Oral History Interview with
Susan Wood, Ph.D.
Assistant Commissioner for Women's Health
Office of Women's Health
2000-2005

FDA Oral History Program
Final Edited Transcript
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Oral History Abstract

Susan Wood, PhD, served as the third head of the FDA Office of Women's Health under the title of Assistant Commissioner of Women's Health (2000-2005). Under her leadership, OWH advanced FDA's efforts to increase the enrollment of women in clinical trials and track gender-based data on drug safety and efficacy. OWH also confronted adverse events linked with silicone breast implants, implemented labeled warnings on hormone therapies, and funded pioneering research on gender differences in heart disease. Dr. Wood resigned from FDA in 2005 due to the agency's refusal to follow the science-based recommendations of its medical officers to approve the OTC application for the emergency contraceptive pill, Plan B. After leaving FDA, Dr. Wood served as the Director of the Jacobs Institute of Women's Health Services at George Washington University.

Keywords

women's health; emergency contraception; hormone therapy; 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.

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Interview Transcript

VB: All right, so this is going to be an addition to the FDA Oral History Collection. I am Vanessa Burrows, for the FDA History Office, speaking with Susan Wood, the former Assistant Commissioner for Women's Health at the FDA. This is Friday, August 23rd, and we are on the White Oak campus. And I'd like to just start out by asking you a little bit about your background -- personal, professional, educational, etc. -- how you got interested in women's health, and involved in it from a policy angle, and what sort of set you on your path towards FDA.

SW: It's a really interesting story, because I have a very zigzag career, and I never could have predicted pretty much any step that I ended up taking. But my basic training is as a basic scientist, basic biologist and biochemist. I have a PhD in biology from Boston University. Strangely enough, my dissertation work was actually in marine organisms, invertebrate phototransduction, the biochemistry thereof. So it was completely basic science, and completely unrelated to anything FDA-related or public health-related, very basic science and neuroscience, biochemistry.

I then went on and did a postdoc at Hopkins School of Medicine, again, working very basic science on olfaction, the biochemistry of olfaction, vertebrate olfaction, and spent a year working with Dr. Sol Snyder, who was my postdoc mentor, in his lab. But during that time and over the years I'd been interested in science policy, not really knowing what that meant, I had done some things in Woods Hole, which is where I did my doctoral degree, putting together a seminar series on the link between science and policy. And I'd been just learning a little bit

about science policy and what it is, but I didn't really know what I was talking about. But I decided to apply for one of the AAAS Science Policy Congressional

Fellowships, so this was to work on the Hill. You're placed as a scientist in a Hill office for a year to provide scientific advice or whatever, and to learn about Congressional-level legislation and policy.

When I did get that fellowship, sponsored by the Biophysical Society, and AAAS, I went and ultimately took a placement working for the Congressional Caucus for Women's Issues, at that time cochaired by Congresswoman Pat Schroeder, and then Congresswoman, later Senator, Olympia Snowe. Pat and Olympia were our bosses, but it was a bipartisan caucus of the women Members. At that time, I believe there were only 17 women Members of the House, a really small group. So it was a bipartisan organization, still is, working on a range of women's issues, one of which was women's health. They had just started at that time -- this was in 1990 -- had just started the focus on inclusion of women in clinical trials, starting first with the focus on the NIH. I was brought in because I knew more about research than anybody else on the staff. (laughs) And although I didn't know anything about clinical research, or clinical research design, or anything like that -- I was a very basic scientist -- nonetheless, I had some understanding of NIH grant processes and research and universities and things like that.

So I became the lead staff person on a lot of the women's health legislation. That was at the time when the Office of Research on Women's Health was established. This is in late 1990. It was when the first Women's Health Equity Act was introduced, which included legislation on offices of women's health around HHS, including at FDA. It expanded research in a whole bunch -- breast cancer, infertility and contraception, osteoporosis. There was legislation in there

that did get passed around chlamydia screening, and the Mammography Quality Standards Act, which was a big FDA piece of legislation. They were a big part of that. There were a whole host of 27 bills compiled into one, and then bits and pieces of them got passed at different times, a lot of them on NIH, some of them on CDC, and some of them on FDA. And so that was what I was doing. I ended up staying on the Hill. Instead of just for one year, for the fellowship, I ended up staying for five. They offered me a full-time permanent position, and so I stayed on as, at that time, the Deputy Staff Director for the Caucus and Science Advisor.

And, again, this was a time when just -- it's hard to imagine in these partisan times -- when actually a lot of legislation got passed, a lot of things got done. This was at the end of Bush 1, and the first part of the Clinton administration. I ended up representing the women Members on the attempt in the Clinton era to do healthcare reform at that time, again, focusing on things relevant to women. You know, how do you make sure that there's not different premiums charged? How do you look at prevention? How do you look at things like contraception? All of these things -- mammography -- how do you make sure some of these things are part of whatever package starts to move through? Because the women Members of Congress at that time could agree on basic principles of what they would like to see in healthcare reform.

Anyway, I did all sorts of things during those five years. At the end of those five years -- oh, actually, there was a big change in Congress in 1994, when the Republicans took over the House. And, at first I thought, well, that won't have any effect on us; we're a bipartisan group. But it turned out there's a long history of trying to abolish the Caucuses. There were a number of different Caucuses, some of them quite functional, like the Women's Caucus, some of them a little bit questionable in terms of what their focus was and what they were doing with the dues

they were getting from their Members. But the Women's Caucus was beautifully run by our Executive Director and the Members. In any case, there had been a long history of trying to abolish them as staffed organizations, so of course there is still a Women's Caucus, and they still do lots of things, but they no longer have a staff or a staff office dedicated to support them. So all of those of us who were staff, (laughs) we all were laid off in 1995.

At that point I got a job at HHS, within the Office of the Secretary, in the Office on Women's Health, which was now established. Now, meanwhile, while back at the Hill I had actually been involved drafting legislation to establish an Office Women's Health at FDA -- we had GAO reports on FDA-regulated studies, and whether there were women included in all phases and all types of studies; and I drafted legislation to permanently establish an Office of Women's Health at the FDA; and we'd worked on getting funding through appropriations language. Again, this was with the leadership of a number of women Members who I have to make sure I give lots of credit to -- Senator Mikulski, on the Senate side -- at that time there were only two women Senators, (laughs) and so Senator Mikulski carried all the water; and on the House side, a number of women were just critical in getting appropriations and budgetary language in to support the Offices of Women's Health around HHS, including an office at the FDA, which was basically directed through appropriations language in the early 1990s, and that was why it was established in 1994.

So by the time I left in 1995, there were quite a number of these Offices of Women's Health established around HHS, and I got a job at the HHS Office on Women's Health, at the Office of the Secretary, where I was the Director for Policy and Program Development. I served as the number two in the office. I stayed there about five years. The last year -- well, much of the last year I was the Acting Deputy Assistant Secretary for Women's Health at HHS, and then

when Audrey Sheppard stepped down as Director of the FDA OWH, and then they posted the job at FDA, I decided to apply to FDA. For me it was sort of a circling around from where I'd gotten extremely far away from basic science and the laboratory and data, direct data, by going to work for Congress, for goodness sake, and then at the HHS level. Again, you're dealing with health policy and science-based decision-making, one hopes, but you're nowhere near the generation of that data. By coming to FDA it was sort of a partial return, getting a little bit closer to research and data. I was not in a review office, I was not dealing directly with data, but my colleagues that I was seeing every day and talking to were, so it was returning back a little bit closer to the science and research that people were doing in a whole bunch of different areas. And so that was a real draw for me to come to FDA, because I thought, well, that'll be cool. I'll get a little bit closer, still nowhere near back to doing research, but a lot closer.

VB: Before we dive into your arrival at FDA, can we talk a little bit about your work at the Department?

SW: Sure. In the Department I was involved in a number of different major projects. First of all, I was the staff person in charge of coordinating the HHS-wide Coordinating Committee, and that represented the people from the Head of the Office of Research at NIH, Vivian Pinn during that era, the FDA, CDC, HRSA, SAMHSA, and the different offices within the Office of the Assistant Secretary for Health. The Assistant Secretary for Health was the co-chair of that, along with the Deputy Assistant Secretary for Women's Health at that time. So there was the Coordinating Committee work that I did. I also was involved with some of the programs that got

developed at that time at that office. Some of the key ones were the National Centers of Excellence in Women's Health, which were established at academic health centers around the country and provided not a lot of funding but some funding for coordinating areas around research, training, leadership opportunities for women faculty, outreach to the community, and actual clinical care, comprehensive clinical care. So the National Centers of Excellence program was developed and launched in that time, so I was part of a team working on that. Also, the National Women's Health Information Center, which was one of the first online, really in-depth, trying to pull together both the federal information on topics related to women's health, but also credible resources outside the federal government, nonprofit organizations and other educational resources. So that was created.

I was managing people who were running programs, and doing lots of different projects, and working with colleagues within the Office who were handling communication, or handling other specific aspects of the programs that were being developed by OWH at the time, so... Let's see, what else was going on during that era? Lots of things were happening. So that was my day job then.

VB: Did you interface with the Women's Health Initiative at all in the Secretary's Office?

SW: Not really, because Vivian Pinn was one of the Co-Directors of that, along with Jacques Rossouw. Vivian was one of the Co-Directors of it, and she would report back on how it was going along. And certainly there were lots of issues around, for example, the National Women's Health Network as advocating and successfully advocated for some redesign of the Women's

Health Initiative, so that you weren't giving women who had not had a hysterectomy, unopposed estrogen, which would increase their risk for endometrial cancer. There were things that were happening that we were aware of. Now, the closure of the Women's Health Initiative, that all happened while I was at FDA. There was a lot of interaction when they closed the trial and FDA put black box warnings on the hormone products. So I was definitely around for that part, and I was very involved with that response. But during the actual development of it… I was there when Bernadine Healy first announced trying to do it. That was while I was still working on the Hill, and then it was getting launched over the next few years at NIH. I was certainly involved when it was on the Hill, on pushing NIH to do more, and working to support the women Members who were fairly insistent that something be changed at NIH. That was definitely my job. And there was a lot of NIH focus in that era.

VB: In terms of enrolling women in clinical trials?

SW: Enrolling women in clinical trials and doing more direct studies. When the Women's Health Initiative came out, it was in response to all this pressure that was happening, because there had been a lot of big studies on men, the aspirin trial, which had all male physicians, and there was another dietary study which was male only, which was seen as just not well thought through, because who does the shopping and the cooking, generally speaking, stereotypically speaking? And yet the study was on men, and getting them to change their diets... So there were a lot of examples, anecdotal but big examples of egregious problems with inclusion or even targeting women-specific things. There also was a lot of focus on breast cancer, -- not entirely

female specific but predominant – and other conditions that had lesser focus. There was a lot of advocacy around breast cancer and osteoporosis and contraception.

I mean, a lot of this started with the tension about between reproductive health and comprehensive women's health.. It's not a real tension, but the relationship between the reproductive health issues and health needs and research needs and actions, and women's health across the lifespan -- cardiovascular disease, Alzheimer's, HIV/AIDS risk -- all of these topics and issues, there are swings that go back and forth into what's in the forefront. And so I am told, before my time, one of the reasons that the women Members in Congress got interested in these issues on women's health was because that there was extremely little NIH-funded research on contraception, and infertility, and there was extremely little investment by the pharmaceutical industry in contraceptive development. And yet, if we wanted to get past the abortion wars, the naïve thinking was that if we had better contraceptive methods, and we all got behind better access to contraception, that we would help at least mitigate against the concerns of abortion politics... And that contraception was common ground. This was something we could all agree on.

When the women Members -- Pat and Olympia -- learned that there weren't many OB/GYNs at NIH, and they weren't doing this research in this area, they started asking questions about other areas that were not women-specific. That led to the whole question about inclusion of women in clinical trials, and the first GAO investigation, which happened before I got there. And there were a lot of people involved in getting that first GAO investigation started, and they were brilliant. When that GAO investigation of NIH came down and said nobody tracks inclusion of women in clinical trials, we don't know, and there are these egregious examples

where they've been excluded, that set the stage for the whole expansion and focus on women's health. So I'm not sure how I got off on that.

But anyway, so we go back and forth. So when at HHS, we were focusing on everything but reproductive health, pretty much. We really were focusing on the women's health across the lifespan, and trying to get at all these other issues, and not just the contraception and abortion wars, which were going on then, and then things seemed to calm down a while, and now they've blown up again. But, it's a back-and-forth about what do we have the resources and the capacity to address, and what are the priorities at the moment, given what's going on at a given time. And, unfortunately, we still keep going back and forth, juggling that all at the same time, so...

VB: Yeah. So thank you for the background. I guess now we can segue into (laughs) --

SW: What actually happened at FDA, yeah.

VB: -- yeah -- to how you came to FDA in November of 2000.

SW: November of 2000. So it was an

[00:20:00]

interesting time. I had applied for the position, and interviewed with Sharon Smith Holston...

SW: Wonderful person. And she was my first boss here. And --

VB: Can I ask you, was the position Director or Assistant Commissioner when you applied?

SW: It had two titles.

VB: Oh.

SW: I mean, I don't know. It was at the level of Assistant Commissioner, and I know it's now Associate Commissioner, I believe, so that's good. But they always seem to be reorganizing the Office of the Commissioner. And I was Director of the Office of Women's Health, but I had the title of Assistant Commissioner for Women's Health, as well as Director of the Office of Women's Health. It got reorganized a couple of different times while I was here in terms of how the Office of the Commissioner was organized, and who was in line where. I think when I left we were part of the Office of Science, whereas when we started we were part of Office of External Affairs.

VB: External Affairs.

SW: And it was at the time right... It was a very odd time in history, because it was during the now forgotten about time when George W. Bush was elected the first time against Al Gore, and for weeks, if not months -- more than one month -- no one knew who was going to be president, (laughs) and so it was really odd. And so that was exactly when I started the job. No one knew who was staying or going as Commissioner. Jane Henney, she was Commissioner, but was she going to last more than another couple months, or was she going to be gone. So I'm starting, and no one knows what's going on anywhere across the nation, so it wasn't unique to FDA at all. But it was an odd time.

I was learning... I think I have to say the first year -- and this is probably true of everyone who comes to FDA -- you learn a lot during those first year or so about how the Agency works, and where it fits in the puzzle of federal agencies, and the role of regulation, and the specific hierarchy that is FDA, and how it works, the different statutory authorities that all the different centers have, how that is translated into the different levels of regulation. And then where does an office like the Office of Women's Health fit in that? You know, part of the Office of the Commissioner, not part of one of the centers, not part of a review division or a regulatory enforcement side of things. And so where do you fit to help make change, again, during that era which, again, initially no one even knew what party or what individual was going to be president or commissioner or any of the political appointments that were going to come down. It was a very interesting time to start.

VB: Yeah, I can only imagine.

SW: Yeah.

VB: So I guess in that period, and then also after you learned who would be president, and --

SW: Commissioner and all that.

VB: -- the onboarding of the new administration, what was OWH like when you joined? Who was --

SW: It was great. It was a great crew, and I have to remember... So, as I mentioned, Peggy Miller was there as the Science Director. Patty Bradfield was there still as the Administrative Officer. There were several other staff members, all great people, really... And I have to say this of everyone I worked with at FDA, that it's a very -- and maybe it's true of the other agencies, but -- very mission-driven, and people really want to have a positive impact on the world, and on the country, and through whatever it is they do within the Agency, they're part of this larger mission. And, yes, people can be frustrated, and yes, there are all sorts of issues, but underlying that was this real goal that this work that people were doing was important. And that's something I feel pretty strongly about.

And so the team at OWH was great. I really enjoyed them a lot. They helped me learn a lot of things. There were also some people we worked closely with pretty much... We had connections with people at CDER, CBER, CDRH, some at CFSAN, less, but there had already been a lot of progress in putting in regulations on the inclusion of women in clinical trials and trying to change the training protocols for reviewers to ask the questions. I mean, there's still progress to go. We were working, also, with the Office of Special Populations, as it was called at the time, and they were doing analyses on actual inclusion numbers, so they were doing some of that work. The work that the Office of Women's Health was doing was in a couple of different areas when I started.

One was a scientific research funding program, which still goes on today, funding things in all the centers. And one of the key areas that we ended up working on during the next few years had to do with studies to be done in pregnancy, that we... I mean, there were the research projects that the folks at the different centers would send in to apply for, that they had an idea they needed to do. Then we want to do something to do with medications during pregnancy, because nobody would touch this topic with a ten-foot pole. That was an area where we actually funded PK/PD studies of pregnant women with health conditions, for hypertension, antibiotics, also for antidepressants. The goal was to demonstrate that you could do these studies of women who had these conditions, and were already on medication, that you could get some useful data of PK/PD to help with dosing decisions across pregnancy, because there's basically no information. Because this was all going in parallel with trying to change the pregnancy section of the drug label during all the label changes that was happening during that time, as well. We needed to change the section on pregnancy, and, boy, that was a long-term process, because everyone was so nervous about anything to do with drugs and pregnancy.

As I mentioned the last two days, I've been participating in an NIH -- well, NIH held it, but it was an HHS, actually, government-wide task force on research on pregnancy and lactation and therapies and medications, trying to make real progress, because of legislation that was passed a couple years ago, and some of the very same issues are ongoing. They're not intractable issues but they're really slow to solve -- you know, the fear of bad outcomes, and fetal effects, and liability, and ethics -- and it just really makes everyone extremely nervous. And so how do you actually stimulate more research on this? Well, we were doing this back in the early 2000s -- trying to show that you can do these studies, and ultimately -- and this is something you'll have to talk to Cook about, because she was the point on this before she became the head of the office herself. She was working with Peggy Miller very closely on getting that research done, and on getting that guidance on PK/PD studies during pregnancy out.

We also put out a guidance -- the demographic guidance. FDA, for some inexplicable reason, as far as I'm concerned, had been exempted from the HHS-wide directive to collect data by race and ethnicity, because the argument was, well, this is industry-sponsored, and we don't know of any reason why we should ever collect data by race and ethnicity, because there's no reason to think it would have an impact on drug safety or efficacy. So they had gotten themselves exempt -- they, we -- FDA had gotten itself exempt from that it may have been even larger than HHS but at least HHS-wide directive that you had to do this, so they were exempt.

Since nobody would take this on, the Office of Women's Health did, and put out the draft, and then ultimately final guidance -- it's just a guidance. This is just on collecting the data that you have, not saying that you need to have inclusion that you can analyze, enough inclusion that you can analyze for racial and ethnic differences, but if you have it you need to at least collect it by race and ethnicity. And that's what's used now in the drug snapshot, for example.

They can break the data down. At least somebody's collecting it now. So anyway, so I thought that was something that was contributed during my time here.

You mentioned the Women's Health Initiative. So several things happened. There was also a GAO report that came out during that era about how seven in ten of the drugs that had been withdrawn from the market in the previous X number of years were disproportionately risky for women, and they were either directly riskier for women --, they had different -- the types of medications that cause changes in the QT intervals, which leaded to risk of major cardiac events, so there were those, and then there were the ones, though, that were more widely used in women, so some of the weight loss products and things like that, that although there wasn't a physiologically increased risk, there were just more women who took them so the impact was greater in women. So that GAO report came out, and that was in 2001.

And then also during that time was the closure, or the stoppage of the Women's Health Initiative, due to the safety concerns that had been found in the study of the Women's Health Initiative for the use of hormone therapy for menopause. So when that happened -- boy, I remember that, too. It was in the summer, because I was on vacation, and I think we got 24 hours' notice. FDA got 24 hours' notice, maybe a couple other places got 24 hours' notice, and then it hit the headlines, because they had to go public. And it was very controversial, because no one really got notice to prepare for the fact that this huge study was going to be shut down, in terms of telling women to go off their study medications, because instead of seeing a benefit, which was what was expected. The study was designed as a prevention trial. This was giving you your vitamins so that you would be healthier. This was not something that was supposed to increase risk. And this result is what was, to some degree, misconstrued all around. It wasn't as if we have now discovered that hormone therapy for menopause, estrogens and combined

estrogen/progestin was dreadfully dangerous, and we had to take this dangerous product off the market. No, it was that a product that they'd started a clinical trial and enrolled and consented people on as a prevention trial that was not preventing things, on balance. They were preventing some things, and increasing risk on other things, and on balance it was riskier than not, and therefore ethically they had to go straight back to the enrolled patients and say, "We're not going to do this anymore, and you should consider stopping taking this medication, but the trial is going to end." And that really blew everyone's mind, and so... And we're still recovering from it, I think.

So that happened, and several things happened related to FDA. NIH was doing its thing and dealing with handling and shutting down of a big study, and trying to collect all the data, and trying to explain the results of what they'd seen. FDA's job was different, and CDER, of course, was the lead on the response, and the Division for Reproductive Drugs, because that was in their bailiwick. The folks there were working on relabeling it and putting a black box warning on essentially all products, all hormone therapy products. What we did in the Office of Women's Health was try to help translate that and come up with some language and some materials that would be useful to both patients and providers about how to respond and how to deal with this seemingly contradictory and confusing situation. So what we did, and what I led on, was convening a lot of the women's organizations and health organizations who worked in this area, to get them around the table, literally around a table -- I can remember this at HHS, down at the Humphrey Building -- and many other times, iteration after iteration, trying to develop words that we would all agree on, because there were people who felt very strongly that the Women's Health Initiative was a terrible study -- I mean, there are still people who claim that -- and that hormone therapy was the best thing since sliced bread, and to take it away from women was

doing them a disservice. And then there were those who thought hormone therapy was poison, and that anybody who took it was, asking to die of a heart attack or cancer the next day.

There were very strong feelings... A lot of women in the heart disease/advocacy world were just angry. They were just angry, because they were on hormone therapy, and they'd had a heart attack, and now they didn't know what to think. Was it the hormone therapy? Was it something else? Their doctors hadn't told them. This was supposed to be good for them! So there was just a lot of high feeling when this study came crashing to an end with totally unexpected results. And the results were validated over the years. And the nuance of it, I always said, this is like many medications: it has its risks and benefits. If you have severe symptoms, this is a really effective treatment. If you don't, you might not... But unlike previous practice, you don't just put every woman over 50, or as she approaches 50, onto it. You look for whether it's needed, and then you balance the individual risks and benefits, if they are higher breast cancer risk, or higher osteoporosis risk. If they have higher osteoporosis risk, you might want to put women on it, because it would help for that. So you had to look at each individual woman, but this was really hard. So we did what we could: we developed a whole set of materials of questions to ask your doctor, basic ones, fact sheets, part of the communications side of the office, which I haven't talked about. That's the other thing that was going on.

That was a big piece of work that we did was to develop materials on hormone therapy for menopause that was useful, and we just really tried to cover the waterfront of getting that information out to women and to providers, because they needed something, because just the FDA label, or just the data from the NIH, wasn't enough to tell women what they should do, and there really wasn't a clear message of what to do; it really had to be very individualized.

Speaking of the communications side, of course, Audrey Sheppard and Marsha Henderson had started the Take Time to Care program before I got there, and that continued throughout the time I was there, and Marsha, of course, was brilliant in developing these different campaigns, and educational materials, and partnerships with organizations outside that really had the ability to push things out and far beyond the usual channels that FDA has. I mean, FDA's great in reaching out to health professionals, or prescribers, to industry, but for the general public is more like just put info up on the website or put out a press release, not directly engaging the general public. And Marsha was actually, I think, a real leader in that, and broke some ground, and allowed for other parts of the Agency to see what she was doing, and they could do things like that, too. And so there's been more spread than would have happened if she and Audrey hadn't started doing that, like I said, before I got there. But that continued.

VB: Do you remember any specifics about how...? Because Take Time to Care has become such a --

SW: Well, she had a big partnership with the chain pharmacies that were putting out information on the basic -- "My Medicines" was the original one, and that was going on; then she developed the diabetes materials, which ranged from food to devices and drugs. So that was a really cross-FDA initiative, because there's all kinds of different ways... And I just remember her working with the chain pharmacists. They were willing to put this stuff out all over the country. She was working on the diabetes thing. I know she was working with folks in Las Vegas, with some of the casinos. She had some just really great ideas and was able to put them

into place. She was doing all of that and we were called in on different things... Oh, then there's the breast implant saga. Oh my gosh. The story that won't go away.

[00:40:00]

VB: Yeah, it's a long one.

SW: The short version of it, (laughter) the version of it while I was there... So when I was on Capitol Hill, I was on Capitol Hill working as staff when Kessler put the moratorium on breast implants in the United States. At that point I believe they had only a public health exception for breast cancer patients. And, this was pretty early days, when I was working on the Hill. I really didn't know anything about the subject, or what was going on. But what I saw at that time was the split that this topic has in our country. And so there are issues related to FDA, and they're very important, and then there are issues beyond FDA, which is why anybody would want these things to begin with, and that's a bit more than FDA can cope with, but it's a reality. So when this happened, because Kessler came to speak to the women Members of the House, because when it happened the industry did a couple of things. First, they sent a wave of women who'd had breast augmentation to Capitol Hill to tell the Members of Congress how terrible it was that they couldn't get these implants because it helped their self-esteem and their depression and, oh, this was just terrible. Well, that may have worked for some of the men in Congress, but it really didn't go over very well with the women Members on the whole. As a whole, most of the women Members, have worked really hard to become Members of Congress, and they were less... It was just not a sympathetic ear, you know?

So then they sent the breast cancer patients -- ah, far more sympathetic, (laughs) far more sympathetic audience --, to come and say, "This is part of my recovery. How can you say that we can't have them? And I'm trying to become whole," and so forth. And they were cancer patients. Meanwhile, there was a woman Member of Congress who was going through breast cancer treatment at that very minute, and, indeed, her doctor had scheduled her, and she was going through her breast reconstruction, perfectly standard procedure. And you realized, when I saw the women Members of Congress debating this, sometimes when Kessler was there and sometimes when he was not there, there was just this real split. You had conservative Republican women who were like, very "Women should have a choice. This is about choice. This is not about..." And then you had very lefty liberal types saying, "You've got to be joking. Breast implants, who cares? Get 'em off the market." And then you had this one woman who was going through treatment, who was -- they knew her. She was their friend and colleague. And she said, "This is part of my treatment. I trust my doctor to give me good advice, and he says this kind, this silicone one, is better. How can you tell me not to buy it?" She needed to believe in her doctor… and bringing tears to everyone's eyes. And it was like, oh, jeez, how do you handle this issue? This is a tough one. And this has something to do with FDA regulatory authority on safety and efficacy, and what is the standard for devices (laughs) and approval in this country.

I knew then, from the very beginning, that this was really hard to navigate, really hard to navigate, and yet, at the same time, it's pretty clear to me that we just don't have... So you had this larger issue about why do women want these products, what is it about our society and our system that makes it so, and then the question is: are these products safe and effective? Effective for what? You know, hmm. But then, are they safe? And, unfortunately, I do believe the

standard is, and it's not controlled by CDRH, but the standard in statute and in regulation is lower for devices. You know, this has been going on now for decades, and we still have these same battles. You have a product that... I will say the companies were relentlessly persistent. They would get told no by CDRH -- "No" (laughter) -- and then they would come back, and they would come back, and they would come back, and they would want another try... And this is such a big market, for both the surgeons and for the manufacturers. It is a huge market, and they make a lot of money off of it, and so they kept coming back. And the insurance companies didn't care about this one, because they don't pay for any of this, you know. (laughs)

So it became this ongoing battle. And, I'm not going to go through all the different levels of it, but as we see today, where the products... It takes a while for products to be on the market before adverse events show up. Are they going to last very long? Are they going to rupture? Are we giving women actual good informed consent? How do you control for that? What do we know? How do we do follow-up? Can we please make the companies do the proper follow-up, which they say they're going to do but, I will say, they never do? And that's where rubber meets the road for FDA, I think. But anyway, it's just an ongoing saga. Some of that was happening while I was here, in terms of new products coming on and getting approved after the moratorium that had happened back in the late '90s.

VB: So, if I have my chronology right, it seems like that controversy got stirred up again when Inamed submitted an application, like, in December of 2002, and I was curious -- because you said, that companies are so relentless -- do you recall if these are companies that are also producing saline implants, and they just saw a bigger market potential for silicone?

SW: No. I mean, I think they'd always wanted the silicone implants... With the saline implants, thought would be that if they rupture it's just saline - so it's less of a problem. There is some problem with the shells. So the saline implants were more easily approved. The silicone ones, it's because of the nature of the silicone, and they're less wobbly, apparently, or something, and they are seen as more desirable by the surgeons and by women, and therefore they are a better product to sell. The flipside is if they rupture, you can't tell so often, usually, whereas if a saline one ruptures --

VB: It's obvious.

SW: -- it's a deflation immediately. And so then the problem becomes apparent immediately. And so then you would get complaints (laughs) from women about what the heck is going on, whereas with the silicone ones you usually don't know, and it isn't unless you're monitoring them closely or whatever that you... And so the follow-up doesn't actually happen as often as it should, and are you getting the right kind of examination or imaging to actually see whether it's ruptured or not. So women think, well, it lasted ten years. Well, maybe it only lasted two but you don't really know; you've had it leaking for that much longer. But they were more popular with both providers and with women, and so that's why they keep trying to make these other silicone or gel-based or textured or all these different versions. And so when they came in with new applications, I mean, I think, again, they never gave up, because, again, I think it's such a large market, and didn't want to lose it, and salines were just not as popular.

VB: So as Assistant Commissioner for Women's Health, you are of course being called upon to respond to this, as the spokesperson for Women's Health at the Agency, and yet you're not on the reviewing team.

SW: Right.

VB: So how did you interface with CDRH, or in general how did the Office of Women's Health interface with the Centers and --

SW: Sometimes we would be involved in meetings with outside advocacy organizations and the Center. This was true for breast implants, other device issues, as well as other products. So if people wanted... We sometimes serve as a liaison between some of the advocacy organizations or other people who are not sponsors, (laughs), that they would want to talk to people at FDA about it, and we would help convene some of the right people together to talk about that, or be invited to join the meetings that we rehappening at the different centers for the different topic areas.

With breast implants, we were also involved, and had been, in, like, trying to develop -- well, at this point it was editing, changing the informed consent document that was supposed to be given out to individual women. And it was way too long, and too many words, but you were trying to get all the information, and also in relatively simpler language -- not simple language

but somewhat simpler language. If it's just too long no one would read it because it's so long. But we were involved in that. We were involved when they were talking about... You know, again, we would just try and be open to talking to them, and giving the perspective of the organizations, outside organizations that we were hearing from about what the perspectives were, and our perspective on what... But we were not part of the formal review process. We would go to the Advisory Committee meetings, and, again, provide our input not at Advisory Committee meetings, but, directly to the review divisions, but, again, not as part of the formal process.

VB: Under your leadership, did the Office of Women's Health do trainings for the Centers on women's health issues (overlapping dialogue; inaudible)?

SW: No. We started developing -- we worked on the Demographic Worksheet, which CDER was developing to collect the demographic data, but we did not... I think there had been some training in previous years that had been developed and done with reviewers. This was right when the guidances and regulations on inclusion first came out, and they needed to train all the reviewers, and there was a whole training process, but that was before I got there. And then it was just within the centers that they were still doing. But we did work on developing demographic worksheets for the different centers to use, again, trying to get the centers to sign off on them and clear them.

The one other thing I'll mention, again, that Marsha did, which hopefully she talked about, was that she was developing as part of Take Time to Care, the contraceptive chart, which became so wildly influential in the Affordable Care Act. And she worked very closely with the

Centers... Because that was a document which was based on FDA-approved products, and the labeling thereof, and data related to that. And so she put it all together but had to get it essentially signed off on by all the different centers for accuracy, and they agreed that, yes, what she'd put through for review was correct. Then it turned out to be one of the most popular handouts that she ever had out there on the road. And then that document became the standard, essentially, for what's covered under health insurance now under the Affordable Care Act, which is brilliant. But, no, this was entirely independent of what its original goal was.

VB: Yeah. But incredible longevity, too --

SW: Incredible. And, yeah, there's stories around that when insurance companies were trying to get around the requirement to pay for at least one or more of each category of contraceptive method, they went to another document that Marsha had worked on and developed. She has several different types of products, and one was on contraceptive products, and it was a more general consumer booklet, and it said, "There are different types of contraception. There's hormonal. There's barrier. There's one or two others. And then within the hormonal there are all these different kinds, and some of them are pills, and some of them are patches, and some of them are rings, and some of them are implants." And some of the insurance companies were saying, "Oh, well, then we only have to provide the pill because the patch and the ring are just like the pill." I mean, this literally happened. (laughter) Companies were denying coverage of the patch and the ring unless you got a medical exception, because you should be able to get the

same hormone through a pill. No, they're entirely different delivery methods. Yes, they use a hormonal method, but that's not what we're talking about here.

There were investigations and studies done by Kaiser Family Foundation and the National Women's Law Center to find out what were the barriers to women getting their contraceptive covered -- this is post-Affordable Care Act -- and they kept running into this, well, there's confusion over what is the FDA list. What is the FDA list? Well, it's the chart. It's the chart. (laughs) No, no, there must be something else that they're using, and the insurance companies are very opaque in terms of being able to understand how they're making their decisions on coverage. They're very opaque. But we finally figured out that we think it was they were claiming that it was this consumer document, this true consumer document, not the chart (that's also a consumer document, but a very specific one), that they were using to rationalize. Then the advocacy organizations went to HHS and essentially leaned on HHS to come out with the new guidance that said, "Oh no, we mean this long list that is based on the chart. That at least nominally solves the problem, at least. I'm sure there's some bad actors out there, but, yes, on the whole everyone's now following that list, which was the one based on the chart that was developed way back when, continually updated, and continually issued by FDA. So that always felt like a connection. All these threads come together, right? (laughs) Trying to figure out how best to communicate to whatever the stakeholder is about what information is available.

VB: So, going back to your leadership of the Office, I wonder if you could give me a little -- I don't know, like, bring us back to the early 2000s, and inside of the Office of Women's Health,

and the role that the Office of Women's Health played in FDA. How did it...? I mean, you talked a little bit about how you interfaced with the Centers when it came to the review process, but how was the Office perceived by the rest of the Agency? What --

SW: You know, it's an interesting question. I don't know how it was perceived... Probably like a bit of a gadfly or something, I imagine. But we were part of the Office of the Commissioner, and it is true during that era there was first Dr. McClellan and then Dr. Crawford. You know, Mark McClellan was pretty much a straight shooter, and he was interested in women's health, and I think he was open to what we were doing, but he also had a lot on his plate at the time. The administration overall was not sympathetic to women's health in that era, across the government, and there were battles of trying to keep funding for all the Offices of Women's Health, and different struggles going on. But overall, I think Dr. McClellan was interested and open to what we were doing. We were not tightly linked, though, but because I think previously there had been a real close connection between the Office of Women's Health and the Commissioner directly, they had more influence on the Commissioner's thinking, or the Office of the Commissioner's thinking and actions, than perhaps we could during that next era. So that was part of our job was to be connected to the Commissioner-- and, again, we kept getting reorg-ed a couple of different times during that period and had different supervisors.

We had been stepped away from reporting directly to the Commissioner, which I think when it was originally created with Ruth Merkatz, and she reported directly to the Commissioner, whereas we were sort of pushed a little bit down and off to the side. But we also worked with the Office of Special Health Issues, and we worked --

VB: Was that Terry Toigo?

SW: Yeah, Terry Toigo was terrific. And we collaborated. We also worked a lot with NIH, and the other Offices of Women's Health, with AHRQ, in terms of co-funding projects, developing training materials that went up on the NIH website about inclusion of women in clinical trials, what were the FDA rules, what were the NIH rules, that they offered as a CME program that's still ongoing.

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There were projects with the HHS Office on Women's Health that were going on... There were a range of different things that we partnered with outside partners, outside of FDA, as well as doing these different things inside. I think part of our influence was, in fact, that we did have funding, some -- not tons, but at least some -- so that was, follow the money, that's where we could act... People were interested in finding out if they could do projects that the Office of Women's Health would be willing to fund. All these are different ways that we connected with either individuals or centers or other parts of the Office of the Commissioner or other parts of HHS.

VB: Did the coordinating committee that you used to be involved in, did it still operate?

SW: Yeah. Yeah, yeah, yeah. This time I went as one of the members instead of coordinating it from HHS.

VB: So just tell me if this is a question for somebody else, but just thinking about how important the intramural research grant program is for OWH, do you remember any projects that stand out in your memory that you thought were particularly impactful or really promising that OWH funded while you --

SW: I think you'd best ask Peggy Miller those questions.

VB: Fair enough.

SW: That's asking me to go back too far in my memory.

VB: That's understandable. I thought it was worth a shot. So another thing that I think was sort of transformative for the FDA in general, certainly during the time that you were the Head of the Office of Women's Health but also since then, is the development of this completely new communications platform, the internet, that --

SW: Oh, yeah. (laughter)

VB: Yeah. And, of course, everything that goes along with that, from being able to build listservs, to --

SW: Yes.

VB: -- cybersecurity requirements.

SW: Right, right.

VB: How did the Office of Women's Health engage with the internet in these early years. Did you, like, immediately see it as a...?

SW: Well, I remember we were developing our website -- and the FDA was trying to figure out how to have its first sort of template for different webpages so that everyone matched, because nobody... And, of course, Marsha, who would have been doing it, she would not have wanted to follow the rules. You know, she'd have wanted to do it her way. But I think we had to. That's my main memory of it. I remember when FDA -- it must have been around that era --

I mean, everything was on the web. But I will tell you, I remember giving advice to people who were looking for information from the FDA website, is that, for goodness sake, do not use the search function. (laughter) Don't. Follow it very logically. If you're looking for drugs go to CDER, and then look and see what the choices are. Now, the problem was you had to understand what the layout, the sitemap was, which, of course, no one knew, and if you don't know anything about FDA you were lost, but if you typed in a search function with a topic, or a drug name, or a condition, or a regulatory something, you got page after page of gobbledygook that was totally unorganized, completely unresponsive to what you were looking... I mean, technically it probably was, but it was the most useless search function I'd ever seen in my life. (laughter) And I'm like, "Just don't do it."

And in a way it's kind of funny, because I remember learning after I left FDA about how the people even ten years younger than I am would find things on the internet. They would just put in the search terms and see what comes up. And I would be like, oh, no, if I want to find something out, I go very logically linearly. You know, what's the organization? What's the subset? Can we track it down? And then I will find what I'm looking for.

VB: Taxonomy. (laughs)

SW: Yeah, the taxonomy, exactly. And that's sort of how FDA thinks, so the taxonomy was beautiful, I'm sure, but, boy, the search... Whereas by the time I left FDA, and I learned to quickly search things by using search terms, that it was... And other places it worked fine, (laughs) you got what you needed, but, boy, the FDA website was just deadly, to search that

way. I think maybe that shaped how I looked at search functions, because you just tried it, and it's like, oh my gosh! (laughs) Anyway, so I would have to say it was not doing much for the Office of Women's Health at that time, so...

VB: Well, thankfully, I think, we've come a long way since then.

SW: A long way. (laughs)

VB: Because the "For Women" section on the website is just, like such a robust bevy of information, and I think it's --

SW: Yeah, yeah, I mean, we were putting up stuff, and -- for example, the other thing that started then, which was very web-based, was the pregnancy registries. And this flowed from the guidance, the study on pregnancy that I mentioned, the guidance that came from that, and then the idea that we needed to pull together -- and this was all in partnership with CDER -- needed to pull together all the existing registries either directed by CDER or that we could otherwise find, and put them in a single place, because although the reviewers and CDER were overseeing a number of different registries that were coming into place as part of their pregnancy medication approach, , medications used during pregnancy approach there, while at the same time trying to change the label -- the pregnancy team, they were doing so many different thigs -- one of the things that was missing was a place for consumers and providers to be able to come and find

information on the pregnancy registries that already exist, and how to enroll. And so putting that together was, I think, a real accomplishment. And that was, again, all web-based, so... And, again, even today, (laughter) today, actually today, the website for pregnancy resources and FDA's contribution to that was really recognized. Also more people need to be aware of it. We need to make it more available and accessible. I mean, it's there, it's beautiful, but we need to get people to use it, and that's the challenge, I think.

VB: And you have to obviously go through doctors, to some extent, to get women...

SW: Yes. I mean, there are ways to go directly at it by women, but they had to know about it. Doctors need to know about it. The prescribers, whoever they are, need to know about it. And more information needs to be added to it, and maybe it needs to be linked to wider networks, and not just live only at FDA where people might not necessarily go look for it, so...

VB: Or might not find it in the taxonomy.

SW: Not if they do a search function. (laughter) Although it probably does show up much better now. I'm sure it does.

VB: I think it's actually much more prominent, and you can find it through multiple channels now.

SW: Channels, yeah, yeah.

VB: Similarly, I think it was maybe not under your watch, maybe, but in the 2000s that OWH started including information about MedWatch on the My Medicines brochure.

SW: Yeah, I think that... Yeah, yeah.

VB: Yeah. So --

SW: To help improve reporting. I mean, I know MedWatch has, gone up and down over the years, and... Yeah.

VB: Yeah. But as another way in which Women's Health touches all areas and impacts, you know, the My Medicines brochure, certainly plenty of men use that now, you know, [just?] --

SW: Yeah. Oh, no, yeah, it's clearly not gender-specific. Yeah.

VB: So I want to ask you about your departure from the Agency.

SW: Right. Oh, there's a story. (laughs)

VB: Yeah. You had dedicated 15 years of your life to advancing women's health within the federal government when you had to make this really hard decision about --

SW: Leaving.

VB: -- taking an ethical stand, yeah.

SW: Yeah, so this is the Plan B story. And so during the final... I mean, it had been going on a while; 2003, I think, was when the application first came in for bringing Plan B over the counter. So Plan B had already been approved as a prescription medication back in 1999, and in 2003 the sponsor came in with an OTC application. And I remember going to some -- not all, but some -- of the meetings that the sponsor had with the Review Division to talk about it, and talk about, what was necessary for an OTC application, and what they needed to bring, and blah,

blah, blah, the whole process, and that was all going along. And I think I was there. Why was I there, you know? I mean, and I think it was because this was just a normal application. There are lots of women-specific products. We weren't involved in all of them. As I mentioned, we stayed in touch about things happening, and would act as a liaison, but these were standard meetings, informational meetings, to try and see what needed to be done to put in an application. And --

VB: Can I interject for one second?

SW: Mm-hmm.

VB: Why do you think there was more controversy about the OTC application than the original prescription application?

SW: The original application was actually quite interesting, because, of course, there was actually another one. There was Plan B and there was Preven. Preven was the combination estrogen/progestin product, and it was approved first, and then Plan B, which is the progestin-only product. They were based on a previous method, the Yuzpe method, which had been published in the literature, about using, higher doses of birth control hormones for emergency contraception, and that had been around since the '70s. And I think, as I am told, the idea was that -- and, again, Mary Pendergast was involved in this -- but the idea was that this was a known

method. It is an off-label use of regular birth control pills, but the only way to get an on-label use was to come in with a new application. And, in fact, CDER had put out a Federal Register notice essentially calling for applications, that if you wanted to use existing data, that that would be acceptable in bringing it first as a prescription product.

As a prescription product it's not controversial, again, because it had been used, and you have the prescriber there. I don't know. You know, it's a good point now that I... I've never thought about it this way: why wouldn't it have had the same controversies? It just didn't. It was just another contraceptive pill. It was the morning after pill. I think people had known about the morning after pill. But before you had to go to a nurse or a doctor to get them to tell you how many of your particular pill pack to take, so it was just only for those in the know who would advise you on how to use a regular prescription birth control as emergency contraception. But somehow that was always seen as just emergency contraception. When it moved to OTC, putting that power into women's hands, may have been what made it more controversial. This was the critiques from outside the FDA, never inside the FDA, outside the FDA were, oh, it's going to promote promiscuity, oh, it's going to promote -- I could not believe this -- pedophilia, oh, it's going to promote, all these other things. And yet, in terms of, like, a basic OTC application, it was entirely straightforward. This should have been a straightforward six-month OTC application when they came in in 2003 with their first application.

In late 2003 there was an Advisory Committee held, and the Advisory Committee meeting was pretty astonishing, in a good way astonishing. It was a combined Advisory Committee meeting between the OTC division and the Repro division. And there were, indeed, members that had been packed onto the committee by the administration. So, the normal Advisory Committee appointment process had not been followed, in that some people had been

named from higher up, and I don't know how high higher up, but had gotten appointed to the Committee who had views on contraception, that they actually were opposed to contraception for nonmarried people. They didn't like to prescribe... They had issues with contraception, and they had issues with contraception over the counter, and they had issues with contraception for nonmarried people. However, that was just a handful of people on this Joint Advisory Committee that met. And the hearing was astonishing in a couple of ways.

Well, first of all, the presentation by the sponsor was brilliant, I have to say. She knew her stuff, boy, and she could answer every question with a slide. She was very good. There was comment by the panel that the data on label comprehension and actual use were as good or better than many that they'd ever seen, that this was a great presentation. There was testimony -- not testimony -- sponsor time (laughs) that was given to the head of ACOG and the AMA to testify on behalf of the sponsor, which is unusual, I would think -- not in the public testimony time. In the public testimony time, there were women from all over the country come to say, basically, if this product is safe and effective then who is FDA to tell us whether or not we should be able to use it, thank you very much. (laughs) And then there were those in opposition, and the ones in opposition came and said this is going to promote promiscuity, this is going to promote pedophilia, could have a field day for pedophiles. I actually remember feeling offended for the men in the audience, because it was like, I don't think so! (laughs) I don't think pedophiles are waiting on birth control pills to help them do whatever it is. I think you're doing a real disservice to the men in this population to say that's all that's holding them back, you know? It was just really offensive.

And so this whole meeting, it was astonishing. The votes were such that it was a unanimous vote, if I recall, for it was safe in an over the counter setting, and I think that's really

important that even those who objected to it couldn't say it wasn't safe. And that's what you really worry about in an OTC setting, right? The worst possible outcome of taking emergency contraception the wrong way -- it's hard to take it the wrong way, but if you took it the wrong way -- the worst thing that's going to happen is you're going to get pregnant. (laughs) It's not going to be like acetaminophen or other things that can kill you, or make you quite sick, and its too darned expensive right now to even imagine having enough that would make you throw it up. But really, you can't overdose on it. It's really very safe. So it's safe in the over the counter setting. And then there was a very strong majority vote in favor of approval, and it was very clear from the reviewers that they also thought it not just ticked all the boxes, but it was a perfectly normal approval for an over the counter product. So at that point in time I was feeling really optimistic, because... I've got to get my timing right. Is this 2004?

VB: After the Advisory Committee meeting?

SW: After the Advisory -- yes, correct. We're in 2003. After the Advisory Committee meeting we're thinking very optimistically, we think maybe it will be approved, but then we start to hear that the decision-making has been taken out of the hands of the Review Division, out of the level of the Division Director and the Office Director, and was being pulled higher up inside FDA, and so it was like, huh, that's really odd. (laughs) That's really odd. And, indeed, there's a GAO report that says this decision that happened during that time was out of the ordinary, the way the decision in 2004 was made. And the decision in 2004 was made by the acting Center Director at the time who said that gosh, this actual use data is good, but we don't have enough of

the -- and the age shifted over... First, it was the 16 and under crowd. You don't have enough 16 and under to -- let me get this right. Sorry, no. The first one was you don't have enough who are 15 and under to do a subpopulation analysis to understand if the 15 and under crowd are going to use it correctly without doing an actual use study. And subpopulation analysis is not, has not, still is not, as far as I know, done on OTC actual use studies. It is the general population of anticipated users, and do they, generally speaking, use it correctly, based solely on the label? But for this particular product, all of a sudden there was a question about whether or not there was enough numbers of the very young teens to show that the very young teens could use it correctly. And, again, no safety issues,

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so why are we all of a sudden worried about a subpopulation analysis and not having enough numbers to do a subpopulation analysis? Which was true. There were not many under the age of 16. But we don't expect many to be taking it, you know.

But anyway, so the decision was that it was not approvable because you didn't have enough of these very young teens in your actual use study, which was pretty outrageous, and it was my understanding at the time that the reviewers in that division were very angry at that decision, because that had never, in any other hormonal product, any other OTC product, this had never happened before, and all of a sudden it's being blocked. The option given to the sponsors was you can come back -- well, you can either give up, go out and get more very young teens in your studies, or come back with a new application, cutting it by age, and keeping it over the counter for those 16 and older, and prescription only for those under that age. And that was the request that went in the letter that said you can either go get more, but we're not going to

approve it as is. So the sponsor decided to come back with a new application that, indeed, cut it at that point and said, OK, we'll only ask for a nonprescription status for those 16 and older.

Well, then it turned out -- and I remember talking with the Center Director about this -- that the data was never analyzed with that particular age cut, so it demonstrated that there was no real data basis on this, but the age cut was between 16 and 17. And so the decision, again, after the new application came in later in 2004, the decision in early 2005 by the Center Director, the Center level, was to up the age one more year to 17 and older, and keep it prescription for those under 17. Did I say that right? Anyway, 17 and older, and under 17. And I heard that with my own little ears from the Center Director and waited. And everyone was waiting for the decision to come out, silently. When it's going to come out? And I talked to people who were involved in the different offices involved and the divisions that were involved, and they were all saying, "We haven't touched this stuff in months. We sent our memos in months ago, and out of our hands. We know nothing about it." I also heard on NPR the Secretary at the time, when asked about the two most important health policy issues of the day, which one of them had to do with Medicare, which is always huge, one of them had to do with Plan B. When is that decision going to come out? And the answer was, "Well, oh, it's still with the scientists at the FDA." And I was like, no, it's not, it's not. (laughs)

Anyway, all this went on. Now we're in 2005. I've now been here for five years. This is just one of the things going on in life. I'm keeping an eye on what is going on. I was hearing from the advocacy organizations saying, "What is going on?" I was answering, "You know, I don't know. I couldn't tell you if I did know, but I don't know. And I can't imagine that they won't..." In my head I was thinking I can't imagine that they will... I mean, they've already decided to approve it for 17 and older, and we don't like it -- that's a wrong decision; there

should not be this age restriction -- but at least we can get it out the door and get some experience with it, and then expand it later. But the decision never came out, and it never came out. And then I believe that was when Dr. McClellan moved on to go over to CMS, and Dr. Crawford became acting Commissioner. And he went up to the Hill and was questioned about it in his confirmation hearings, and he made a commitment that he would make a decision by the end of the summer, or by September. He was confirmed with that promise. And so I thought, he said he's going to make a decision. The Center's already decided 17 and older. It should just come out that way. Why are they holding on to it, you know? Why is this being dragged out? And, again, I talked to other people within CDER who had no idea, or at least they didn't tell me if they had any idea.

I went fairly high up the food chain, trying to find out what the answer is going to be, and I was told that the decision was being made elsewhere, and these very high up people within the Agency did not know the answer, what it's going to be. And I thought, huh, now that is really crazy. (laughs) Why is that? And so we were waiting. And then it was end of August, right about now, right about now, almost exactly to the day, in 2005. I actually had taken the day off, because my daughter was going to school, and it was a back-to-school day, so I had taken a day off, a Friday in August, late August. And Dr. Crawford called a press conference to be held at Parklawn, gave two hours' notice to the press, on a Friday afternoon, and if you didn't show up in person you couldn't ask a question. So I got notified about it just before it happened, got on the conference call so I could listen in, and heard the decision that although the Center for Drugs had recommended it be approved for those 17 and older that this idea, which the FDA had asked for two years earlier, to keep it bifurcated, was so complicated we needed to go through a federal rulemaking, and therefore an advanced notice of proposed rulemaking was going to be issued...

And we were going to start the rulemaking process on how to handle that complicated question about how pharmacies would handle this two-tiered system, and we'd get back to you. Meanwhile, it is not approved for anybody.

Now, I should mention that I had been in government for 15 years at this point, and understood a little bit -- (laughs) it's always hard, challenging -- understand the rulemaking process, and thought, you have got to be joking? We're throwing this into rulemaking, which can last, as we all know, for as long as you want it to last? And meanwhile, no one is going to get access to this OTC? No one? Not adults, not teens, not anybody? It's going to remain as a prescription status for everybody for the foreseeable forever, because this is a black box that we've just thrown this into.

And over that weekend, I gave it thought, and I was just so distressed that the FDA had been put in this terrible position, that I had been put in this terrible position of trying to either... The choices are: to publicly defend the decision that's just been announced, which I couldn't do; or to stay completely silent, which would have been highly stressful; to be an internal whistleblower type, also highly stressful; or just step away. And that's how I saw it. It wasn't really quitting my job and doing some protest action. It was I have to step away. I can't condone this, and I can't... I can't condone this decision, because it's wrong in so many different ways. It's abusive of the regulatory process. It was disrespectful of the reviewers and the review teams. It is a wrong decision based on the evidence. It is counter to the FDA mission. All of these things, in a simple... (laughs) advanced notice of proposed rulemaking... All of those things were at play, and I just couldn't see how I could continue doing that.

So that was a Friday, and the next Monday, end of the fiscal year, we had contracts to get out and grants -- (laughs) you know, things that had to be done. So I had a lot of things that had to be done, so I did all those things, and then on Tuesday. My immediate supervisor was on vacation, so I had to call him, and the Commissioner, indeed, had gone immediately upon vacation (laughter) after making that announcement and so I gave my notice to the Deputy Commissioner that I would be leaving, effective immediately, at noon that day. And then the hardest part, the hardest part was coming back and talking to the staff at OWH, who are all just fantastic people, and to tell them that I was leaving. That was really hard, because I felt really like I was leaving them in the lurch. I wouldn't be there to protect them, or to take the heat, or to explain, (laughs) you know. And I don't know what they thought. I hope they didn't think less of me of it, but I did worry about that, because that was really hard.

And so I had to pack up all my stuff and load it in the car, and I did send out an email to colleagues at the FDA before I left, and it was an email that ended up going 'round the world -- speaking of the power of the internet, at least email at that time, before social media -- and, , saying not just, "I'm leaving," but that I'm leaving because I can't support the decision that ran contrary to the recommendations of the reviewers and the scientific expertise and FDA policy and practice, and so, thanks very much everybody. You can probably find that... The email's probably still online somewhere. And so I sent that out to a number of people at FDA who I wanted to let know that I was leaving after I had talked to the staff at OWH.

And then, as I was driving away from Parklawn, I was on Rock Creek Parkway, and it must have been the one o'clock news, NPR, and I heard my name announced as resigning from FDA. Now, I nearly wrecked the car, you know. (laughter) Like, whoa, that's really scary! So it became a much bigger deal than I ever imagined when I left, because that was not what I was

expecting. I was expecting to maybe get a small notice, -- again, this is before online journalism -- a small mention in the *Washington Post*, somewhere on the page before the op-ed page, the government gossip page, but it blew up a lot more than that. I ended up spending the next eight months, really just traveling and speaking about this, really hitting on the very important role that FDA has, and that the career staff had worked really hard, and works really hard, as I mentioned earlier, to accomplish the mission of the FDA, and to have a positive impact on our nation and the world through their work, and that this type of decision is just a little decision, it's just one little decision, but it is reflective of a disregard of that. And that affected the morale, I would say, of the Agency at the time. It affected the perception of whether or not you could trust government at the time. You know, now we're in a whole different world, but at that time it was a crack in the trust of the government, and in the scientific integrity of a place like the FDA, and importance...

And, again, the key message that I have is that it is fine to argue with an FDA decision. Nothing a group of scientists and physicians like to do more than argue about things. Great. Love it. Do it. This is what you do, but make the argument about the data and about the evidence, about what you think is best for patients, or whatever, the safety issues. And prescribers and other health professionals should be able to say, well, I trust that whatever the decision FDA made, they at least did it on their best judgment, their best scientific judgment, their best medical judgment, their best whatever judgment they're using that the team that's brought together that makes these decisions. It's not because of political interference, or it's not because a company wants to open a manufacturing facility in somebody's district. (laughs) You know, political decisions are made about roads, and about economic investment, but FDA is supposed to be protected in statute and in practice by that it's decisions are supposed to be based

on the best available evidence at the time. And if we break the trust between the prescribing community and patients with what FDA is doing, that's a really high risk. And so even though this is one little decision about one little niche product, about one little thing, but it has implications that we really have to resist.

And so part of that was why I stepped away from FDA, which was really a great... I really loved my job here. That was what I tried to talk about whenever I talk about it, is that we need to support FDA to be allowed to do its job properly, and insist upon it, actually, and not allow for this politicization of specific review decisions that should be based on safe efficacy, public health, all those good things that we are all here to work for.

VB: In terms of the impact, you gave a sweeping idea of how much it impacts the people's faith in FDA's regulatory decision-making process, and science in general. What about women's health?

SW: Well, so emergency contraception, when it finally... I mean, the story went on for another... It went on until 2013. It involved not just the Bush administration but the Obama administration. I was just almost as mad at the Obama administration (laughs) as I was at the Bush administration over how they handled Plan B. It just drove me nuts, because it finally was approved first for 18 and older, with another Commissioner. Again, the age slipped up again. Then the courts got involved, and the ultimate court rulings forced, absolutely -- this is now in the Obama administration -- the courts forced the Obama administration to essentially approve it fully over the counter, which they never should have had to do. It should have just been sorted

long before then. And it wasn't finally approved for all users until 2013, a full ten years after the first application came in. And I like to point out, as I was trying to tell people for years beforehand, is that we are making a mountain out of a molehill here. When this finally gets approved, you will have two weeks' worth of stories about that and then it will be done, because it's one more tool in the toolbox. It's useful. It's effective. It's not as good as some of the highly effective contraceptive methods, but when you need contraception in an emergency situation, something has happened where you have a risk of an unintended pregnancy, this is a great product, as well as Ella, which is now available prescription-only; it's a different type of emergency contraception.

Anyway, it's a great thing to have. It's not going to change people's behavior, particularly. It may help prevent some unintended pregnancies, which is a very good thing. And life will go on. It's one more tool in the toolbox. And sure enough, this story, which had been so controversial for ten years, causing political just upheavals with commissioners coming and going, and me having to quit my job, and people just outraged, and letter-writing campaigns, and huge brouhaha, and media, just story after story after story after story, once it was approved in 2013 you heard about it for another few weeks and that was it. There's nothing more to tell about it. It's on the shelves. It's still too expensive, so that's an issue. There are things to work on. There's been more data coming in about obese women. There's other products like Ella; should it be over the counter? I mean, there's ongoing incremental aspects of it still to be worked on, but the overall story about would bringing emergency contraception over the counter be this dangerous, radical, crazy.

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controversial thing, it's not. Once it's over the counter, it's no big deal. And, sure enough, that's what happened: it's no big deal.

And so now we've gone another six years, and there's a whole generation of young women who just think it's normal. They think it's a bit expensive, I'm sure, and access to it can still be an issue, but the basics are... That huge controversy just doesn't exist anymore, and you can see, why did we go through all of that? But I think, so there are still organizations working on expanding access to emergency contraception, whether it's through trying to lower the price, putting it in vending machines, getting it more available. Can it be covered by insurance? And it can be in some states now. And so, I mean, trying to get expanded coverage. And, again, those are all the things that once you get it past the FDA approval process, all those other issues come into play, but they're not directly FDA-related.

VB: So within three or four weeks after you resigned Lester Crawford resigned, as well.

SW: Yes.

VB: What went through your head when you learned that?

SW: I was stunned! (laughter) Absolutely stunned, for a couple reasons. One, it was like, wow, did all this controversy bring down the Commissioner? That can't possibly be. The

second one was it was more of a shock, and still, maybe it's my own naivete, but it's also having been an FDA-er for only five years, but nonetheless. The idea of having that kind of financial conflicts, and that he ultimately was charged with -- it was about money, you know -- was just shocking. It's like, he'd worked at the Agency before. Everybody knows the rules. These are really strict rules. We all live by them. You live by them. I lived by them. Everybody lived by them. It was just normal behavior. No, you don't own anything, (laughs) you know, right? You can't. You just can't. And so to hear that, that was sort of a shock. I was stunned that that was the reason, because it's such a known thing, an accepted thing. It's part of working at FDA is that you can't have investments in anything, you know. So it was a shock that way.

But I do not know, and I did not know, what were the bigger politics-with-a-capital-P that led to that, because there was clearly... You know, his resignation potentially involved lots of other power players in the White House and in HHS, and I have no insight as to what that was about. But when he announced that he was leaving, on the day, to spend more time with his family, I did know that that couldn't possibly be true, because he had gone through a lot to get appointed and confirmed, and he'd lived through a lot with all the Plan B controversy, and so he wasn't going to give up the pinnacle career job for that. So I was just stunned. And then when I found out that it had to do with financial improprieties I was shocked, (laughs) but that's just because I'm easily shocked, so...

VB: Did you wish that you could turn the clock back and...?

SW: No. I mean, it didn't make any difference, because Commissioner Crawford was not the reason that this was blocked. As far as I could tell, he did not have a vested interest in the outcome of this. He didn't seem to have a strong opinion. It wasn't what he worked on. It wasn't his area, his field. It wasn't what he cared about. He had a lot of things he cared about. You know, he's interested in nutrition policy for women. When he talked to me about women's health, he was talking about nutrition. I mean, there were things he was interested in women's health. This just was not his shtick. But there were plenty of people in the White House, and in HHS, higher up. So it made no difference whether Commissioner Crawford was here or not, except that he was willing to do whatever it was, that that decision was. But I imagine that any Commissioner in place would have done that.

VB: So, as you said, there is a long aftermath from the fall of 2005, and you've written in the past about the role that Hillary Clinton and Patty Murray played in that.

SW: Yes, yes.

VB: I was wondering if you could talk a little bit about --

SW: They had both been asking questions of Commissioner Crawford when he was nominated for Commissioner... At that time they did not have the votes to even block his nomination, and even though I believe, if I'm remembering correctly, the Democrats were still in charge of the

Senate, but they didn't even have 40 votes to block his nomination over this... At that point, it was just a delay, this just strung out delay. They couldn't understand why it was so delayed, and so they didn't have the votes to block it, but they did ask questions. The other person involved, of course, was Senator Mikulski. They were all on the Senate Help Committee. So after there had been the confirmation that they were involved in for Dr. Crawford, and then he resigned in the fall of 2005, and so there had to be a new one, and it was... Help me out here.

VB: The acting?

SW: Yeah, acting, and then he became Commissioner.

VB: von Eschenbach.

SW: von Eschenbach. So von Eschenbach was brought over from NCI to be acting, and then nominated to be Commissioner, and he at that point was going round the Hill -- because I also was going round the Hill at that point. (laughs) I was invited to come around, and I met with Senator Clinton and Senator Murray and Senator Mikulski, but also with House Members, some of whom I'd known from the days when I used to work for them: Rosa DeLauro, Nancy Pelosi, Nita Lowey, and Louise Slaughter, who was actually very helpful, as well. But von Eschenbach was going around the Hill telling people that this need to go through rulemaking was just very serious. You know, "We're in the middle of rulemaking right now, so I can't really talk about it,

and, yes, well, there's some very serious concerns about how this would be managed by pharmacies, and we have to go through the process, and so no, hmm, no, no, I can't really..." And the Senators were saying, "You're not going to get confirmed. (laughs) This ain't happening, you know? This time around... You know, fool me once. You said you'd make a decision. That meant a real decision." He didn't say, though, but Dr. Crawford had. There was a promise to make a decision, get this done, and they said, "That's not a decision, and you're not going to get confirmed."

And so it went through to the next summer, and by this time the litigation by the Center for Reproductive Rights, which had been filed against FDA, which ultimately resolved the whole set of issues, was going forward. I was being deposed by the HHS lawyers this very day that was the day before von Eschenbach was going to have his confirmation hearing before the Senate Help Committee. So I was being deposed by the lawyers, which was not a fun day, and then I'm leaving from that and I get a call that says, "You won't believe it: von Eschenbach has just said he's going to approve Plan B for those 18 and older because he's had a revelation that he can do that." (laughter) And the revelation was that... And he had contacted... By this time the product has changed hands. I think it was owned by Barr at this point. He had contacted the head of the company to say that if you throw in an application for 18 we will approve it -- 18 and over, over the counter; under 18, restricted. And they got the application in. It was approved within around three weeks. Pretty astonishing. (laughs) And so he was able to go into his confirmation hearing the next day, and the Senators, who I feel fairly confident were prepared to take him to the cleaners about this, (laughs) were faced with, oh, we're going to approve it for those 18 and older, which is a little different from 17 and older but, hey, it's still getting it

approved. And so that was considered a big win, huge win. Again, that was in late August of 2006, and that's where it stood for a number of years.

But anyway, so that was the first big approval, and that was von Eschenbach. I mean, the role that Senator Clinton, Senator Murray, and Senator Mikulski is that they were ready to hold the Commissioner accountable, and they weren't kidding. And they were very careful, very careful, to never tell FDA what decision to make, which I thought was really good of them. They focused on FDA doing its job properly, and that if this is a safe and effective product that fits the guidelines and regulations for an over-the-counter product, it should be approved. If it doesn't, don't, but if it does, do. (laughs) And make a decision, and don't just keep making up reasons to keep it off the market, and keep it -- oh, not off the market; keep it behind the counter, keep it as a prescription drug. And they were very careful to show the appropriate respect for the FDA to say we don't want to politicize the FDA, we don't want to tell you how to make decisions, but this is a product that's important for women, and it is not right to hold it up for political reasons, and you need to do your job. And so they were really quite good at that, I thought. And, you know, politicians, it's hard for them to (laughs) not do that.

And it's always fair to provide input. I always say it's always fair. FDA is pretty good. You can get input from everywhere, and then FDA will screen it, and say we try to take just the input that's relevant and is based on data, and is based on public health, and not the input that... We're not going to say you can't give it to us, but we're not going to respond to the input that's inappropriate. But in this case, I think the Senators and Members of Congress were on the appropriate side of wanting to know what the heck was going on, and that they were not going allow a commissioner to be confirmed until they got a straight answer. And so he did. And I was shocked. Again, another one of my naïve moments, I was shocked. I couldn't believe it. I

thought, you've got to be joking. I thought they would have left von Eschenbach out, the administration would have left him to hang out to dry, because this is something they had made a decision on earlier that they just weren't going to let happen, and all of a sudden they did -- I mean, with a higher age restriction, but nonetheless. So, again, this is where I don't know what the thinking was, who were the power players that made these decisions. I don't know, but they decided to let it go through, maybe it was because after a year of having the public rise up and say, "This is not acceptable, we want an FDA we can trust," and there really was...

The other thing that was really interesting was that the opposition to Plan B going over the counter was limited to a very small number of organizations and individuals who were very loud, but they weren't numerous or influential... I mean, so they had influence, clearly, somewhere in the White House, but they weren't representing a large segment of the population. The large pro-life organizations stayed silent. (laughs) A lot of the conservative organizations just didn't say anything, whereas all the women's health organizations and the people in support of it and all the medical professions and all the scientific organizations and all, they were all publicly and loudly saying this is absurd. There's this huge, silent vacuum in the middle, or to the right, and just on the very fringe were some vocal opponents. And that's true of Members of Congress. There was a silence on the part of Republican Members of Congress who were in support of President Bush, and they just didn't... The media would go to them; they wouldn't comment. There were no comments. There were no debates. No one ever asked to debate me. No one ever had... There was no credible opposition, if you will. There was no one making a case that had any weight or any strength. And so maybe after a year of that environment happening, where the only arguments on the table were in favor of it being approved, there was

no strong opposition, if you will, because there really was no logical (laughs) opposition, that they decided just to let it go, it just wasn't worth it. I don't know. I don't know.

VB: So what do you think the impact of this whole controversy was on the Office of Women's Health? I know you were outside of the Agency, but from the outside looking in...

SW: I don't know. You know, I was really happy when Cook took over, because she's terrific, and Marsha then became Head of the Office, and she's terrific. And I think they were... I don't know. I mean, I honestly don't know. Each of those individuals have enormous talents and skills, and they brought what it is, but I don't know... And I've never asked, (laughs), how people felt after I left, in terms of people in the office, about whether they felt like it threw them into a place where they were just hunkering down for a year, or whether... You know, Cook has years of experience in CDER. She knew a lot of people. A lot of people had a lot of respect for her. So she could come in and I think the career people there could feel comfortable and feel good about supporting her work. So I think, in that sense, she was a great person to come in because she did have the experience... You know, she wasn't new to FDA, and neither one of them were... Maybe they never bring anybody new to FDA again. (laughs) But, she knew a lot of people across FDA, and was able to come in as a very strong and stabilizing person, so I feel that that was an excellent way to go. But I don't know.

VB: So of course this played out over a long time but after you left the Agency tell me about what life was like after FDA.

SW: So I spent the next, like I said, six to eight months traveling the country, speaking to medical school audiences, law school audiences, women's groups, public health lecturers, talking to editorial boards at newspapers around the country just trying to make the case, and really trying to be not an advocate for any kind of political action, but rather I spent a lot of time explaining how FDA worked, you know. I had my slides so I can show -- "Here are all the regulated products, and the centers, and here's how decisions are made, and here's a timeline." So it was very didactic lectures on what happened, and how FDA normally works, a big picture way of explaining it, and then what happened with the Plan B story, and that people should care about a strong and effective FDA. And I think that did help. I did not try to rabble rouse or like that, but rather just to really tell the story so that people would understand, and then they would

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do whatever they felt they needed to do. And some of them, as health professionals, or as legal people, or as public health people, their voices have weight because they have expertise, and they could bring that to the table when talking to their local media, or their elected officials, or their colleagues. So that's what I did for eight months.

Then I got a job at GW on the faculty there. There's a project called Project on Scientific Knowledge and Public Policy, led by David Michaels, who went on to become the head of OSHA under the Obama administration. And he had a grant to do work on the use of scientific knowledge and public policy, and so, hey, why don't I come and do some stuff on FDA? So I

did some work, actually held s conference on the future of FDA, with former FDA Commissioners, and trying to talk about new ideas about FDA. But then in 2009 I became Director of the Jacobs Institute of Women's Health. Now, the Jacobs Institute, the short version: it was founded by ACOG back in 1990 as an independent 501(c)(3). It is the home of one of the peer-reviewed journals in women's health called *Women's Health Issues*, and it's a peer-reviewed journal on women's health, public health, and policy. When it was an independent 501(c)(3) it would do some advocacy and public education type stuff, but in 2006 it had merged with GW and became a research center inside the School of Public Health at GW, and still has the journal.

And in 2009 the dots were connected. It was like, oh, we have Susan here on faculty; why don't we connect her with the Jacobs Institute? Because Jacobs Institute was in a different department… so I went over and since then have been the Director of the Jacobs Institute of Women's Health. We still publish the journal. We do a lot of projects. I do traditional faculty things. I teach, and I teach a women's health class. I have been doing research in community health centers and access to healthcare for women, including family planning services. I've done work with other colleagues on issues related to cardiovascular disease, and done things on a range of different topics, research projects, grants, and contracts funded sometimes by HHS and other agencies. And so, that's my life now as an academic.

VB: In your role in the academic/public sphere, whatever, how do you... Well, I'm going to do two questions at the same time; forgive me. How has your experience at the FDA influenced the way you approach women's health issues? Do you teach it differently? I mean, it's a

counterfactual, but... And, separately, now that you have over a decade of experience outside of the FDA, what is your perspective on how the Office of Women's Health has impacted women's health overall?

SW: OK, working at FDA, it profoundly affected how I see the world, as everything you do does as you move forward in life. As I said at the very beginning, I've had a very zigzag career, basic science, go to the Hill, go to HHS, go to FDA, go to academia. I would never have predicted any of it. So I never know what I'm going to do next, but each time it has been educational... So because of my zigzag career, I don't have the usual perspective on FDA that most FDA-ers do, probably, I'm guessing. But, at the same time, I've absorbed and learned so much from my time at FDA, about the value of the work, the nature of the work. You know, I've had people who came to FDA later say to me, "Oh, I had no idea. This is..." Like, yeah, it's really important that you understand what FDA does and does not do, and you don't necessarily get that until you come inside. And so maybe that's a lesson there about how we need to teach, communicate with people, but nonetheless, that's...

So I do think I have a sense of what FDA's mission is, and what it should do, and how it can do it, and what its strengths and limitations are, whether they're statutory or whatever. And so that's influenced how I think about women's health, because I understand, based on FDA experience and previous, all the different pieces that have to -- all the pieces of the puzzle that have to come together, that no one place does it all, and you have to bring all these pieces together, and sometimes it's really hard because everyone's in silos. So I think I have a real sense of the silos of government, but also the potential of collaboration when it does happen.

The Offices -- well, not just at FDA, but the Offices of Women's Health... So in 2010, I think it's really important that in the Affordable Care Act a number of the Offices of Women's Health were put into statute, including the FDA Office of Women's Health. Prior to 2010, it was only, basically, some leftover appropriations language that had kept the budget going for FDA's Office of Women's Health, but also the fact that it exists at all. And all the way back to 1994, when I had worked on legislation trying... We got the Office of Research on Women's Health at NIH in the statute done. That was done in '93. Ninety-four, we had legislation that was led by Olympia Snowe, and Connie Morella in later years, putting forward Offices of Women's Health, but the moment had passed. The legislation was not getting passed. It was just not happening. But when the Affordable Care Act came up, a number of the outside organizations who'd worked on these issues -- the Society for Research on Women's Health, the National Women's Health Network, WomenHeart, others -- made this part of their agenda to get this as part of the Affordable Care Act, and sure enough they did. It's not exactly the same language as was written back in 1994, but it was all the same concept. And although some of it had changed over the years in terms of how things were going to be structured, the language is there, and it was passed into the law, and it is the law. So the Office of Women's Health, thankfully, cannot be abolished nor reorganized into a lower level because of the language, without signoff by Congress. It can be, but you have to get signed off by Congress, and so that makes it really hard.

The women Members of the House and Senate still are still very loyal to the Offices of Women's Health around HHS, and these issues. Just as I mentioned, I've been working on this Pregnancy and Lactation Task Force. That was statute because of the 21st Century Cures Act, and that is directing all the agencies to work on this issue, which is a lifetime's work, to move forward in research and medication and therapeutic developments for pregnancy and lactation,

which has enormous challenges. That's because of the action of a number of the women Members, I think primarily in the Senate but both sides. So to get rid of the Offices of Women's Health is going to be really difficult, unless the entire Affordable Care Act goes down, which is possible.

That being said, what those offices can do depends a lot on not just who's the head of the office, but also what kind of support they get from the leadership of the agency, and what sort of environment they're trying to work in across the agency, and whether or not they actually have the resources and budget to do those things. So I think it's always a really good question about... I would say FDA's Office of Women's Health is in the middle range, or maybe upper range, of the offices in terms of their effectiveness and their focus and ability to get something done. Some of the other agencies, they've really been sidelined. Other agencies, they're much bigger. You know, NIH is... But some of the other agencies, I think they've really been sidelined. They've been moved down the food chain, put into one of the equivalents of being put into a center, a subdivision of the agency. You know, the leadership is someone who wears three different hats, not just the hat for women's health...

FDA's Office of Women's Health now is strong, and has the ability to be stronger, but it'll depend on... I will say we are in a political environment now, where issues of women's health are under the gun in a lot of different ways, and so I would say maintenance is a good place to be, and at the same time FDA is still in a position of transition where you have an acting Commissioner, and so it will depend on who's the next Commissioner, who's the next permanent leader or full leader of the Office of Women's Health, and what else is going on in the larger world around women's health. So I'm pretty optimistic, actually, for FDA OWH... Again, in this particular era I am generally pessimistic around women's health, pretty seriously, but I

would say in that picture FDA is a relative bright spot overall, and the Office of Women's Health within the FDA is still a bright spot. And figuring out ways to help these offices, including the FDA Office of Women's Health, become more effective, and not just stronger in and of themselves but having stronger connections with the Centers, stronger ways, more ways to help them accomplish their goals related to women's health, I think that always requires more creative thinking and more ideas on how to do that, because there's always potential to do that.

VB: Do you have any other final thoughts you want to...? Anything I forgot to ask you about that we should capture?

SW: Oh, I'm sure. There are so many stories.

VB: Any people?

SW: Oh, there are so many people. No, I'm not going to talk about specific people. (laughter)

VB: Well, if anything comes up perhaps, we can footnote it in the transcript.

SW: OK.

VB: But thank you so much for your time --

SW: Sure.

VB: -- and for sharing your memories, and --

SW: Sure.

VB: -- I'm just going to close the recording.

END OF INTERVIEW