, 1998.

63. To Your Health, Madame, The New York Women's Agenda, May 15, 1998.

64. Heart Disease and Women, Washington Hospital Center, January 15, 1999.

65. The Changing Face of Women's Health, Introductory Remarks; Maryland Science Center, Baltimore; March, 1999.

66. From Seneca Falls to Women's Health, commemorating the 150th anniversary of the signing of the Declaration of Sentiments, Seneca Falls, NY, July, 1999.

67. **Keynote Speech**: Beijing +5 Conference on Women: "Health Issues for Women: A Global Perspective", United Nations Headquarters, NY; June 8, 2000.

68. Women's Health in the New Millennium: Focus on Mental Health; New York University Medical Center, Department of Psychiatry; September 17, 2000.

69. Developing Leadership for Women's Health: A Look at Changing Policies at the FDA; Society for Women's Health Research, Medical Health Advisory Board; Washington, DC, October 25, 2000.

70. History of Gender-Based Medicine and Future Directions - University of Kentucky Medical School Grand Rounds, April 17, 2001.

71. The Prime of Our Lives: An Innovative Women's Health Education Program; Dept. of Obs/Gyn & Women's Health Grand Rounds; Dec 3, 2002.

72. Women's Health-The Model Has Shifted; US Congressional Briefing Sponsored by the Jacobs Institute of Women's Health; May 13, 2004.

73. Journey to Uganda: Personal Reflections: Department of Ob/Gyn- Grand Rounds, Sept 20, 2005.

74. The Role of the FDA in Ensuring Safety of Drug Therapy: Grand Rounds, Dept. of Ob/Gyn, Lenox Hill Hospital, November, 9, 2005.

75. Presentations to the International Committee on Contraceptive Research (ICCR) (2005-2018-Supplement available on Request).

76. Development and Acceptability of the NES/EE CVR: A Year-Long, User Controlled Contraceptive Method. International Conference on Family Planning, Sponsored by the Bill & Melinda Gates Foundation. Uganda, Nov. 2009.

77. Phase III Investigators. Preliminary results from a phase III study of the nestorone®/ethinyl estradiol contraceptive vaginal ring: A new, long acting (one year) user controlled contraceptive method. 11th Congress of the European Society of Contraception and Reproductive Health. The Hague, May 2010.

78. A dose-finding, cross-over study to evaluate the effect of a transdermal Nestorone®- Estradiol (NES/E2) gel on ovulation suppression and assess acceptability in healthy ovulating women. 66th Annual Meeting of the American Society for Reproductive Medicine. Denver, CO, October 25, 2010.

79. Acceptability of the Nestorone®/Ethinyl Estradiol Contraceptive Vaginal. Ring. North American Forum on Family Planning, Washington, DC. October 24, 2011.

80. Translating Contraception Research to Product Delivery; Better semi long-acting methods: Acceptability of new contraceptives in development. International Conference on Family Planning. Dakar, Senegal, Nov 30, 2011.

81. A Phase II, Dose- Finding, Crossover Study to Evaluate the Effect of a Transdermal. Nestorone®/Estradiol (NES/E2 Gel on Ovulation Suppression and Assess Acceptability in Healthy Ovulating Women. International Conference on Family Planning, Sponsored by Sponsored by the Bill & Melinda Gates Foundation. Dakar, Senegal, Nov 30, 2011.

82. Family Planning for the Postpartum Lactating Mother. International Conference on Reproductive Health with Emphasis on Strategies for Family Planning and the 22nd Annual Meeting of the Indian Society for the Study of Reproduction & Fertility. February 19-21, 2012.

83. Efficacy, Safety & Acceptability of a New Contraceptive Vaginal Ring Delivering Nestorone® 150 µg & Ethinyl Estradiol 15µg daily: Results from a Multi-Center Open Label Phase 3 Clinical Trial. First global conference on contraception, reproductive & sexual health. Copenhagen, Denmark, May 22, 2013.

84. Plenary Session: An Acceptability Model for the Nestorone®/Ethinyl Estradiol Contraceptive Vaginal Ring. International Conference on Family Planning, Sponsored by the Bill & Melinda Gates Foundation. Addis Ababa, Ethiopia, Nov 15, 2013 (Awarded best in class scientific paper).

85. From Bench to Bedside: Public, Private, Regional and Donor Perspectives on the Challenges and Opportunities for Introducing New Contraceptives- A Preformed Panel: Donaldson R (Moderator) - 2013 International Conference on Family Planning. Ethiopia.

86. User controlled long acting reversible contraception: the pharmacokinetic profile of the Nestorone®/Ethinyl Estradiol Contraceptive Vaginal Ring. European Society for contraception. Lisbon, May 29-31, 2014.

87. Effects of a one- year reusable contraceptive vaginal ring on vaginal flora and vaginal infection: A prospective evaluation. European Society for Contraception. Lisbon, May 29-31, 2014.

89. Advancing Development of Multipurpose Prevention Technologies to Reduce Unintended Pregnancy and Acquisition of Sexually Transmitted Infection, ICFP- Kigali, Rwanda, Nov 2018

90. Discovery, Development, Delivery:A New Long-Acting Contraceptive Under a Woman's Control/ Grand Rounds, Albert Einstein College of Medicine, Montefiore Medical Center, Dec. 18, 2019.

U.S. CONGRESSIONAL TESTIMONIES AND BRIEFINGS

1. Breast Implant Update. Briefing before Committee on Energy and Commerce, US House of Representatives, October 24, 1991.

2. Breast Implant Update. Briefing before Women's Congressional Caucus, US Congress, October 31, 1991.

3. The Breast Implant Moratorium. Briefing before Energy and Commerce and Committee, US House of Representatives, January 6, 1992.

4. FDA Testimony on the Status of Women's Health. Before the Subcommittee on Regulation, Business Opportunities, and Technology: Committee on Small Business; US House of Representatives, May 8, 1992.

5. Women's Health Issues at FDA. Briefing before Subcommittee on Agriculture, Rural Development, Food & Drug Administration & Related Agencies, Committee on Appropriations, US House of Representatives, May 5, 1993.

6. Tamoxifen Update. Briefing for Congressional Staff on new information on Tamoxifen; Its use for treatment and prevention of breast cancer. U.S. House of Representatives, April 11, 1994.

7. Creation of the Office of Women's Health at FDA. Briefing for selected members of U.S. House of Representatives, November 16, 1994.

8. Creation of the Office of Women's Health at FDA. Briefing for selected members of U.S. Senate, November 17, 1994.

9. FDA Testimony on Breast Implants and Medical Devices. Before the Human Resources and Intergovernmental Affairs Subcommittee of the House Government Reform and Oversight Committee, U.S. House of Representatives, August 1, 1995.

10. FDA Office of Women's Health Update. Briefing for Selected House Members and Staff. May 23, 1996.

Speech Presented to The North American Menopause Society
Cleveland, Ohio
September 17, 1992

by
Ruth B. Merkatz, PhD, RN
Special Assistant to the Commissioner:
Women's Health Issues: USFDA

A FOOD AND DRUG ADMINISTRATION (FDA) AGENDA FOR WOMEN'S HEALTH: LEARNING FROM THE PAST TO PROMOTE AND SAFEGUARD THE FUTURE

It is a great honor for me to be with you today and to speak at this important meeting. It is especially rewarding to be in Cleveland where I spent nine professionally stimulating years during the seventies and early eighties at the Francis Payne Bolten School of Nursing and University Hospitals. Many of us during that period became embroiled in examining the impact of the Women's Movement on the Health Care of Women. Together with one of my most important mentors, the late Dr. Nancy Lytle, we published a book, Nursing of Women in the Age of Liberation. The bulk of the chapters focused on pregnancy and family planning, the major issues of change and upheaval at that time. We were concerned about quality of care, about women's voices being heard in the health care system, and about paying attention to the developmental needs of women and families. Menopause, however, was the subject of

just one chapter and only in relation to hysterectomy.

If we were to write that book today, there is no doubt that there would be an increased focus on menopause. You and I are part of the generation that witnessed major change in childbirth practices and a dramatic upheaval in the scientific and technologic expertise that is applied today in caring for pregnant women. This same incisive reevaluation process is now taking place in caring for women during menopause. It is no coincidence that this week, at the top of the NY Times non fiction best seller list is Gail Sheehy's book, The Silent Passage. This book is a journalist's investigation of the myths surrounding menopause and an attempt to deal with what is currently known and what is being debated about this normal developmental process in a woman's life. Unfortunately, we do not have enough scientific information to definitively answer many of the questions that arise with respect to this period of a woman's life, and especially about the desirability and longterm safety and efficacy of postmenopausal hormone replacement therapy. That is why the Women's Health Initiative (WHI), one of the largest studies ever to be initiated by the NIH is about to be launched. It will address questions such as what effect does

adding progestin to a regimen have on protection against cardiovascular disease, the leading cause of death in women? Who should be targeted for such therapy and what should the recommended dosage and regimens consist of? Should progestins be recommended for a woman who does not have a uterus? What is the relationship, if any, between estrogen only and estrogen with a progestin and the development of breast cancer, which today affects one woman in nine? What is the role of diet and lifestyle on development of breast cancer, cardiovascular disease, osteoporosis, and other medical problems. It will be many years, however, before these study questions can be answered, even though women want answers to these questions now in order to conduct their own risk/benefit analysis. They also want to know if there are other agents that can be used to prevent bone loss or stimulate new bone formation should they not choose to use HRT. Practitioners are in the same situation.

Let me share with you the current mood and goals at FDA, and what some of our experiences with Women's Health issues bring to the current debate about the potential widespread application of drug therapy for women during menopause. Since joining Dr. Kessler at FDA

one year ago as his Special Assistant for Women's Health, I have been heavily involved in FDA's decisions about silicone breast implants. Passions and fervor that have been expressed on all sides of this issue have generated enormous debate, both within and outside FDA. The decisions that had to be made had monumental public health consequences. As part of the team analyzing what our decisions should be, I examined similar controversial issues that have affected women's health and have directly involved FDA. I am eager to share some of my insights from that review with you today. For me, the story begins with Thalidomide.

Thalidomide came on the market in West Germany and Great Britain in the late 1950's, and became popular throughout Europe as a sedative and tranquilizer. Its chief attraction was thought to be its low level of toxicity, and for this reason it was thought to be safe for even pregnant women. In 1960, when the Merrill Richardson Company applied to FDA for permission to market the drug in the US, it was felt to be a fairly straightforward new drug application and was assigned to a new medical reviewer, Dr. Frances Kelsey. Despite the drug's reputation as being non toxic, Dr. Kelsey was concerned about the scarcity of information

concerning its absorption and distribution in the body. She wondered whether the low toxicity could be related to poor absorption in the human species, and requested further studies on the metabolism of the drug. Along with other reviewers at FDA, Dr. Kelsey was also concerned about the effects of the drug on the fetus. Despite pressure from the drug company, Dr. Kelsey recommended withholding approval until assurances about the teratogenic effects of the drug could be provided. Her concern was heightened by a report in the British Medical Journal which drew attention to possible neurological side effects with prolonged use of thalidomide. By May, 1961, attention had already been drawn in Germany to the sudden alarming increase of congenital limb deformities in newborn infants, and inquiries were underway to determine their cause. In November, 1961, Dr. Lenz from Hamburg announced his suspicion that thalidomide was the cause of the deformities. The same conclusion was reached by Dr. McBride in Australia. It is of interest to note that, in the course of these inquiries, several centers in the US were queried as to whether a similar increase in such anomalies had been noted. The FDA was not aware of these inquiries until the role of thalidomide in the phocomelia defects of infants had been established-

an example of inadequate scientific communication.

In Europe and Australia, over 5000 babies were born with the characteristic phocomelia deformities. In the US there were a few such babies because Merrell Richardson had distributed thalidomide as an experimental drug. Dr. Kelsey's reluctance to approve thalidomide for marketing unquestionably prevented more birth defects in this country. The thalidomide story and Dr. Kelsey's role in delaying its approval appeared in the Washington Post and inspired President John F. Kennedy to award her the US Medal of Honor.

The thalidomide event also unleashed public scrutiny of the entire drug approval process in this country. It aroused widespread support for stronger drug regulation and resulted in the Kefauver-Harris Drug Amendments of 1962 to ensure greater drug safety. These amendments strengthened the regulation of new drugs under investigation and provided for immediate withdrawal of drugs found to present an imminent hazard. In addition, companies had to include evidence of a drug's effectiveness as a prerequisite for marketing.

While the 1962 Drug Amendments required that drugs must be shown to be effective, they applied only to new drugs coming under

review for approval by FDA. Thus, some older drugs on the market were not initially subjected to the efficacy standard. Included in this category was DES, a drug familiar to all of you in this audience, I am sure. I merely remind you of the tragic legacy of in utero exposure to diethylstilbestrol which continues to unfold even now. A well known professor of Obstetrics and Gynecology recently recalled to me that the drug was prescribed in pregnancy by physicians such as he who genuinely believed it was helpful, and because there was nothing else to offer women at risk for pregnancy loss. It must be noted, however, that in the early 1950's, Dr. Dieckmann and his associates at the Chicago Lying-In Hospital conducted a double blind, prospective study using DES with pregnant women. They found no benefit in pregnancy outcomes among 840 women receiving DES compared with 806 women who received placebo. This study was presented in 1953 at the 76th annual meeting of the American Gynecological Society in Lake Placid. Despite the negative findings on efficacy in improving outcome, and even the suggestion that preterm birth was increased with use of DES, the drug continued to be prescribed during pregnancy until the 1970's. In 1971, when Drs. Herbst and Scully of Boston reported on the significant

linkage between in-utero exposure to DES and later development of adenocarcinoma in female offspring, its usage in pregnancy was finally stopped.

We have had other painful, recent lessons with respect to products prescribed for women. From the Dalkon Shield disaster, we again learned what can happen when enthusiasm for a product's potential benefit is not balanced against a careful and scrupulous examination of its risks, in this case a device. Before 1976, the FD&C Act did not require testing of devices prior to marketing as it did for drugs and vaccines. With no premarket clearance, a manufacturer could put on sale an untested, hazardous device and dangers might not be evident for decades. Only after a device had caused injury or death could the FDA go to court for seizure of specific devices or for an injunction to halt interstate sales. For the political science and history buffs in this audience during this election year, you may be interested to know that Presidents Kennedy, Johnson, and Nixon sent 3 consecutive annual messages to Capitol Hill urging premarketing clearance of medical devices for safety, efficacy, and reliability.

But the resulting 1976 Medical Device Amendments did not take care

of all devices. There were thousands already on the market that were grandfathered; they were allowed to stay on the market pending a decision from FDA about whether safety and effectiveness would have to be demonstrated. Included among these were silicone breast implants which had been introduced in the early 1960's. In 1982, FDA proposed that manufacturers of breast implants demonstrate product safety and efficacy. But as provided by the law, this proposal was followed by additional rulemaking, and it wasn't until 1991 that the companies actually submitted their data. The rest is history. Seven companies submitted applications, but only four of them were accepted for review by FDA. In November, 1991, FDA's outside advisory panel determined that the manufacturers had not provided sufficient data to demonstrate safety and efficacy. Under ordinary circumstances, this would have meant that these devices would be off the market. But the breast implant issue was not an ordinary circumstance. Not since the Saccharin debate of the late 1970's had FDA received the quantity of mail as it did in this case- more than 22,000 letters during this past year. The majority have come from women asking that silicone breast implants remain available, that women be given information about safety and the

right to choose what would go into their bodies. The same message came out in the public panel meeting. But we have also received quantities of mail and verbal testimony from women on the other side, women who have been harmed and believe that they have suffered a variety of illnesses as a result of these implants. As I analyzed these letters, several themes emerged from the latter group of women: 1) they had been given virtually no information about any potential problems that could arise from the implants; 2) those who had problems were generally put off by their physicians and told their problems could not possibly be related to their implants.

The FDA has been both praised and criticized for its decision to markedly restrict the use of silicone breast implants. Those who believe we did the right thing tell us that after much delay, FDA and Dr. Kessler acted with courage to demand that women receive information about these implants, and that manufacturers provide the evidence of safety that should have been accumulated during the preceding 30 years of unmonitored use.

Those who criticize FDA, such as the editorial staff of the NEJM, accuse FDA leadership of sexism in targeting a device used only by

women. To this argument, I, for one, say it would have been truly sexist to ignore a device used by women, particularly given some of the events of the past that I have reviewed today. The NEJM accuses FDA of coercion by insisting that women enroll in study protocols in order to obtain silicone breast implants. To this I can confidently reply with information from FDA's Breast Implant Information Service (our hotline) and the letters written by thousands of women with breast implants. They are pleading for the opportunity to be to enrolled in a registry and a data base so that they can be monitored closely and be informed periodically of future developments.

The agency has also been criticized for allowing implants to be used more readily by some women than by others. Women who need implants for medical reasons such as reconstruction following breast cancer surgery, congenital malformations, or trauma may have open availability to enter into research protocols and receive the implants. However, the number of women who desire implants for cosmetic augmentation purposes will be more restricted in gaining entry into protocols. As we at FDA debated the issues before us, it was clear that the indications for breast implant surgery were different between the two

groups. While these implants serve a cosmetic purpose in all cases and may provide important psychological benefits for both groups, women who choose reconstructive surgery do so as part of medical treatment for their disease. In many instances, and particularly in the case of women with breast cancer, availability of breast implants and reconstruction enables them to go forward with cancer treatments. Thus there was a public health need to allow the continued use of silicone breast implants under close supervision for women with a medical indication. In balancing the decision, we also considered that women choosing augmentation are generally younger than those requiring reconstruction. For these younger women, the potential risks became especially worrisome because of serious unanswered questions about the long range performance of silicone breast implants. Additional concern for younger women with healthy breasts included interference with critical breast cancer screening.

Regardless of this reasoning, critics still argue that women should be able to choose for themselves. Why should FDA presume to tell a given woman how much risk she may take to gain the appearance she desires? The answer to these dilemmas resides in the law and, more

fundamentally, in what FDA is all about. Congress established FDA to protect the health of the American consumer. The need for that protection is greatest when there is inadequate information about a product, when people are ill, or when they are in discomfort- either physically or psychologically.

In the course of the breast implant story, we at FDA learned of unpardonable marketing and advertising schemes, and of an insensitivity to the seriousness of a woman's decision to obtain silicone breast implants. We also learned that, in general, women were not given adequate information about these implants prior to giving consent. It goes without saying that such mistakes must not be permitted to recur in expanding menopausal therapies to women. Regardless of social class or ethnic background, women deserve suitable unbiased educational materials. These materials must be available and utilized with appropriate counselling and time for deliberation. Health care professionals have an obligation to ensure that companies be held accountable for the accuracy of direct to consumer advertising and for including an accurate representation of risks and benefits along with a favorable portrayal of postmenopausal women in the media. FDA will be

seeking your help in this effort.

For consumers, the silicone breast implant story provided the painful lesson that no device is completely free from risk, regardless of how long it has been used. The public often expects that a product regulated by FDA will be absolutely safe. But, of course, nothing in life is absolutely safe. Our goal with breast implants was not to assure absolute safety. It was to clarify and quantify the risks and determine whether they had been shown to be low enough to be acceptable, and then to be sure that those risks were adequately conveyed to physicians and patients.

It is the manufacturer's job to satisfactorily demonstrate that a product is safe and effective for marketing. Accordingly, it is not FDA's job to prove that the product is unsafe. However, no amount of premarket testing can catch all potential problems associated with the real-life use of medical products. It is at this point that professionals, attuned to the complexity of human biology, and the variability of individual responses must be alert in recognizing unanticipated events. This is particularly true for off label use of drugs. As new regimens of hormone replacement therapy and anti-bone resorptive agents are instituted, each of us must maintain a healthy vigil and there must be a

willingness to communicate both through the literature, and through reports to the FDA as the nation's designated regulatory body. I remind you once again of the key historic roles played by Dr. Lenz of Hamburg, Dr. Diekmann of Chicago, Drs. Herbst and Scully of Boston, and also of Dr. Frances Kelsey who is now in her late 70's, but still on the job in Washington.

Women, too, will be more alert and on guard in the 1990's than ever before in the past. Health care practitioners must appreciate the concerns, fears, and background experiences that perimenopausal women may bring to the doctor-nurse-patient relationship. Women of the post war and baby boom generations were the ones who stimulated major changes in childbirth practices. They were also the same women who witnessed the ramifications of the untoward historic medical events I have reminded you of today. It is the same generation of women who now seek care for problems of menopause at a point in time when concerns about cancer, heart disease, the spread of AIDS, and quality of life are paramount. FDA recognizes its special responsibility to this generation of women. It is an agency determined to strengthen its partnerships both with them and with the academic communities, health

professionals, and industries developing new concepts of care.

In cooperation with its sister agencies of the USPHS, FDA emphasizes Women's Health as a top research and public health priority. It intends to be very active in support of the evolving understanding of the physiologic and health needs of menopausal and aging women. Its professional staff and advisory committees will focus particular attention on the progress of research in prevention and treatment of heart disease; lung, breast, uterine, and other cancers afflicting women; osteoporosis; and AIDS which must include the prevention of the spread of AIDS even in post menopausal women. It will also focus on issues of Alzheimer's disease, a condition which is not only more prevalent in women, but is one which profoundly affects women who frequently are the caretakers of those who are afflicted. FDA also intends to further its educational role for women about nutrition, physical fitness, and life style in an effort to prevent some of the medical problems that afflict women as they mature. The Nutrition and Labeling Education Act of 1990 mandates that FDA provide clearer labeling of food content and the relationship of specific nutrients to the prevention of disease. This includes the role of calcium in prevention of osteoporosis, and excess dietary fat in the

etiology of cardiovascular disease.

FDA's role in food and drug labeling, drug advertising, and availability of objective health information is fundamental to its mission. The agency must simultaneously insist on appropriate consent procedures about new treatments so that women are empowered to participate in important decisions about their health care options. As we approach the twenty first century with eagerness and enthusiasm about our ability to provide the very best care for all citizens, it is important to incorporate the lessons of the past in ensuring the safest and most effective health care for women.

Thank you very much for the opportunity to share this message with you. I wish you well during this conference.