Oral History Interview with
Audrey Sheppard
Assistant Commissioner for Women's Health
Office of Women's Health
1996-1999

FDA Oral History Program
Final Edited Transcript
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Oral History Abstract

Audrey Sheppard served as Deputy Director of Women's Health (1994-1996) and then Acting Director of Women's Health (1996-1999), playing an integral role in standing up the Office of Women's Health, building stakeholder relationships and developing OWH's outreach strategy. She was a principal architect of OWH's longest running campaign, Women's Health: Take Time to Care, and played a key role in interfacing with the DHHS Office of Women's Health and the NIH Office of Research on Women's Health in studying the health impacts of silicone breast implants. After leaving the FDA, she remained active in advocating for women's health issues related to FDA-regulated products as a private health consultant.

Keywords

Women's Health; Stakeholder Engagement; Gender Differences in Health; Mammography Quality Standards Act; Silicone Breast Implants

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Interviewer Biography

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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Interview Transcript

VB: This is an oral history, contributing to the FDA Oral History Program, with a focus on the work of the Office of Women's Health, and I'm with Audrey Sheppard in her home in Washington, D.C., and joining us is Maria Esposito, and this is Vanessa Burrows speaking for the FDA History Office.

So, I'd like to start, Audrey, just with a little bit of background about you, if you want to talk about growing up or school or early career, things that brought you to Washington and to working with FDA.

AS: Sure, Vanessa. I'm happy to do that. I evolved into caring a lot about women's empowerment and women's -- less about women's health, but that just happened when I was appointed as a political appointee to the FDA Office of Women's Health. I was always fairly political, and had already consulted a bunch, and even done a survey of women running for high office. So early on, in my thirties or so, very oriented toward women's issues, and women's opportunity. I grew up in the Boston area, and then for a while in Westchester County, New York. I went to Syracuse University, and was a dual major in political science and journalism, and it all just kept pointing toward government. And so I was in the McGovern campaign in '72, and just kept doing political things.

It was in '77 that I attended the Houston Conference, which was the first conference related to global women's health and women's empowerment, and that set off a lot of interest and sensitivity to women's issues. That became a passion over time, and one thing led to another, and I was in the Bill Clinton campaign as a volunteer. That led me to getting a political

appointment with the Clinton administration, and my third actual administration job was going to the FDA.

VB: Before we get into FDA stuff, were you involved in the National Conference on Women's Health in 1985 [World Conference on Women]?

AS: Not a National Conference on Women's Health. What I did reference was in 1977, that came out of the first UN -- I have the poster; I can show it to you -- the first global conference on women's issues led to every country that participated going back and in their country having a national conference on women's issues, and that's the Houston Conference that I was fortunate enough to attend. I was hired to be one of a very few staff members to it. So, no, I don't know that... Well, the '85 conference may be the next one, '75 and then '85, every decade.

VB: I think it might have been just HHS, or PHS, but it sounds like it was an outgrowth of that in one way or another.

AS: Yes.

VB: And I bring it up, in part, because it seems to be a signifier of this trajectory that led towards, by the end of the 1980s, certainly by the early '90s, a growing interest throughout

government, particularly in HHS, to look at how to incorporate women's health officially into the structure of different OPDIVs. And I was wondering if that was on your radar, if you were particularly involved.

AS: I was not involved in that, per se, because HHS wasn't really even on my radar screen. I knew it existed, of course, but I was a political appointee first in '93 at the Pentagon, in the Office of the Secretary, and then when that Secretary, Les Aspin, was -- being really candid – retired by President Clinton -- after several months, he lost the confidence of the President, and I had gone to work for him in July of '93, in the first year of the Clinton administration, when I ended up being selected by David Kessler to -- it was referred to at the time kind of as a package, where there were people that the Office of Presidential Personnel wanted to place, and there were people that David Kessler wanted agreement to bring to FDA, and it was sort of a deal for a few people, and I was part of that package. So what I learned at the time, as I started finding out that I might be fortunate enough to go to the brand new, about-to-open Office of Women's Health was that David Kessler and a woman named Mary Pendergast, who was his principal deputy and others were... Some women's health issues were bubbling up.

And, you know, my frame of reference is that he, with others at FDA, started thinking of opening an Office of Women's Health. In this case -- I think it was part of a movement -- NIH Office of Research on Women's Health had been opened maybe a year or so before -- but I think Kessler... I mean, no edict came down, I don't believe, from HHS to do this. What did happen is Kessler was interested in it. There were, as I say, a number of issues. Perhaps you know that Ruth Merkatz was already at FDA as a friend and colleague of Dr. Kessler's, handling women's

health as a special assistant to him for a year or two. And there was a retreat of some kind, led by Kessler and Mary, to discuss what it would look like. Simultaneously, Barbara Mikulski, right in that period, had put in appropriations report language that the Commissioner should create an Office of Women's Health at FDA, putting $2 million into it of previously appropriated funds.

VB: And I think previous interviewees have suggested that the first attempt at founding the Office of Women's Health wasn't necessarily going to be a permanent office. Is this true?

AS: I can't and won't exactly contradict that. I was there on the first day of the office opening, and we assumed that it would be permanent, but we didn't have any report language or anything that said it will go on ad infinitum. I think we all just wanted it to continue, and found a way for it to stay funded.

VB: Yeah. So obviously even before Mikulski mandated the creation of the office, there was a need to address women's health issues at the Commissioner's Office level. Do you have any insight into the background of why Kessler needed to bring in a Special Advisor on Women's Health in the early '90s?

AS: Yes. Well, I think there was an ADCOM [Advisory Committee meeting] on breast implants prior to the opening of the office. There were other issues. I mean, I frankly thought,

when I got there, since I was, you know, not a scientist, not a public health or a health professional of any kind, I thought that I had just landed in a bowl of alphabet soup of new terms, new words, new acronyms. I know that when I got there, there was already a new law addressing mammogram safety (MQSA). So there were a number of things that she (Ruth Merkatz) had been drawn into by Kessler, and it was especially fortuitous and positive that she was a colleague of his at Montefiore, and that Dr. Kessler, Ruth and Ruth's husband Irwin were all professional colleagues and social friends. And so it made for a very easy relationship between the Commissioner and his Special Assistant for Women's Health, and it made a smooth transition.

When I interviewed with Kessler -- (laughs) I'll digress in this way -- my résumé showed at that time that I had virtually no background at all in FDA things. My résumé indicated one place where I intersected with FDA, and that is that I had married a Chicagoan, was living in Chicago starting in '90, and through my political and women's activities there I met a woman named Judy Irwin (who later went to the state legislature) who was very political. And when I met her, she said, "You must meet a friend of mine who is the president of the company with the female condom, and she is having fits because she can't get approved, and it's a very worthwhile product, and so, you know, you seem Washington-savvy; maybe you can help her." So I did meet her. I took her to Washington a couple of times, and we went around the Hill, and we did a couple of other things. And it was a foreshadowing of my work for the last 20 years, really, which is related to advocacy for women's health issues, that can fulfill unmet needs in women's health. So I met Mary Ann Leeper, and had -- I find it amusing and delightful to this day that I met Mary Ann Leeper and helped her.

Kessler looked at my résumé, where I said that I had worked on the female condom prior to its FDA approval, and that I worked on advocacy related to it, and Kessler looked at me and said, "We only approve products based on science. What's this advocacy business? That is just irrelevant." But, you know, I think he liked me enough. I had been sent to be considered for the job that he had already promised, or had in mind Sharon Smith Holston for, which was Deputy Commissioner of External Affairs. She was one level down from that, and she had come up through the ranks. Have you heard her name?

VB: Yes, we've done an oral history with her in the past, too.

AS: OK, well, she's a dear friend of mine. Anyway, he signaled to me that he would like to consider me for something, but that I would not be getting the job. He already had someone in mind for the Deputy Commissioner job that she then got. And I went in, and I reported to Ruth, and Ruth reported to Sharon, and a year later, when I became the head of the office, I, for five years, reported to Sharon.

VB: So when you came, I think it's very funny that as someone with so many accomplishments and such a talent for advocacy was being razzed in the interview about (laughter) not focusing on that. And one of the most notable accomplishments of the Office of Women's Health in the first decade it existed, and actually to this day, is Take Time to Care.

AS: Which I invented.

VB: Yeah. So can you tell me a little bit about where the idea --

AS: With Marsha.

VB: Yeah. And can I just, before we dive into this...? When did Marsha come on? Did you have anything to do with her being brought in?

AS: I brought her to the Agency and to the office. And I did look very briefly at her oral history with you, and she's wrong about how exactly she came to FDA, I think. Marsha, forgive me, if you ever read this. But there was a woman -- you may be familiar with her -- named Sarah Kovner, and Sarah Kovner is, to this day, one of Donna Shalala's best friends. And Sarah's a New Yorker, and I've known her since the McGovern campaign, because she was very, very, very politically engaged, very liberal. Her husband is a prominent First Amendment lawyer. They're not kids; none of us are. Well, I understood that my strength was in communication and management, not, obviously, the science of the Office of Women's Health, and that I very quickly became convinced --

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-- that my contributions could be much more in the communication area. And I was struck, when I got to the Office of Women's Health, that there was an outcry by American women for health information. We were overdue. And as, at that time, an agency of 9,000 employees, you know, that had reliable information, good science -- and I was in the Office of External Affairs in Women's Health -- that we could do a great deal to fulfill the role. And I should show you -- I know Marsha referred to a brochure when she arrived that the cover photograph had literally been taken in my backyard. It was an osteoporosis brochure, and I can show it to you. It's pictured in one of the gifts I was given when I left.

Regarding meeting Marsha, I would go to meetings of political appointees at the Department pretty regularly, and I would see Sarah Kovner, who attended them because she was obviously a notable political appointee, and eyes and ears to the Secretary. And so I'd chat with her afterwards. And I said, "You know, I'm thinking of starting some kind of outreach program to really use the resources of the Agency well for women, and women's health. Do you know of people that might be good in my office?" I'm quite sure that it was through Sarah, and another woman in the Secretary's Office as the AIDS czarina. That's how I became aware of Marsha, and vice versa.

VB: So how did you guys hatch the idea for Take Time to Care? Where did it germinate from?

AS: We wanted to do something that would really hit a sweet spot in terms of women's health, would take on a significant matter, issue, whatever. And so I think we got the idea first

of starting to have meetings with leading women's health advocates, and asked them what interested them. And what floated to the top pretty quickly that really played to FDA's strength was medicine adherence, safe taking of medicines, understanding that you don't mix alcohol with medicines or supplements, and so forth. So we designed something that Marsha called a purse chart where women (or men) would list the medicines that they took, and the dosage, and so forth on this small brochure. And I know she also talked about going out for a contract with somebody, to bring in some professional assistance, but at a very low-cost level. We ended up selecting Ogilvy, as she mentions, and the person that we worked with was Tom Beall, who already had worked with a friend of mine, and who kept working with us in the Office of Women's Health, a very, very lovely man who has won awards and been extremely effective raising awareness around public health messages.

VB: So you mentioned that you did these sort of information sessions with women's health groups, and it seems like the relationship that the Office of Women's Health had with advocacy groups has been strong since the beginning, and a really crucial piece to the success of the office, and I was wondering if you could talk about some of the groups you worked with.

AS: I think that's right. I'm not certain how we put initial lists together. I think I knew some groups, obviously far, far fewer than I did even then when Marsha and I merged who we each knew. I think part of it was not knowing them necessarily personally, but saying, hmm, AARP should be involved and come to the table; nurses' groups should -- I'd already done work with nurses' groups; you know, pharmacists; various kinds of women's health and disease groups; and

so forth. So I think we made up a first group, and then expanded it as time wore on. And, you know, it just was crucial. I think it was the beginning of really amplifying the fact that there was an FDA Office of Women's Health that was open for business, that we wanted these different groups to know of us. We were creating a constituency for ourselves that would start expressing opinions far beyond one communications program, but would, much more than they had before, come to ADCOMs and weighed in on products that were being considered, and so forth.

VB: Did you also, in addition to the industry and advocacy groups, work with Congressional women?

AS: Yes, for sure. This will be an area of total candor: the Agency wasn't -- and probably a lot of agencies and departments are like this -- instead of fabulous working relationships you stay in your lane, I'll stay in my lane, so that I know that there were lots of times where it would have been beneficial to initiate conversations with the women on the Hill, or male Members on the Hill. But, if we asked to go to the Hill -- sometimes we would get to go; sometimes we wouldn't -- we always needed to take someone from the Congressional liaison office. I guess what I'm saying, if this is of any interest, is that it wasn't as smooth as it could have been. It still may not be as smooth as it could be. It just would be very advantageous to the public health if it just was really smooth, because you definitely want Members of Congress on your side, and to be well-informed.

VB: So you brought Marsha in, and you had these great stakeholder engagement initiatives, and you guys come up with this wonderful campaign to shine a spotlight on how women can better take care of themselves. And it's grown so much since then. Is there a reason why you've particularly focused on women over 45 in the initial rollout of the Take Time to Care campaign?

AS: You know, I'm not sure that we intentionally did that. I'm answering some things you didn't ask, and some that just occurred to me. You know, how did we come to Women's Health: Take Time to Care, that exact message? We didn't have a budget to do survey research, or even focus groups or anything, but there were places in the literature, as well as just kind of intuiting that a message that said women put everybody else first -- That was our message: women put their children, their partner, their aging parents, they put everybody else first, but if there's a breakdown in their own health, the health of the family breaks down. And so I think we pictured... I don't think we ever put an age. If Marsha said we did, that's interesting, and, you know, she would know, but at the very beginning we really thought of it as universal. And there was information from other groups on the Sandwich Generation, women who had children, aging parents. I, of course, wouldn't consider them aging anymore; (laughs) I'm older than that. But so in all the things we did, in reaching out eventually to pharmacies and all that, I'm quite sure we did not put any age on it at the very, very beginning. I know Marsha may have taken it years later toward conditions of older women: diabetes information, and some other illnesses and diseases, but at first we were just sort of looking at various ages and stages.

The way we came up with the title was in concert with Tom Beall when we already had Ogilvy. And I remember, actually, some different artwork symbols that they did, that Marsha

and I rejected, and stated, "No, no, back to the drawing board." I don't know exactly, but we had help from Tom, for sure, as well as Joanne Symons. I need to mention her name. Joanne was passionate and brilliant as a women's health consultant working in partnership with Tom. Joanne was a personal friend of mine, a political friend of mine, and she has now been deceased for, I don't know, 18 years, something like that. She died of ovarian cancer. But she was a freelance women's health consultant who partnered a lot with Ogilvy. So she and Tom were who worked on this with us. And so she deserves a lot of credit for some of the conceptual stuff and all, too.

VB: I feel like Take Time to Care alone was, has been, continues to be very influential, but it also, I think, really created a paradigm that the Office of Women's Health pursued for a long time after the '90s, which is the campaign strategy for identifying an issue and stakeholders and rolling out communications around that -- like with college women's health, and so forth. And I was wondering if there were any other campaigns that occurred while you were still directing the office.

AS: Because we were in the Office of External Affairs, and because, as the number two for a year with Ruth, and my heading the Office as Acting Director for four years is what I was -- you know, I didn't push ever to get the title Director; I was always Acting Director, if that's of any interest.

VB: I didn't realize that.

AS: Yes. As a nonscientist, as a non-health professional, and, I should say, as somebody who brought my own SES (Senior Executive Service) to the party, it wouldn't have really mattered in my pay, or that wasn't fundamental to how I thought of it all. But, I was secure where I was as Acting for four years. But in year one, under Ruth, and in year two, in both of those tenures I had a lot, a lot of free rein in the communications area. And I had been a political consultant, doing campaigns and brochures and all that, for candidates, and also posters and whatever. So I immediately did a display that the PASs (Public Affairs Specialists) used. We produced four of them and sent them out around the country. We had this whole system where the displays could go from one PAS to another without coming back to our office, and we paid for it. There was one PAS in every state. I don't know if they currently exist. They would go to health fairs and various events. And there'd be FDA materials on a table with one of our big displays, and I hired the models to pose for it. I don't know if you've ever seen it. I don't think I have any image of it anymore, but it would be interesting to come up with them. One, there was a Hispanic woman with a young daughter. There was an older woman with maybe weights, but running, in a jogging suit. So I had shot these different women of various ages and stages, and then copy on this display, and then this other brochure. Over time we did materials, and in collaboration with the Office of Public Affairs, we did a whole magazine. And that's the image on the display, which is a tabletop for a health fair.

VB: I haven't seen it, like, in a full display, but I have this brochure [showing OWH brochure].

AS: That's the display. So those were models, and I had a shoot at my home. Oh my goodness, it's really... (laughter) It's very gratifying. So somehow it came together that the Office of Women's Health lent some expertise and perhaps some input as to the topics, but Public Affairs or Consumer Affairs or both played a role in publishing this complete magazine with articles on women's health.

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You know, in the few years that I remained there, Marsha and I worked on various materials together did it, with her playing the biggest role. I was aware after I left at the end of 1999 that she created offshoots into menopause, diabetes and different things, but for a number of years it was the efforts I'm talking about that we went out speaking about a lot. We accepted a lot of speaking engagements. We offered to speak at health conference.

VB: And it seems like you mentioned all of these other women's health issues that got rolled into the Take Time to Care model. It's a great model for layering in new things because it's familiar, so it's easier to introduce without launching a whole new thing.

AS: Right.

VB: But just looking at the brochure, I mean, the number of issues that you had to address are overwhelming, and some of them quite controversial, some of them quite complex. Obviously the science is always evolving, and you have to find a way to translate it to a popular audience.

AS: I can't believe you have that. It's really quite --

VB: We keep records. (laughter)

AS: OK, and I might... I mean, there are some other things I probably have in my office that you may or may not have. You probably do, but... Did you see Take Time to Care brochures and all, the purse chart?

VB: I have the more recent "My Medicines" chart with the yellow and purple flowers on the cover. The one that the National Association of Chain Drug Stores distributes.

AS: They still do it.

VB: Yes.

AS: Oh my goodness.

VB: It's very successful still. I haven't seen if there was an original design.

I was going to say, there's so many different issues, and there's a couple in particular I'd like to ask you about, but what stands out? Like, what women's health issues, when you think of that time period, did you feel like were at the forefront or that were the most important that merited the most attention?

AS: Well, this is the part where I may be the weakest. I mean, I actually am picturing different medical officers that my office had, and things that they worked on, and I was always integrally involved in discussions. We collaborated but I depended on their strong science. Have you talked to Dr. Debra Smith?

VB: No, I haven't.

AS: Debra Smith was our Medical Officer for a while. She has had any number of other big jobs since. She may now be at Blue Cross Blue Shield as the person who is in charge of Blue Cross Blue Shield's dovetailing with the federal government. She's a very bright physician, an OB/GYN. She has been active, I know, in ACOG [American College of Obstetricians and

Gynecologists]. And she got extremely involved in device issues at FDA, reporting to and with me. Because, again, I was no expert. I was there from October of '94 till December of '99, and it was a time when the Center for Devices was still mainly known as very strong on engineering. Staff asked did the product work as designed, but not necessarily did the product work as designed in a human woman. You know we still have issues to this day about whether a stent is small enough for some women's arteries, that sort of thing. Well, back then nobody was asking at all about gender differences.

So Debra was really ahead of her time in a lot of medical device issues. Some of them had to do with -- (pause) I'm not even sure I can think of the right word, but -- ablation or whatever of, you know, female tissue, of a device being inserted. She worked very, very smoothly as an adjunct to the Center for Devices. So the Office, in some respects, offered a technical assistance to some of the centers, and especially the Devices Center. I can't tell you exactly what devices they were.

One area where I was deeply involved was breast implants, and there's a story there that nobody else may have told you, which is that... Let's see if I can really remember the origin of it, but there was a lot of pressure coming out of the earlier period when Ruth Merkatz was the Special Assistant to Commissioner David Kessler, a lot of pressure to understand rupture rates in breast implants. And there was a ton of litigation on whether breast implants triggered autoimmune diseases, and such that, I believe, David Kessler put a fine point on the budget, or had his budget people do it, and came up with $500,000 to do a rupture study. But there wasn't certainty that that was enough money, so he basically gave me the half million dollars and said, "See if you can raise more." I went to Vivian Pinn, who was the Head of the Office of Research on Women's Health at NIH from day one of that office until, I don't know, less than ten years

ago, maybe between five and ten, and who was an African American woman, who I think first worked there under Bernadine Healy, who was the head of NIH. Anyway, so Vivian and I had a really compatible, congenial relationship. She came up with some money, and she and my staff member, Marietta Anthony devised a protocol where the research would be done at NIH, in part at NCI, I believe. A rupture study was done for six or seven hundred thousand dollars, that I think was, and may still be, the definitive word on rupture. And it was something I took very, very much to heart, and I testified a couple of times at public hearings, at ADCOMs, in the years after I left the Agency, not making outrageous claims, but sometimes in conjunction with some of the anti-implant people, that there may not have been proper informed consent, that women, including really young women, were given breast implants as a gift by their parents for cosmetic reasons. In addition, women were having breast surgery for cancer, and then opting for implants.

So it's just something that interests me a lot from those times, and at the time when Ruth was still there she led a group of us that wrote and updated the breast implant manual, which was on the FDA website, and it was a book. I remember being on the phone with the plastic surgeons, trying to get them to adopt the book. FDA did some very good work on informing women, including having on their website pictures of breast implants that became really deformed. Much of the period when I was there, silicone implants were off the market. It's still my strong impression that the FDA Center for Devices did a horrendous job. Maybe they did the best job they could, but it just seemed to me, from a lay point of view, that they were hiding behind the fact that "This could be from doctors, from the patients; this could be repeat complaints," whatever, isn't good enough to discount the fact that there were tens and maybe hundreds of thousands of complaints about breast implants, and some did result in triggering autoimmune responses, and some reported rupture. The study we sponsored came up with a

rupture rate of over not that many years something like 69% of breast implants ruptured, and silicone traveled inside women's bodies.

Saline was more benign when it was saline implants, but with silicone I, to this day, believe that a small but consequential number of women who had breast implants where the silicone leaked, it did trigger an autoimmune response that made them very, very sick. And I always argue that women don't want to be sick, so this whole idea that there are all these thousands of women who wanted to be sick and complained that they were ill and, you know, needed to sue and all, I believe that most women, people want to be well, and that these were not people, you know, creating illness.

VB: I feel like that's certainly one of the iconic issues of the 1990s, and something that predated your arrival in the office that had long political, controversial roots that you inherited (laughs) as you --

AS: That's right.

VB: -- walked through the door. And one of the other things that was on your plate in founding the office was updating the FDA's policies regarding clinical trials, and the inclusion of women in clinical trials, and also one of the great achievements of the Office of Women's Health. And I was wondering if you could speak a little bit about that.

AS: At the beginning, at least, you know, in '94, maybe even before we were an office, Ruth was involved with that. Did you ever get the books, the different books that were published, little, thin books this big but, you know, this thin, that were regulations and updating the guidance documents, that kind of thing?

VB: No, I've not seen those.

AS: It was a trajectory of trying to take action that would be meaningful in getting industry to include women in clinical trials. And so there were a number of guidance documents over time, and a number of efforts, and to me, as somebody who just likes to get things done, some of it was just kind of interminable and taking absolutely forever. And then the other side of it was NIH, which I thought slowly required some animals, the mice to be female, but in terms of the research that they sponsored, I thought that it wasn't that meaningful or didn't have that many teeth in terms of saying, OK, now we have the women, but what are we learning? So I think it's been a really long haul for both agencies, in terms of saying what are we learning? Nowadays, I guess, some of those reams and reams and reams of data that applicants need to submit --

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-- at least they are strongly encouraged to report on gender differences. I'm not as close to it, because I work almost exclusively with products only for and studied in women. My clients are all women's products, so I don't see, and I'm not as up to date on all that, but I know Marsha

says that there are lots of companies that are doing a good job on getting women into the trials, and determining the gender differences.

VB: Well, I think it's a very good point, too, though. And I will digress, as well, to just match you. One of the things that strikes me in giving the Office of Women's Health and the Office of Research for Women's Health this mandate to increase women's enrollment in clinical trials, there wasn't, in the early '90s, when the mandate first comes down, there was no mention of what kinds of women you needed to enroll. But it strikes me that the Office of Women's Health, and I might have the wrong impression, but that there was always this attitude that diversity was an essential component of that, even before the demographic rule came down in 1998. Am I wrong, or (laughs) was that, in fact, the case?

AS: I think that just my impression is... I mean, Debra Smith was African American. Marsha Henderson, in the office, was African American. When we started, David Kessler gave us three FTEs.

VB: For the whole office. (laughs)

AS: For the whole office. And we had to find detailees, and so forth. And so, unless I'm mistaken, the first people in the office, both detailees and the three staff -- I mean, there were more than three people at the beginning, but we were given people who, frankly, in some cases

weren't cutting it in their own offices. You know, an office would say, "Oh, we'll lend you so-and-so," and that wasn't always out of the goodness of their hearts. In some instances somebody had been really hard to manage or something. But my point is going to be that we were all white, unless I'm forgetting somebody. So, I think that whether it's in clinical trials or in all the work that these offices did, we may not have been sensitive. Our consciousness was, I think, increasing. So, you know, it was very beneficial that Debra Smith became the medical officer, that Marsha, in addition to all the other qualities she had, that she was African American and had a different perspective. And that gets amplified. Then people are raising the issue and, you know, wanting to reach out to others and have different experiences. So, I think it was a growing consciousness, and I think we were far from perfect at the beginning. Back then there were many more Indian physicians and reviewers, and the diversity was there in that regard, but not in terms of African Americans and Hispanics.

VB: I believe it was also in 1997 that the Office of Women's Health sponsored the first Hispanic Women's Health Conference. You talked about different campaigns, and, of course, it ends up spinning off into the Hispanic Women's Health Campaign, as well, but where did the idea for this conference germinate from?

AS: Well, there was a woman named Jane Delgado, who was in our lives in those days, who came to the Agency with issues and ideas. I remember that we started printing a lot of the Take Time to Care literature in different languages and we engaged a firm headed by a Hispanic woman to translate things for us. I'd give Marsha a lot of credit, and maybe Deborah Smith and

to engage her we may have been above the average in that kind of consciousness. I do know that we led an effort, starting way back with Ruth of going around to train reviewers in the Centers, not on demography at the beginning but just on the importance of women in clinical trials. I think we kept raising different issues as they came along through the years, and we would train reviewers that these are important issues. I can't speak to the Hispanic Conference, per se; I just know there were a bunch of things that we did where we were reaching out to Hispanic constituents, so perhaps that's how it evolved. We also funded initiatives by the Public Affairs Specialist and that may have been its origin.

VB: Well, I guess returning to the clinical trials issue before that moment passes, it seems that it's paired with, or at least in my thinking, anyway, the concern about women's enrollment in clinical trials sort of stems from the Physicians' Health Study in the late '80s, and the awareness that there were absolutely no women being studied on this massive survey about heart disease. So the sort of founding mandate to enroll more women in clinical trials is also paired with this concern about creating more data about women's experience of cardiovascular disease, and I was wondering if you could speak a little bit about how the Office of Women's Health engaged with that issue.

AS: I guess I just have to give credit to Ruth and the other scientists. I was not a clinical trialist, so I don't think I have a lot to contribute.

VB: That's fair enough. You know, the Office of Women's Health began this intramural program with a budget of $2 million, which has thankfully grown over time, but sponsored tons of projects within the Agency, and some really impactful ones over time. Are there any that stood out to you during your time there that you felt were particularly valuable?

AS: I'm a good process person, so I played a role from the beginning in shaping the funding process. I took a calendar, OK, by what date do these applications need to be in, what will the rules be for them, and all that sort of thing. I think the relations between the Centers and the scientists at the Centers and the offices in the Office of the Commissioner, I think, really benefited from -- and it was very good politics that Janet Woodcock, who's still there, who, you know, is such a survivor -- that money went to the different centers, and that we had the centers involved in, as I recall, maybe not selecting the projects outright, but playing a role, having a seat at the table to decide what was funded.

I remember at the time Dr. Ray Woolsey did very important work on heart issues, and the QT interval. It has to do with heart rhythm. An important advance in understanding women's heart disease. When I was there we funded projects that involved a lot of important science to raise awareness on gender differences. We also did a lot of funding of outreach, taking advantage of our position in the Office of External Affairs. I know that Marsha built up the portfolio of funded projects greatly over time.

VB: Would the funding for outreach primarily have gone to ORA? Or did the other Centers do any particular outreach?

AS: Let me think about that for a minute. Some outreach projects might have been on cosmetics. But, I think it was in a lot of cases that PASs -- and this was, you know, really beneficial and in the public interest, too -- that PASs would be out and about, realizing that women didn't know enough about hormone, quote-unquote, replacement therapy at that time, or menopause overall, or contraception, or specific other questions that did pertain to women's stage in the lifespan. And the PASs were closer to the ground, they weren't regulators; they were communicators. So, we funded quite a few things; I just can't remember what they are now. It was over 20 years ago!

VB: Sure. I have a couple examples.

AS: OK, good.

VB: So in the '90s there were workshops on women's health empowerment, which I imagine you'd get PASs involved in, right? And in particular, I think there were Philly-based and Delaware-based workshops, women of color outreach, Hispanic women's health outreach that we talked about, and working with Asian-Pacific Islander groups --

AS: Well, there was a very important national Asian women's health group, not Asian nurses, which there are now, or Asian this or that health professionals. But at that time, based in San Francisco -- and they even opened a Washington office -- there was an extremely impressive, formidable Asian-Pacific advocacy group, and I got to know the Director really well. You know, that's really part of what it takes is somebody raising the issue. "Hey, we're here. Work with us. Fund us. Collaborate with us." I remember going to see her in San Francisco when I was out there for other things.

VB: Do you recall if their priorities focused on increasing women's health literacy, or in making sure that OWH materials were inclusive of the group?

AS: I think probably both of those things. I remember learning that... You know, a number of cultural things were brought to our attention, like the fact that middle-aged and older Asian women were too modest to go to a male doctor, so they did not see a doctor; that a lot of these middle-aged or older women were not adept at English, and so their daughters were their translators. Just a lot of cultural things. I sort of associate it with having read Amy Tan. Some of the same cultural things. You know, we printed literature in Hmong, having numerous translations for our materials.

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I remember going out to do Take Time to Care in San Francisco at one point, and going around to different drugstores in ethnic neighborhoods. We had a whole pilot in San Francisco, which is

obviously a really, you know, Asian-oriented -- part of it is Asian. I don't have much more to say about that.

VB: Well, I think especially at this point, 25 years down the road, the amount of materials that the Office of Women's Health makes available in different languages is kind of astounding, and I imagine and --

AS: We did start that.

VB: Yeah. But I think it's a guiding light for the rest of the Agency, too. I can't imagine another office that matches -- and I think Marsha might know best how many different language, different translations there are.

AS: Well, I am sure you're right. We did a lot of that, and sort of a broader point is that at least in those days the Agency and the different offices, even some of the ones in External Affairs, were not as proactive as I thought they could be. I remember talking to the political appointee in the Office of Public Affairs, and saying, you know, "We have this Take Time to Care program, and a component of it should be media outreach, not just giving speeches or just partnering with the chain drugstores or whatever, but actually, you know, if we go to San Francisco, getting on the radio and saying this whole week or, you know, for some time to come you can go to your drugstore and get a brochure that you'd put your medications on, and then

take it to your doctor." I had to fight them on it. I finally broke through, and occasionally they would help us, or not stand in our way of doing media.

VB: Just a resistance to putting it out there? Do you have a sense of why they were opposed?

AS: I think its typical bureaucratic malaise, or... I'm not sure. I wanted to be, you know, super, super proactive.

VB: Were there any things you really wanted to launch that you just couldn't get through?

AS: I truly can't remember such things. It's so hard to reach people in their busy lives that I just wanted to... Again, I always would think, there are 9,000 employees here. Surely we could get experts on this or that, you know, whether it's osteoporosis or arthritis, etc. I mean, it's sort of gone full circle, and now I guess far fewer people take osteoporosis medication, at least Fosamax, which is what people were taking at the time, and there's some reason for that. I think there's been a tremendous evolution in terms of FDA going from a very buttoned-down regulatory agency to what I would call sort of the softer side of FDA, which I first witnessed as part of the patient-focused drug development workshops that Janet started, and the whole strategic idea that they should hear what illnesses, conditions, diseases are not being addressed, and should hear from patients and all that. But at the time it was "We're regulatory. That's it."

VB: Well, as a historian, my perspective is the ’90s were a huge turning point for the FDA in moving towards more not just protecting but also promoting the public health, right? We changed our mission statement in that time period, and the creation of the Office of Women’s Health is a major signifier of that. And another office, which I think maybe predates the Office of Women’s Health by a year, too, is the Office of AIDS and Special Health Populations.

AS: Mm-hmm, yes. Terry Toigo.

VB: Yes, and Patty Delaney. I imagine, especially, you know, in the sort of... I guess we weren’t in the throes of the AIDS crisis at that point, but still responding to it. There was a lot of overlap between the engagement they needed to be involved in women’s health issues, and making sure women got proper information about AIDS risks and therapies. Did you guys partner with --

AS: I think we did. I can picture Terry and Patty in and out of our office, and, you know, there were things related to cancer but definitely AIDS. I remember being at the Parklawn building when there were protests by AIDS activists and so forth. I can’t remember specific initiatives. I mean, there were all kinds of things. I can remember more on cancer that Patty would be in our office a lot, and one example was the informed consent about breast implants,

writing that book, and working together to get plastic surgeons and others to adopt it. But in terms of AIDS, I remember -- do you know the name Tom Sheridan?

VB: Yes.

AS: It's when I first met Tom Sheridan, who was really doing a lot of work on AIDS advocacy. He and others were pressing for more rapid approval of AIDS therapies.

VB: Sure. So, since it was such a new thing for FDA to be creating offices like this dedicated to advocacy work and intramural research, how did the rest of the Agency perceive the Office of Women's Health? Do you have a sense of what the reaction was?

AS: We had an agency-wide coordinating committee. We would have monthly or bimonthly meetings with representatives from all the offices and all the Centers.

VB: The Gender Effects Steering Committee?

AS: This was just an agency-wide steering... I don't know for sure if we called it a steering committee; maybe we did. It was featuring women's health, and having center directors appoint

one very senior person from their center or their office to be the representative to this working group, whatever you'd call it. It was a coordinating committee. People would come to this meeting, and, you know, I chaired it in my years. People would come and report on projects, maybe the funding that their area had gotten, bring attention to things related to women's health that should be looked at or worked on. So they were kind of our eyes and ears, whether they brought things -- oh, gee, there's, you know, a problem; or we're not paying attention to this or that in our center -- I think that was sort of the attempt to organize all that.

VB: Was there a lot of enthusiasm for it?

AS: I think there was.

VB: Were there some center...? I don't mean to make you call anyone out but were there some that were more engaged than others? I know that there was a lot of grants that went to NCTR in the first maybe ten years of the grants program, and CDER, of course.

AS: Mm-hmm. I don't think I have a lot to say about that, but I can't remember... You know, as I said, Devices was especially grateful. I think that Drugs people were in and out of our office a lot, and we did well with them. We weren't rivals by any means. I think we may have wanted to work more closely with them than necessarily it was practical to do, because they were so big and so occupied with their regulatory mission. I remember smooth relations, nothing bad,

nothing other than the Devices issue where... You know, I remember working on biologics, and, you know, ART and so forth, and having people really explain to me what a pressing and growing women's health issue ART was, and working closely with them, and wanting... Kathy Zoon was the head of Biologics; I don't know where she is now. And I remember a really nice fellow at one point, if he was the head of it, too, a really impressive, pleasant guy. (laughs)

VB: Did you know that Jeff Shuren, who's the head of Center for Devices now, has appointed his own advisor on women's health?

AS: I didn't know that. I don't know him, but I have had clients or just in conversation have known that he has been good on women's health issues. So that would just be within his center, and I guess it would be informal, that he or she would work with OWH?

VB: I think it's so that he has someone inhouse who can provide the expertise. I don't think it's meant to undermine the relationship with OWH.

AS: I think that's ideal for all the centers. I mean, the more expertise you bring to the table, the more sensitivity. I've been aware of not so much in Devices but there are definitely some areas in Drugs where there are divisions that like to give certain subjects -- sexual dysfunction, some other subjects kind of a hard time.

VB: Mm-hmm. And so the training program for medical officers is one way of -- not top-down; more middle-up (laughs) way of keeping women's health issues on the radar, and I know that that program is still going strong, and in the virtual format, even, I think now.

AS: Good.

VB: Which actually leads me to another question that isn't directly related to women's health, but in the midst of trying to stand up the Office of Women's Health the internet became a thing that you can use to communicate to stakeholders. And you were in the Office of External Affairs. So what was that like? Did you immediately realize what an awesome tool it would be, or was it a slow start?

AS: I think what immediately comes to mind is that the Office on Women's Health at the Department got involved in it very, very quickly, and had great graphics. I can sort of picture the opening page or whatever, the graphics that I thought were very woman-friendly. I think we understood pretty quickly that it would be a revolution to put materials up, but I don't have a clear picture of what we did when. We weren't a backwater, that's for sure. We did start using it, and putting some of these things -- osteoporosis, some of the other conditions and all -- up pretty quickly, but I don't have a lot of specifics. Do you have specifics?

VB: I don't have any specifics, but the Agency archives, old pages of... It would be very interesting, I think, to go back in time to 1996 and see what it looked like.

AS: It would.

VB: And certainly now, it's just... I think the original handle, URL for Take Time to Care was, like, fda.gov/ttc.html.

AS: T-T-T-C, mm-hmm.

VB: Yeah. Just the way that we even construct a URL these days has evolved. But the resources currently on the For Women site are so vast, and, like I said, translated into a million languages, and just a lot there for women of all backgrounds to learn from.

AS: There's so many areas that I've worked in that, you know, the groups have their own thing, from, you know, ASHA, the American Association of Sexual Health, or all the different groups that I now work with, NOW... A lot of groups related to contraception. Of course, some administrations, even ones that --

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-- I would be more sympathetic to, are a little squeamish sometimes about contraception, or... You know, it shouldn't be that way. It should be, if it's an FDA product, a contraceptive or whatever, should be lots of information on it.

VB: Yes. How does your experience at the FDA continue to inform your consulting work now?

AS: Well, I never felt like I could be, or there was no attempt at all for me to be a regulatory consultant, so often there might be a regulatory consultant, either in the form of a law firm or somebody who was in a center. And what I do is work with advocacy groups that have a common agenda with us. What I work with is mostly small companies that are developing, or even have approved products for women, and then work to advance them together. And it's helpful, in a very general way, to have been there, and know the culture of sorts, although it changes. But I've been lucky enough to stay involved. Marsha had me with Phyllis Greenberger and some others, be involved in helping organize a women's health meeting with Scott Gottlieb several months ago, not that many months ago. Years ago there was a meeting with Peggy Hamburg and we women who'd run the FDA office.

So I've had some exposure in terms of insider kinds of things, and I've had a lot of exposure to continue, going to ADCOMs, or sometimes advising clients on ADCOMs. I just very fortuitously... It's like family, kind of knowing how it works, and some of the players still. So it's helpful. I know that it's a norm for many people at the FDA to then go to industry, and they're more typical in terms of, you know, companies making a beeline for them. I think I've

developed a niche, which is to work with women's health related companies, and partner them up with likeminded advocacy groups. And, you know, I think it's all for the good. I think women are better for it. When I work for a company and a product, the advocates know that it's not some fly-by-night company or product and that I know enough about the processes of the FDA, or at least I know where to find out if I don't know.

So, you know, it's the closest I've ever come to a revolving door, in the negative sense, but I don't feel like there is anything negative about it, that I basically went to school at the FDA in terms of learning about the Agency and women's health. And I remember at the beginning, oh, 25% or whatever of the nation's economy is regulated by the FDA. How do people end up having the careers or the whatever that they have? I just ended up in something that really, really, really interests me, and that I feel good about.

VB: What prompted your departure from the Office of Women's Health?

AS: I was a political appointee for six and a half years, and one more year and my tenure with the administration as a political appointee who served at the pleasure of the President would have been up. But I kind of moved at a pace that was more... I absolutely understand that the leadership of the FDA, that reviewers, that lots of people there work plenty hard, but I worked more at the pace of a political appointee, which is faster and harder, I think, than the average government employee. And so there was that consideration, that I was a little bit burnt out. The other consideration was that I actually felt that I was being kind of piggish to serve for six and a half years, to be paid for six and a half years, whatever, and that it was time to give somebody

else a chance to have that, and so somebody could come in and get that slot, whether it was my exact job or whether it was just my SES going to someone else.

VB: Were you involved in recruiting Susan Wood to the office at all?

AS: Well, I knew Susan Wood. Yes, I was. I recommended her to Sharon. Yes, she's very good, and obviously she... You know, she has good lay leadership process skills, as well as the science.

VB: Yes. Going back in time a little bit, you were heading the Office of Women's Health when the first female Commissioner of FDA was appointed.

AS: Jane Henney.

VB: What was that like, to be at the Agency then, and what was it like for the Office of Women's Health? Did you have a good relationship with her? How did she react to women's health issues?

AS: Well, she was very professional, and very by-the-book, I think, not that I'm suggesting anybody should be anything but by-the-book. I know that we got along well. I didn't get to know her well, super well, but I can even picture running into her at places other than at the FDA, and... I can say I think she did take a bit of a special interest in Women's Health, and was supportive, but -- I'm trying to think if I'm forgetting a Commissioner, but I do remember Michael Friedman very positively, also, that I was under. So after Kessler I think was Friedman, and then Henney. And, you know, everybody was... They were all supportive of the office and of me.

VB: I mean, there were some women's health controversies, certainly, that drew heat, I guess: the development of RU-486, for one thing, and concern about the carcinogenicity of tamoxifen, in terms of uterine cancer, and things like that. I mean, those got to be very high-profile issues. Do you remember the Office of Women's Health having to engage or provide talking points or anything like that, or do you remember the Commissioner's response to any of those issues?

AS: My mind's sort of leaping on one issue and then another.

VB: I threw a bunch out there, sorry. (laughs)

AS: Yeah, no. OK, so tamoxifen, I don't think I have anything to say. I was thinking real hard about an issue... One issue early, early, was thalidomide for... I mean, I was very aware of

thalidomide as something that could be an anti-AIDS drug, and that it was being considered for that. I don't recall the outcome, but I remember that was highly visible. Say again the different issues you threw out.

VB: RU-486.

AS: RU-486. So, as I recall, that was sort of when I was first coming to the Agency, and years later there was the issue of the morning after pill. I can't say I really remember... I mean, I feel like RU-486 was already an issue before I got to the Agency. I know that it was. I think, you know, anything related to abortion... is highly controversial within the agency as well as in society at large.

VB: That's fair. I have one other I'll try on you, more positive but still revolutionary, I believe it was '95 so while you were there: first evidence that breast cancer had genetic correlations, with BRCA1 being discovered. Do you remember what that was like?

AS: Well, I remember that, and I remember actually marching myself somewhere near the office, the Parklawn building, maybe even in the Parklawn building. I'm a Jewish woman, and I put myself in a trial where I was tested to see if I had BRCA1 or BRCA2, but was not allowed to learn the results. But yes, there was a whole evolution in the science of breast cancer, and I know -- and I'm not as up as I should be -- now there's so much more that's known in terms of

the genetics of it. So I don't think I have a lot to say, just that, I mean, breast cancer became something we were more aware of. The Office of Consumer Affairs and the Office of AIDS and Special Health Issues are where we sort of shared those.

VB: Well, is there anything else you'd like to share? Like, any fond memories? Anything I didn't cover in my questions that you think is important to capture?

AS: Well, some of it was the sisterhood and friendship of the office, doing something that was really important. We were strong advocates for the office growing. When you started and said, you know, the office wasn't necessarily thought to be permanent, I mean, we had absolutely no doubt that it was needed, that we could make a difference, and that it was our job to fight for further funding. And every time we saw the evil eye of the budget people, or somebody eyeing our money, it was like pushback time, because we knew that we were sort of -- not too little too late, but we were overdue to put these issues and consciousness on the FDA table. I made friendships there that are lasting friendships. It wasn't a huge factor, but I enjoyed sort of another hat, which was the political appointee going to the Department all the time, and interfacing with those folks. Some of the things that were less wonderful had to do with how bureaucratic things were, but it was all worth it --

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-- to be challenged, to, you know, get an additional FTE, or after wading through this many résumés to fill a position, reading people's KOLs and God knows. I mean, some of it was very

bureaucratic, for someone who, you know -- I'm more used to political campaigns, or political consulting, or having a small business. Of course, I've worked at the Pentagon and worked at places that were huge, too, but my preference is non-bureaucracy.

END OF INTERVIEW