Oral History Interview with
Marsha B. Henderson, M.C.R.P.
Associate Commissioner for Women's Health
1998-2018

FDA Oral History Program

Final Edited Transcript

December 19, 2019

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Marsha B. Henderson, c. 2018

Oral History Abstract

Marsha B. Henderson, MCRP joined the FDA Office of Women's Health (OWH) in 1998 as a deputy director. She spearheaded various communication strategies to engage stakeholders, improve women's health literacy and promote awareness of pioneering research on sex as a biological variable funded by the OWH. She was appointed Associate Commissioner for Women's Health in 2011 (after acting in that position for a year), bringing a new strategic vision to OWH with the creation of the office's first Research Road Map.

Keywords

Women's health; stakeholder engagement; sex as a biological variable; heart disease; clinical trials; mammography; contraception

Citation Instructions

This interview should be cited as follows:

"Marsha B. Henderson Oral History Interview," History Office, U.S. Food and Drug Administration, Department of Health and Human Services, December 19, 2018.

Interviewer Biography

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

FDA Oral History Program Mission Statement

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

Statement on Editing Practices

It is the policy of the FDA Oral History Program to edit transcripts as little as possible, to ensure that they reflect the interviewee's comments as accurately as possible. Minimal editing is employed to clarify mis-starts, mistakenly conveyed inaccurate information, archaic language, and insufficiently explained subject matter. FDA historians edit interview transcripts for copy and content errors. The interviewee is given the opportunity to review the transcript and suggest revisions to clarify or expand on interview comment, as well as to protect their privacy, sensitive investigative techniques, confidential agency information, or trade secrets.

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Interview Transcript

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VB: Okay. So this is an addition to the FDA Oral History Collection. I'm Vanessa Burrows, for the History Office, sitting with Marsha B. Henderson, in her office, on the White Oak campus. It is Wednesday, December 19th, 2018. And usually when we do these interviews we try to start with just a little biographical information, so could you tell me a little bit about where you're from, where you grew up, where you went to school?

MH: Oh, sure. I grew up in Washington, D.C. I had a very interesting early childhood. My parents, when I was about five or six, moved to a section of Washington, D.C. on Colorado Avenue, which was right after segregation. The city was desegregated, and, as a result, there was a lot of white flight. So I grew up in an upper middle class African American neighborhood. We were assigned to school in Georgetown, even though it was a great distance from us, because they decided there was a certain type of middle class African American that they wanted in their schools, and so that was a challenge. We all went as a neighborhood to Gordon Junior High School and Western High School in Washington, D.C., and most of our teachers were Daughters of the American Revolution. They wore their pins. They were very proud of their experience. And many of them had never had experience teaching students like us, so we had the best of exposure and a lot of in-classroom challenge. Most of the students there, when we graduated, it was the '60s and most of us went to sexually-segregated Ivy League schools, because we were being heavily recruited.

I think during that time was my interest in health because my mother was a breast cancer victim, at a time when we did not have mammography or oncology products. And so she was a social worker who was very active in helping homeless families, working for the District of Columbia, and, you know, motivated her children to always, you know, keep it moving, whether you're sick, whether you're, (laughs) you know, having a bad day. Just, you know, do well and be successful. Our neighborhood was across the street from the Carter Barron Theatre, which now has the tennis courts, but when I was a child the Carter Barron was the amphitheater in the summertime for concerts, and it was before we had the Kennedy Center, and so, you know, the symphony would play there or the ballet would play there. And it was up the street, and people would wear long gowns to come to the Carter Barron Theatre.

So it was a very different point in time, and our neighbors were very focused on family. To my knowledge, there were no families in my neighborhood that didn't have two parents, so when I went to college I was shocked to find that African Americans didn't frequently have two-parent families. That was, you know, a learning experience for me, and it was a neighborhood where everyone went to the same churches. If you were Catholic, you went to this church. If you were Baptist, you went to this church. If you were, you know, Congregational, (laughs) you... So we all, you know, in our neighborhood, had a lot of the same, you know, community groups all working and playing together, and my parents were Sunday school teachers, and Boy Scout troop leader, and all of that kind of thing. And we had, really, a very interesting kind of what I would call *Leave It to Beaver* neighborhood. We didn't know it at the time, and I thought it was very boring, and, you know, directly across the street from my house is Rock Creek Park, and I always said I want to live somewhere that's going to have neon signs when I look out the window, not trees. (laughter)

So anyway, so that's sort of my immediate background. I was never a traditional child, so, you know, when people would ask me what I wanted to be when I grew up, I didn't say a nurse or a mommy; I wanted to be Lucy, because I thought Lucille Ball was like the epitome of how you wanted to live your life, and she was always getting in trouble, but not bad trouble, and she had a sidekick, and her sidekick did whatever she wanted, and I just thought that was fabulous. So that's sort of my background history.

I was going to go to Sarah Lawrence College. As I said, you know, we went to those kinds of schools, but because my mother really was then terminally ill, they allowed me to go to Howard University, and I was going to transfer my credits, except I had never been to an African American school, and I loved it. And it was the '60s, and it was the mecca for higher education, and I was exposed to every superstar in the African American community, whether it was a Muhammad Ali, or a Stokely Carmichael, or a Malcolm X, or Martin Luther King, or great authors, like Toni Morrison, who taught there, or great artists, like Mailou Jones, a brilliant artist. All of them were at Howard University. Everybody came through Howard University. And so after my freshman year -- and my mother died my first semester freshman year, when I was 18, and I just told Sarah Lawrence no thank you, because I was having a ball. And, you know, did all the college things. I was a coed who didn't have to work, and so I just had to do well in school, and move along. And so I did.

I met my husband there. He was not like me. He worked, and was a very studious, deliberate person, and so we were just friends, but later, when he graduated and went on to law school I then dated him there, and then we got married, and I went to Rutgers graduate school, to the City and Regional Planning School, because my intention was to focus on health planning and hospital administration. And he became the assistant dean. He was the youngest dean of

any law school in the country. He was the dean at Rutgers University in Newark. And we came back to Washington, because he changed jobs, so I finished my graduate work at George Washington and got certified in hospital administration. And this is why I always tell graduate students, "Figure out who you are and what your passions are," because I decided I only liked hospitals on paper. (laughter) I didn't care for being in a hospital.

And so because I was in Washington, D.C., and the federal government was here, I had the opportunity to come into the federal government, into a unit that was called the Bureau of Health Planning, and that's how I was able to come in as a health professional, because they were looking for people who knew how to get started, (laughs) at least, planning health services. And I came in with the agenda of national health insurance coverage. And it's interesting that as I leave it is on the cusp of demise, but, you know, it just teaches you that there are no permanent solutions. You have to continue to push for what you think is the right thing for public health. And so I've always been dedicated to that.

When I came into government, now 40 years ago, almost -- because I got credit for my little student work -- not quite 40, but close -- I came into public health in an area of hospital services. There was a program called Hill–Burton, and Hill–Burton was a grant that hospitals all over the country got to modernize. Many years before I got there -- I want to say right after World War II -- hospitals modernized with things like elevators and air conditioning, and it was very expensive to either build or retrofit your hospital with that type of infrastructure. So they got no-interest loans. However, they had to give what they called uncompensated care to patients, and so their bill, if it was a million dollars, over many years -- I can't remember now; it may have been 50 years, but over some period of time -- they had to give that amount of uncompensated care to poor patients, and they had to document that to the federal government.

And there was an office, which was the office I originally entered, that was tracking that, so that they could log that off of their debt to the federal government.

And I went from the Hill–Burton program to the Health Planning Office. And the Health Planning Office was setting up the state and local government programs that were supposed to be responsible for the future of national health insurance. And I had grants. I started with being a grants manager for a couple of regions, and then suddenly, the next year, I had all ten regions. So this was very early on in my career. It was $10 million, which was a lot of money then, for ten regions, for training. And it taught me a lot. I learned about planning services at the state and local level through these training institutes, because I would get to travel to watch them, and I would get to learn about how one does that with state and local governments.

And then, after that, my city, the District of Columbia, got in trouble. They did not meet the requirements for this planning program. And so I asked if I could go and be on detail to the District of Columbia, to help them get these conditions removed. They had one year to have the conditions removed, and so I had the luxury of going to do this one function, which was to help get this series of conditions removed. So I got my taste of a state and local government experience through that, and then when I returned I ended up -- the Reagan administration decided that that was overreach, federal overreach. They were not in favor of national health insurance, and so the program had to be dismantled. And one of the things I had to do was to go then to those ten regions to help them archive the records.

And after that, because I was a career employee, I was placed in the Bureau of Maternal and Child Health, and I was the supervisor for that for a unit that was responsible for evaluation. And at that time we had a very high infant mortality rate across the country, and I was (laughs)

responsible for this statistical unit. And I had very good statisticians, PhD statisticians, but their problem was they didn't know the questions to ask, for some reason. And I noticed that we had a major grants program in our division, and I noticed none of the money was going to places like D.C., and they had one of the highest, if not the highest, infant mortality rate in the country. So I asked my lead statistician to take a look at the grant locations, and to analyze why money was going to these places versus a place like the District. And we concluded that the senior members of the division department were sending all the money to their alma maters, so that appeared to be the priority. And, of course, I identified that in writing. That didn't make me a favorite.

I also made a couple of proposals for our special projects money. We had something called SPRANS grants, and they were special area initiatives, something like that, for regional something-or-other, but they were research grants that were supposed to go to various... They were identified as priority grants, and you would do an announcement about the program to states, and they would bid. So we decided we wanted to do one focusing on Hispanic infant mortality. That had never been done before. Very high rates across the country, so we wanted to put a bid out. They didn't like that idea, but I identified that in the last legislation we had made that commitment, so it was not optional. So they had to fund that particular initiative.

The second initiative that I recommended was for women and babies that were HIV-positive. This was before we had AZT or any effective treatment. So I took my lead statistician -- and, by the way, he was an alcohol, an active alcoholic; brilliant, but, tragically, an active alcoholic, but knew his stuff. So we went to this meeting, and we proposed this initiative for people with HIV, women and children, and they were going to be predominantly black, African American, because that's who was presenting, places like Harlem and Chicago and Detroit. And they told us that, quote, "They're gonna die anyway." And I was quite horrified by that

comment. And so they didn't think that they should invest in that. And I said, "Well, what do you think is better to invest in, since we are an infant mortality-focused unit?" And they told me that lactation was more important. They had two people there who were experts in lactation. They happened to be single, childless women who were nurses. I said, "Well, let me just say this: you have three, because I successfully nursed two children, so I am an expert in lactation, (laughter) and I want you to know that it doesn't take any special research. This has been going on since the beginning of time." So my alcoholic statistician said, "Yeah, we can call the program Tits For Tots." (laughter) And the two of us fell out laughing. They didn't find it funny, but we left, and so I didn't last very long there.

The next year, I was sent to what ended up being a wonderful experience, which was the National Health Service Corps. And, by the way, one of the things I became known for, and the way I got promoted, was I would often get the worst staffs. (laughter) They would have problem staffs, and they would, you know, want somebody to get them together. And so I would say, "Well, you've got to promote me," and so that is how I was able to kind of move. It was at a time when there were very few African American supervisors, and certainly not women, in the part of government where I worked. So this was in HRSA, and I was in the National Health Service Corps, directing placement. There was only one other African American woman -- well, supervisor, period (laughs) -- in HRSA at the time, and that was Dr. Audrey Manley, who became an Assistant Surgeon General after this experience. But she selected me to help with the National Health Service Corps placement.

I did not know at the time that I went there that they called it the sweatshop. At that time there was a program, a grants program, for people who wanted to be physicians, nurses, pharmacists, veterinarians, but predominantly physicians, to go to health shortage areas. So at

the time you would get your money in advance, and you would use that money to go to medical school. And at the end of your medical school experience you would have to place to a low-income place for two to three years. And, of course, they paid you, you know, a salary and everything, but that was the way you paid off the loan.

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And apparently before I went there you would get a list. They would market the program to... You would get a list, and on the list you would see D.C., New York, Chicago, Memphis, L.A., and you'd say, "Sure, I don't mind working in a poor community for a while, in a clinic, and I'll take the money."

Well, a new administration came in, and they didn't like all these urban areas getting this money, and the way the program was saved was they shifted it to rural communities, and prisons, federal prisons, and Indian reservations. So now, four years later, you are a physician. You have finished matriculating. You're boarded. You're ready to place. You get a list that looks nothing like the list you were recruited into the program with. So you see Bethel, Alaska. You see Marion Prison that's, you know, many stories underground. You know, you say... (sighs) And, "I'm now married, and my wife and I are not interested in going to these desolate places." And you get a bill for 200, 300,000 dollars from the federal government, due immediately upon receipt, and it cannot be expunged with bankruptcy. So now you're a physician who can't even get a car loan, much less a house loan, and there was no -- the courts were siding in the government's favor.

So they went to the Hill, and Congress decided to give them something they called amnesty, so you could then come in and do straight time with one list, or you could get a

preferred list, but you would have to serve longer on the preferred list. You still wouldn't get D.C., but you might get someplace outside of sort of a known city. So that meant that rather -- we usually had about 2,000 people coming in; this tripled the list. So when I became the director I had 6,500, rather than the normal 2,000, and these were legal documents that they received. When you got your letter, you were getting a legal document. In addition to that, you were on a timeframe. Every quarter, there was a placement opportunity. You started with a very long list -- let's say a hundred places you could go -- but people would then start to place, so if you didn't place in the first quarter you would get a new list, but it would have fewer places, and fewer places, and then the last quarter you were assigned; it's take it or leave it. And everything was done manually, in terms of the letters, and logging in. That's why they called it the sweatshop: because people had to record everything. You're getting phone calls constantly from people who are disgruntled. Many of them have sued the government. Many of them look on the list and they're not happy. And they had been doing this for many years.

So I walk in -- I was relatively young -- with an older staff, not happy, had never been recognized for doing the hard work that they did. And it was a great lesson for me in terms of supervision, because first I realized that they felt disrespected, and the first thing that I had to do was to say, "We're a team. We're in this together. We're going to work hard, but we're going to start getting recognized for what we do. And, if nothing else, we're going to recognize ourselves." So after that very first quarter, we had been rather successful. I called in a woman, Arlene. I always remember Arlene, because Arlene always told me that there were certain things that she just didn't do. (laughter) First meeting, you know, "I just don't do this or that," and "I'm in a carpool, and my carpool leaves at 5:00 on the dot, and that's it." And I called her in, and I said, "Arlene, I think my impression is something tells me you're a good cook," because

she always had this big thing of food. And I would be there so late, she had started coming to me with food. She would say, "You gotta eat. You need..." And I would say, "You know, I'm just learning. I don't really have time to do this or that." And she'd start bringing me food. And so I said to her, "You know, Arlene, we really did well this first quarter. I think we need to have a party. And we need to just celebrate ourselves. And we're going to invite in, you know, some of the rest of the division," because we used some of them to help us with various things. So we'd put up big signs, and she was responsible for the cooking, and all of this, and she orchestrated all of that, and people came in, and they started feeling good about themselves.

And during this time I had gone to my first meeting with the director of the bureau, bureau director, because I was one of the supervisors. He had a diagnosis. Everybody knew it. In his case, they claimed he was brilliant. He was the one who turned the program from urban to rural. And he supposedly was a cousin of Orrin Hatch, so he was viewed as untouchable. And I went to a meeting, and he cursed the entire time, and he had a long telephone that he paced with, a long cord, and he would pace, and he would yell at people over the phone, and I realized with my first meeting the reason why my staff was concerned was because he was intimidating. He ruled by intimidation. And they claimed that when he came in he got rid of all offices. The walls came down, and he had to put some up for supervisors because the union said there needed to be privacy. So all of my team was an open-space team, where I had the only office.

And he asked me some questions about placement, and this is why I tell people some of the worst experiences can be your best. He said to me, "How many placed last week?" I didn't have an answer. "Do you know if any Indian reservations got placements?" I didn't have an answer. I was embarrassed. This is the entire division supervision staff. So I went back to my office, and there was a woman there who, you know, I said, "I need some help with this. You

know, I need to know this." She had a child who had learning issues, and she had mastered how to display information, because we didn't have a computer to do this. So she put together a matrix with cells, and showed me -- she took it off the computer and put it on this set of sheets. And I could tell you down to the number how many went to an Indian reservation, which reservation they went to, whether they were physicians, pharmacists, or nurses, or veterinarians. I mean, she maxed out.

The next week he said to me, "Henderson, how many went to such-and-such?" I gave him a number. "How many...?" He asked me about six different questions. For each question, I rolled. And I gave him a copy. So the next week, same thing. He said, "Okay, our agenda, each week, will start with the Henderson report." (laughter) And that was because many of the people around the table were recruiters, right? They were doing things that were direct... They were certifying the locations that people would be placed in, so that this document became the lead for how are we doing, right? "We only have a few in this; you need to recruit more to go here." Or, "We've got enough in this location." So on the agenda it became the Henderson report. So that experience taught me something I tell everyone: know your job. (laughs) Know what your individual staff are doing, but what is your goal?

We recently, here in this office -- and that'll come later -- we went through a strategic planning process, our last one for the year, and it was a self-congratulatory experience, (laughs) and we had listed a lot of things at the beginning of the year, and we did them, plus we did some others. And many people around the table said, "I'm surprised we did that, we were able to do all that." I wasn't surprised. I'm watching it, right? I watched that flow. If we're going to do X, we're going to do X, even if it takes a while down the road. Always know where you're

headed, what you expect the end product's going to be for that term, and make sure you're getting there, because there will always be blockades.

So as time went on we continued to congratulate ourselves. People got government awards they had never gotten before, because no one took the time. Something else had happened was he started rating my people, you know, because I always had believed that you showcase people who do good work. Well, of course, when you get showcased you become a commodity. And I would always say, "Well, fine, you can take her, but you better pay her. You know, don't just think you should take her, because she likes it here, and if you want her to go somewhere else, or him to go somewhere else, you'd better give them a promotion." You know, I always felt that that would be appropriate.

Then there came the time that this individual, who -- Dr. Martin, Ed Martin, because everybody knew his story -- got very upset with me. We had the inevitable run-in, because he had run-ins with everybody. And one of the things I tell people is no matter how wonderful you are, when you see a train coming down the track, (laughs) it may not hit you this time but you will be at some point a target. We had the situation with amnesty, and I did it, frankly, two years before amnesty, so when amnesty got there I was onboard, knew how to do it. I'd gone from 23 hundred now to 65, 67 hundred. And he didn't like amnesty. He felt that these people cheated, and he did not like that they could get a better spot. So he asked me to make all of the letters to the amnesty people, which was two thirds, to change their letter, and direct them only to Indian reservations or federal prisons. And I went to my boss, Audrey Manley, and I said to her, "You know, whenever I change a letter, general counsel says it has to go through them. This is a legal document. So I'm drafting it the way he has asked, but I'm going to send it to legal counsel

before I send it out of here." She said, "Well, you do what you have to do." I sent it to legal counsel.

Well, here's the backstory. Dr. Martin had become the head of the Commission Corps, period. He was the top of the Commission Corps. What do you have to be to serve in a federal prison or an Indian reservation? A commissioned officer. He was going to build the Commission Corps using amnesty people. It went to legal counsel. Legal counsel did not send the response to me; they sent it to him. And what did it say? This is illegal, because it is mandatory enlistment. It says, "You civilian have to enlist if you are to serve your term." So he was very annoyed. He became very annoyed with me. So when I came in the following week, my desk was in the hallway by the elevator. And the Fire Department said, "You cannot have someone out in the hallway next to the elevator, so she at least has to be in an open-space location, behind a door." Very interesting experience, because, as I said, he led by intimidation.

Oh, but before that, before that happened, I had an... (laughs) So, well, before that experience, he decided to change one thing in the letters. Now, I told you these are all handwritten... I mean, they're not handwritten; they're all logged into a... They were all return receipt, so we had to assure that you got your letter, and that you send this back, and they were all logged out with numbers in these big books. So that meant the day before they were due to go out on Monday, on Friday he tells me at, you know, middle of the day, he wants every letter changed. The assumption was it couldn't be done. So I called everyone in and I said, "You know, we've done so well. You know, over the years we've met every deadline." I said, "Now, I'm sorry to say we're not going to meet this one on Monday, because we're going to have to change every letter, and I can't offer overtime. He's told me there will be no overtime. There will be no extension." And someone said to me, "Do you have a dining room table?" I said,

"Yes, I do." "Will you buy us pizza?" (laughter) I said, "What do you mean?" She says, "Oh, we'll get it done. We'll come on the weekend."

And so we carted all of those... They spent Friday printing out every letter, with the change. They took boxes and brought them to my dining room table, and they redid every log book. On Monday, when I went in with the Henderson report, "Henderson, so those letters didn't go out." I said, "I never said that. Every letter was at the post office today. They're downstairs. You can check with the mail service." "What?!" "Every letter has been logged, sir. Everyone is there." So that was how he tried to get me. He was furious. Every letter went out. We didn't miss a deadline. That's when my desk the following day was in the hallway.

It was interesting, because people were afraid to speak to me because he was so intimidating, but I would find things on my desk. I might find a card, or some chocolate, or a flower. So I was reassigned, and truthfully I can't even remember what the little work was I was supposed to do, but, luckily for me -- see, here, again, one of the best things that ever happened to me -- they dug out... Of course, I would get awards all the time, and they came to my desk one day, and there was an award that he had gotten me, for me, but, of course, he threw it in the trash. You know, in this big meeting he wanted everyone to know that, you know, he was sick of me, and so he had this award and he threw it in the trash. So somebody went in the trash to give me my award, and they presented it to me. And I realized I have to get out of here. This is not a good place for me.

And so I had some contacts elsewhere in government, and I knew that there was this program downtown focusing on homelessness, and my passion has always been related to poverty and low-income people, etc. So I took leave, and I went and had an interview, and they

liked me. And, ironically, it was a political office. It was under George Herbert Walker Bush. Under the Reagan administration, we had a lot of homelessness because of disruption. There were families that went on the street. Now, people weren't as concerned about singles, but they were very concerned about mothers and children, so there was a new piece of law that established something called the Interagency Council on Homelessness, and it was cabinet-level. All of the cabinet members were to have this separate unit called the Interagency Council. So Labor, Housing, Education, HHS, Transportation, all were to bring together their resources to get families off the streets of America. It was led by Jack Kemp, and co-led by Dr. Sullivan from HHS. They were the co-chairs.

And this council, staff council, Patricia Carlile, Pat Carlile -- wonderful person -- wanted me. And I indicated that I worked for someone who was very difficult, and I kind of told her this backstory, and whatever. So I'm sitting there one day, and, of course, Ed Martin never answered her calls. She would call to get me detailed there. He wouldn't answer her calls. So she got Sullivan, head of HHS, to sign a letter saying I was being detailed to her. So he was in a meeting with the administrator, who said, "We have the opportunity to support this new legislation, and Marsha Henderson will be going downtown." And I worried about it. I talked to my husband about it, because I was not a supporter of many of their initiatives.

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And my husband said, "You know, you're a career civil servant. You work for every president that's elected, whether you know it or not. You've been back here doing this, and back here... But everyone, you worked for. You have a mission that's consistent with that office's mission,

which is to get families off the street. You need to go down there and do it." Best experience I had had in my career to that date at that time.

I went there, and I learned so much. And the thing that I learned was public/private partnerships, because that legislation opened the door to allowing government to take private resources to help families. And I didn't know anything about that. I'd only done grants and report writing and that kind of thing. And in this office, there was a great dedication to that, and I didn't have to do any typical evaluation. We decided very early on that we were going to do -- my team -- I ended up directing a team related to assessment, best practices, and we had regional offices, and the regional offices would tell us that a program in a particular location did very well with getting kids back in school, or with nutrition programs, or with healthcare, or whatever. And my team would go and look at the program, and briefly describe the program, and send this around the country, so that if you were running a facility you would have the opportunity to see a description of something, and you could call that person directly. You wouldn't call us; you would call that other facility and say, "How did you do this?", and etc. And the goal was to try to create national -- an infrastructure that was telling the story about things that were working well. So you didn't have to have a wonderful program; all you had to do was have a component of a program that was doing very well.

And it allowed me to really travel and see poverty all over the country, and some of the best practices, as well as some that weren't so good, in these settings. And one of the things I learned was: talk to people. Because, of course, you're going to be shown around to what they think are the good places, and early on something said to me, you know, talk to some people who are using these services. And I remember speaking to an older lady, and said, "How are things going?" She said, "Well, they're doing okay. You know, I'm off the street now, but, you know,

they could be a little better." I said, "What does that mean?" She said, "Well, you know, I'm old now. My body doesn't look so good, and when I go to the bathroom some of the other women laugh at me," she said, "because, you know, we don't have doors on the toilet." I said, "You don't have...?" See, the ways in which people live never occurred to me, because I'd never lived that way. It didn't occur to me you would go anyplace where a toilet didn't have a door on it, or a shower didn't have privacy. And so, you know, I just learned to talk to people and, you know, make suggestions, and report things that I thought were not good.

One of my biggest disappointments -- because I think the program did very, very well, but one of the disappointments that I learned about, and have since learned is still in practice in some places: if you were a child, a male child, between the ages of eight and 12, you might not be allowed to come into a shelter, family shelter, with your mother. And I thought that was just outrageous. And I questioned a number of shelter directors about this, and they would say, "Well, you know, we can't put them in with the women because some of these women are very sexualized, and we can't put them in with the men because they might get raped." And I said, "They're eight. They're ten. They're 12. They're little kids. What do you mean, they can't be here with their mother?" Even places where they had their own little apartments, they would not allow male children to come with their mothers. And I said, "Well, where do they go?" "Well, the mothers have to make other arrangements." And I said, "Well, if the mother has to make other arrangements, she'd be there. If she had a safe, good place, she'd be there." So, many of these women would try to make an arrangement with some other very poor person, in a setting, you know, so these kids are on the street. So when you see young boys hanging out on the street, many times they don't have any other place to be.

I brought this up because one of the things we would do is we would bring it -- they'd have quarterly meetings of these cabinet members -- that was the Council -- and we would bring up things that were typically supposed to be regulations or guidances that got in the way of maximum support. So, in some cases, let's say, if you got HUD money for something you couldn't get Labor money for it. And when we would bring it to their attention, they would do a modification so that you could do that. And I brought to their attention that these young boys were being rejected from entering spaces with their mothers. And I really felt you shouldn't be able to get federal dollars if you did that. And they wouldn't bring it before... They would not allow that to come for a vote.

So that was very disappointing, but I did learn a lot about other government programs, how to coordinate across them, and how to leverage private resources to be available to shelters, because that's what we worked with. Got a lot of opportunity to visit Indian reservations, which became an issue, because HUD is responsible for Indian reservation housing. So what did that mean if the Council was visiting a reservation? It implied HUD wasn't doing its job. So we got a little trouble for that. We also did a lot with runaway kids, and learning that, you know, many homeless people on the street, young kids, often gay, often being sexually trafficked, and often the only places, and preferred places, for these kids were run by LGBT groups, because they were very serious about helping these kids and really poured real resources into it. Got in some difficulty from some Congresspeople about, you know, that. Now, that was also, though, in the early '90s. Hopefully a lot of that has changed, but it was challenging.

So from that experience -- and I was there for, like, five years; that was, like, great -- I went to the Department of Labor, and worked in the Women's Bureau. And in the Women's Bureau, I worked on FMLA, which was, you know, new legislation, how do you implement that,

and something called the Working Women's Honor Roll. A brilliant woman led that operation, Karen Nussbaum. She was the founder of 9to5, that they made the movie with Dolly Parton and all of them. She was the founder of that, what was called Pink Collar Unions, and they were women who worked in offices, and on assembly lines, etc. And she was really very focused on making things better for average women in the workplace. So she created the Honor Roll, and the Honor Roll was for the purpose of saying to employers, if you create something brand new for working women, then we will recognize you with, like, a certificate or something from the Secretary of Labor, who was then Bob Reich, a brilliant economist who was Secretary at the time.

But we were all doing this, you know, figure out what could be done, and I learned a lot about, here, again, how other people live. It wouldn't occur to me that it would be a big deal to have a phone number -- this is pre-cellphone -- have a phone number your child could call to say, "I'm home from school safely." So there were plants, manufacturing places, that allowed the phone call, and then they would post the name of your kid having checked in. They were thrilled with that, great. There were people who offered English-as-a-second-language in, you know, garment industry, where women were from other countries, and didn't speak English, and they were going to have some upward mobility because the company was now going to have them trained in English. Or some of the big ones, like the IBMs and, you know, etc., that put in major daycare facilities, that were... So, you know, that was sort of my background before coming here.

VB: While you were at the Women's Bureau, there were these working groups and thinking towards creating offices of women's health throughout the federal government, particularly at HHS. Was there a buzz?

MH: This was before that, and I really think that it was the nature of that administration. It was a brand-new Clinton administration that had a big focus on women. And understand who I just said was the Women's Bureau Director, this woman who had become nationally and internationally recognized as a women's labor union person, whose whole focus was on better things for women in the workplace. I think the tide was beginning around that, and she started before I got there with a survey called Working Women Count, and it was everything from executive-level women, CEOs, to, you know, office workers, assembly line workers, agricultural workers, a big huge number of women, and what was important to them; and quality of life for themselves and their family, that work/life balance, economic ability to, you know, succeed with being able to save money and invest money; and, of course, safety for your children, because women don't feel they can be effective in the workplace if they don't think their children are safe. And that meant, for them, things like a phone number that says, "My kid is a latchkey kid, and they're at home, and they're okay," or that "I've got a place that I can bring my child," because this was before there was a lot of places that were work-related where you could get childcare. Now that's very common.

When I came to the Parklawn Building in the '70s, they voted against a daycare center. I was shocked, because, one, there were probably a lot of male determinants, but they felt that if you had children you should go home and be with them. That was the mentality. And they

voted against having federal support for a daycare center. Now, I was like 27, and I was like, "What? What?" I was just shocked. But the tide turned, and you're right, that was, you know, the very beginning, and so that at the Women's Bureau they had this national survey of women in work locations that voted -- that registered their interests. Then she had the Honor Roll to try to encourage industry to do that. And then they had a big White House welcoming, and that was an amazing experience, because I'm from D.C., and the White House has not meant to me what it means to some other people, because I see it all the time. I've been there as a kid for, you know, tours or whatever. But can you imagine being an assembly line worker, or a woman who picks crops, getting in the mail a letter on White House stationery with that seal of the President, saying, "I'm inviting you to come to Washington because working women count."

And they came in their best. I loved just sort of sitting there watching, because I wasn't going to go. It was going to be limited. I've forgotten how many, you know, few thousand. And, you know, I had been one of the leads on this, and I said, "No, let somebody else go," you know. And she said, "No, no, you must come." And I'm glad I went, because the whole experience was so rewarding to me, to see people know that this is their White House, and this is their government. So that was amazing. But then I had to come back, and I was like, "Oh, God, I don't want to come back to where I was before." (laughter) And I met Audrey Sheppard, who was then the Director of this office. And so that's sort of the backstory to coming to FDA.

VB: So I really want to hear about how you were recruited to the FDA Office of Women's Health, but could you also, just for the sake of chronology, could you tell a little bit about how the Office of Women's Health was formed?

MH: Mm-hmm. Here, again, women's advocacy. Nineteen ninety-two, GAO report, indicating that there was a dearth of women in clinical trials, particularly in phase one and two. Many people have assumed that meant no women were in clinical trials. That's not accurate, but the numbers were rather low, and particularly in phase one and phase two, as well as phase three trials. And that was because in the '70s we issued a regulation that said women of childbearing potential should not be in clinical trials, due to risk for the fetus, and for the pregnant woman, as well. And that was, from my perspective, an overreaction to thalidomide and DES as two main examples. Once this report was issued, and women became aware that products that they took every day, whether it was for a headache or diabetes, was tested on men almost exclusively, they became very annoyed about that, and really we hadn't kept up with modern day contraceptive opportunities. You don't have to get pregnant while you're in the clinical trial.

And so the guidance then got changed. In '93, women went to the Hill and got legislation passed, and language in appropriations guidance, and the people that really got money were the Department and NIH. There was a recommendation in the appropriations language that FDA establish a women's office for $2 million. The then commissioner, Dr. David Kessler, was in agreement, and so he hired the first director in '93, who established the office in 1994. And her name was Ruth Merkatz, and she was very dedicated to this, and she set the office up predominantly with lawyers, because the first requirement was to change the regulations and guidances. And so they went through a process, which you know was very laborious, (laughs) and had those guidances changed, and then, you know, obviously there really wasn't a need for their services, so they went back, and the new group of employees were predominantly grants managers, because with the $2 million, in addition to the staff salaries being paid out of that

money, there was an opportunity for intramural grants, where FDA reviewers would have an opportunity to bid for our money to do some research in areas that were to focus on women's health.

Ruth left the position, and her deputy became the acting director, who was Audrey Sheppard. Audrey Sheppard knew Karen Nussbaum, the woman I was working for at Labor, and she recommended me, and I came and interviewed. She wanted to do outreach to these women's groups. This office, from its inception, has always understood that we are a direct beneficiary of women's advocacy, so we have always listened to the voice of women, and it has served us well. It's served the Agency well. So when I came, I was just by myself, no staff. I was to start to get information out there to various women's groups.

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I had an exhibit that had never been out of the box. It was literally a photo of Audrey's backyard, with some women sitting around the lawn table. And we had no publications, so I went to what was then the Office of Consumer Affairs. The Office of Consumer Affairs had a big repository, like a warehouse area, storage area, that had all of the publications from each of the centers that were for consumers. So I literally pulled what I thought might be of interest to women from CDRH -- from CFSAN, predominantly -- and put them in a box, and went around to some conferences. And I concluded this was not a good approach. (laughter) Okay. The approach was call these women in and say, "Okay, we want to do outreach to you, and what should we do?"

And we started by thinking about what we would present to these groups, and we concluded that we needed a contractor. We hired Ogilvy, a marketing firm, to help us, and they

came up with this catchphrase: "Take Time to Care." And "Take Time to Care" was based on data that indicated that women were so busy helping everybody else -- family, friends -- working, that they didn't take enough time for themselves. So our message was take time to care for yourself. And I had to present this to the executive team here at FDA, so that was the Commissioner and all of his senior staff, all the Center Directors, the Director of Communications for the Agency, the COO, the financial person. And so when I went, the first thing they said was "Is 'Take Time to Care' copywritten?" "No idea." "Well, come back when you know." So we had Ogilvy do a search. They figured out it wasn't copywritten. We went back, said, "It's not copywritten," and they said, "Well, you know, you want to talk to these -- you want to work with these advocacy groups."

And basically, they didn't think that was a good idea, for a variety of reasons. One, FDA's view at the time was they were mecca. We are the pinnacle of products, and what we do is we review and approve products. That information we put in labels, that goes to the provider. The provider communicates with the public. So that was one. That is not our role; that's what HRSA does. Number two, they had had bad experiences, from their perspective, with the public. They had had people come in who were taking what we considered a quack product, laetrile, which was, I believe, for cancer, and it was some kind of infusion of urine, so when these people came in they reeked of that. And so that wasn't a pleasant encounter. They had also just gone through a shutdown from ACT UP, because we were not releasing AZT to the public, and the outcomes were so positive that ACT UP, as you know, the HIV community, wanted that made available quickly, and it wasn't consistent with our protocol. So they were in the process of changing the protocols for compassionate use and etc. so that this could get out there, but their experience was conflict (laughs) when you deal with the public.

So here we've got women's groups, who we know can be quite forceful with what their perspective is, and you want to open the door to just randomly, for no reason, interact with them? They weren't feeling it. So we then came back with a plan about what we were going to do, and we were going to focus on eating right -- what was it -- eating right, taking your medicine appropriately, and something else. There were like three of them. And they were really trying to take our hashtag, "Take Time to Care," and make it something FDA-ish, like "Regs." (laughter) No, literally. And it was like, eh... And so Mitch Zeller -- I always give him credit -- who was here at the time, and he was like Dr. Kessler's lawyer, said, "You know, David, if we approve the perfect product and no one knows how to use it, we will have failed." And Kessler said, "Okay, okay, go on, go on." So it was sort of like, "It's okay."

And when I got here I also read the background on our office. There was an original meeting once the legislation was passed, and they knew there had to be an Office of Women's Health, and Ruth was here. There was a transcript of this go-away, and the recommendation was the office would sunset in one year, that the regs and guidances would be changed, and they could go away. And clearly that didn't happen. And one of the leaders in that was Janet Woodcock, from whom I just got, you know, a lovely note and a wonderful call and great relationship with, but that took a while. So with that backdrop, you know, (laughs) there were no guarantees for the Women's Office, but we called in twenty-some national organization heads, and we did something very different from what would be typical for FDA. We --

VB: Sorry to interrupt you. Can I ask you who were some of the most important organizations that you worked with during that time?

MH: Yeah, sure. The Society for Women's Health Research, under Phyllis Greenberger. We called in, you know, the American Diabetes Association, Heart Association. We called in the National Consumers League. We called in Cindy Pearson and Diana Zuckerman, who focus on women's health research. Partnership for Women and Families, which used to be the Women's Legal Defense Fund. So we had a mixture of groups that represented disease, women's advocacy, health professional groups. We called in nurses, organizations, physician groups. We defined our stakeholders as any group that had an interest in the health of women. And so that morphed into insurance companies, and big businesses, and voices for women like Dear Abby, and Las Vegas casinos, and that's a story I'll get to, but... So we never said you had to have "Woman" or "Consumer" in your name to be our stakeholder. Our stakeholders have a vested interest in the health of women.

And so we, you know, started small, and we brought in these groups, and we said, oh, we want to, you know, eat right, and, you know, take your medicine right, and, you know, go get checkups or something. They said, "Wait, wait, wait, that's too much." You know, you want everybody to change their life. (laughter) The other thing was, you know, we walked them through what FDA did, because everybody knows a piece, and we have such a broad portfolio of things that we do. And so the first couple of meetings was really for them to understand our role, and the breadth of what we do. And so they said to us, "Okay, take one thing, not 50 things, one thing, and it should be safe medication use, because people are talking about eating right, people are talking about go get your checkups, but there is no group that is out there saying, in general, this is how you take medicine, and no one will ask why is FDA talking about taking your medicine safely. That is a safe thing that you can do." And we said, "Great. Well, we're going

to have a conference." And they said, "Don't have a conference, because the enlightened come to conferences. We have had enough conferences. We need FDA in communities where, quote, 'women live and work.'" And I said, "I am the staff. You're looking at the staff. I don't disagree with you, but I'm the staff." And they said, "Well, if you put together some good material, we are your network. We have the health professionals. We have women members. We have the networks that will allow you to do that. If you make it available and make it accessible, we will use it in our venues, and we will tailor it to our audience."

So we started with our first piece, which was... And we said, "We need to test this." We said, "We can't just go do something crazy." So we picked two cities to talk to, and we wanted, from the very beginning, for it to be bilingual. We wanted English/Spanish, because that's the population of information needs. So we went to Hartford, Connecticut and Chicago, Illinois. And why Hartford? Because, one, they have insurance companies, but, more importantly, they have multicultural Spanish populations, and we knew that we could only do one translation, and we wanted to know whether that translation would work across different Spanish language communities. The PASs were very helpful in that, because they said, "Whatever you do, when you translate, do not use the FDA translator." (laughter) We said, "Why?" "Well, he is Castilian, and he is elitist, and nobody can read it, so get a contractor." So we did. We got a contractor that did what they call multicultural Spanish, so in addition to translating they tested it across different Spanish-speaking people, so if the word was "red," I might say "red"; you might say "rouge"; somebody else might say "magenta"; but whatever word they picked, they made sure even though it's not your preferred word you understood it to be "red." And they might also put a tweak or so in there that was consistent with sort of the acculturation of how they prefer to get information.

So when I first went to Hartford, I had nothing. I mean, I didn't have a draft. And so we called in this group of women's groups. We met someone who... There used to be -- oh goodness -- women's caucuses around that same time. That was the '90s, and there were these women's caucuses, and they represented different women's groups. And so they let me be on the agenda, and I talked about "We want to do a safe medication campaign, and coming soon we'll have some information for you." And they said okay, and we did our first test, and we had an envelope full of, like, pieces of stuff. Oh, we had a bookmark, and a... It was an envelope. And we took it to this community center, and the community center ladies took that envelope and folded their arms with it in their arm like it was personal mail. And you literally had to say, "Now, take the envelope and put all that stuff on the table." And it was distracting. I mean, it was like five or six pieces; what do you look at first? So that's when we concluded the only thing in there really worth keeping was a recordkeeper, not all those other messages and this and that.

So we then started to work on a recordkeeper, and that was our My Medicines brochure, and we did focus group test it, and we were going to focus on older women, because we said older women are the ones that take medicine. And so the campaign was going to be on older women, and when we focus group tested, we had pictures of older women on the covers. And we first asked them, "What do you like? Which one do you like?" They didn't like any of them. "That doesn't look like me. She's old. Blah, blah." And at the very end, there was a picture of flowers, and they all agreed they wanted that one, because if they were to keep it in their purse, they wanted something pretty. They didn't want anything that looked like medicine. Medicine is not something, like, you know, warm and fuzzy. And the moderators said, "Well, what should they call it? You know, safe medication use, or da-da-da?" "No, My Medicine. My Medicine,

because if somebody finds this, they will know what it is." And we laid it out so that it could be faxed for their medical record. They wanted it in a way that you could just take it, and when you opened it I could give it to my doctor, and my doctor could put it on a Xerox or whatever and copy it and put it right in my medical record.

And so that's how, you know, we went through a lot of things about simplicity. We knew the reading level of the average American is fourth grade, maybe to sixth. And so we had the ability to hire, then, a consultant to put it in that format. Later, I hired people that have those inhouse skills, but at the time we sent it there. And so we started with New Haven, and then we were to go to Chicago. So we go to New Haven, and we meet with these women, and we say, "This is it, and we're going to have a week of this, and we're going to make as much as you want available to you, and we'll ship it up here, and then we'll come the week of whatever." And I get this phone call from this woman who was there at the meeting, and she had been to all of her local drugstores, and she needed 20,000. And I said, "What?" "Well, you said anybody, and that's where people go to get medicine, so I went to the drugstores, and they said they'll take 'em, and I need 20,000. And if you're not gonna do it, well, then, the federal government needs to call them and tell them they're not getting 'em." And I was, for the moment, quite horrified, but we printed her 20,000, and we went up there, and we, you know, looked at the activities, and who would do what, because people say they'll do things, and some won't, and blah, blah.

And so then it was time to go meet with people in Chicago, and luckily for us the dean, a woman, Dean of the School of Pharmacy at the University of Illinois in Chicago, was in the meeting. And, you know, I told them the story of Hartford, and we couldn't possibly do that. And she says, "Well, maybe we can, but we won't have you pay for it." So, with that, she contacted drugstores, and they said that if we gave them a print disc they would print. And, you

know, here again another week, and it was very successful, and where was it most successful? At the drugstores.

So I called the National Association of Chain Drug Stores, with her support. She's the dean; she knows these people. So I went to their association, talked to the foundation director, Phil Schneider. Phil loved the idea. He says, "Oh, we want to do this with you nationally. We can do this." And so that's I learned about co-sponsorship agreements and the FDA, because, of course, everybody said, "Oh, they'll never let you do that. That's industry. You can't do that." So I went and talked with Vince Talino, and Vince was in the Ethics Office at the time, responsible for this. And I started talking about working with Chain Drug... "No, no, no, no, you can't work with them." I said, "Okay, let me say it this way: we want to get FDA information out to women, and we need help." "Oh, well, I didn't know that's what you wanted. (laughter) They can't give you money, but if they can -- if they want to do it from their stores, and we don't get any money..." I said, "I never said we were going to get money." "Oh, you can do that."

And so we sat down and, together with the drugstores, we drafted they will do this and we will do this. And the things that they were willing to do were going to cost real money. They were going to print millions of our guide, and distribute them from our store. They were going to do their own -- what do you call them -- newspaper announcements about it in the grocery store circulars that come out, you know, once a week, whenever, in the local papers. They were going to do some announcements about it when you were in the store. There'd be an announcement. They were going to do an evaluation, because, you know, we would have to go through OMB. They don't have to go through OMB. They can do anything they want, and give us the results. And, you know, we would do some local things. When I say "local," we would

use our PASs. So they picked, at the time, ten markets, as they call them, around the country where they were going to do this, and it was very successful, they spent a lot of money, and then the next year they wanted to do an even bigger all over the country.

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And it was very gratifying, because when the evaluation came in -- and we couldn't, anyway, dictate or describe, you know, what we thought should be in there -- they got Merck... They used industry, okay. (laughs) They got their money from Glaxo and Merck and wherever, and so they were able to do flashy things.

So here are some of the things that they did. They had at a National Pharmacists Association meeting a booth, a glass-enclosed booth, in the middle of the conventional hall, with pharmacists, a bank of pharmacists, and they put in *USA Today* a phone number about women and medication. And you were to call this 800 number, and it was something like 1-800-4WOMAN, and you could call and they would answer your questions about your medications, and they wrote all about, you know, why it's important to use your medicine safely in *USA Today*. And then the next day they were going to come back to you and say, "Here are the common questions that were asked, and here are the answers to those questions." They got Merck Medco to do an evaluation that went to two million people. The only thing that I said was, "Well, maybe you want to say whether this is for men or women, because we do have flowers on the front," so... (laughter) Because they were just going to give them out randomly through mailings, and return. They paid to go back and forth. And I can't remember, but it was something like literally 98.9% approval of women, and 94% approval by men, and, you know, some very large number said they were actually using them, and etc.

So I got a very nice salute, so to speak, after, you know, the first really national effort. The then COO, the money man, said in the executive meeting with Dr. Kessler, "I was wrong. I thought it was going to cost FDA a lot of money, and we were going to get entangled in a lot of unnecessary things." He said, "But, you know, this has really worked out well, and it's gotten good visibility for the Agency, and based on what you've done, you've really generated money for the Agency's mission. And I have to say I was wrong." I was like, "Yes!" (laughter) to myself. But that was a nice compliment. And the PASs really got engaged in this, and one of the things we learned was the PASs needed structure. They sent us proposals to do some of this, and they had their own designs that included teddy bears and things that were not going to be consistent with what we wanted. Some of them wanted to take people on camping trips, wanted to use our money for sweatshirts and balls and...

So we learned that not only do you have to structure, that you have to really get a proposal from them so you know what they want to do with your money, but also we put together a guidebook, and we brought the ones in that wanted to participate and that were approved by their directors. We brought them in, and we put them through a seven-step process of this is what you do in the community, this is how you do it, and they reported that into their system, into their ORA system, and then we would get a report from their ORA system so that they wouldn't have to do two separate reports. They would just blend it with the reporting they had to do anyway.

And then after that we did diabetes with the Chain Drug Store Association, which was great, and the American Diabetes Association. So we had two cosponsors there. The first time, with safe medication, the Secretary of HHS gave us the highest award HHS gives, Shalala. And then the second time we got another one. If you stood up, you could see it on the other side.

You won't see those anywhere else in FDA. The obelisks are from the Secretary. And, you know, we brought in everybody who was part of our team to get that group award, including, you know, our IT people and our PASs, etc., because all of them were needed to get this moving. You know, and during that time, personally, I got... You know, there's something called Service to America, which is governmentwide, and so I was nominated for one of those awards, and was one of the finalists, and I just knew I was going to win, until I realized one of the five was someone who had invented Do Not Call. (laughter) And we all sort of said, okay. We all thought we were great, right, until they said, oh, that Susie Q. or whomever it was, had invented the Do Not Call. Like, oh, that's you. (laughter) You know, because all of us had actually tried to do the Do Not Call. But it was, you know, a very nice experience in that, you know, you can be identified as one of the top five people in the government in a category that is important to you, and, truthfully, I don't remember what the category was, but I'm one of those people.

VB: Was this in the late '90s, when you first rolled out the program?

MH: Yes. Mm-hmm, mm-hmm.

VB: So how did Time to Care come to evolve so much?

MH: So it has evolved, and I'll tell you why, because we did diabetes, etc., etc. And it was so funny, because Tommy Thompson was off-script, and the chain drug stores, where we had our

launch events, decided he was going to get a finger prick. You were only supposed to get a finger prick if you had already been diagnosed with diabetes. This was to help you understand whether you were in compliance. And he just decided he wanted to do it, and we were like, you know... The story is supposed to be our program, not Tommy Thompson may or may not have diabetes. So, luckily, the pharmacist who did it when the reporters asked -- because it was a press event, of course -- said, "No, it's confidential, so we won't, you know, inform people about the results," which was a great message, and no, he didn't have diabetes, which was also good news, because he chose to tell people after he got his results.

But it morphed, because we had all of these groups involved, and, you know, who's most involved? Nurses, right? Not so much physicians, right, because they tell the nurse. So we had all these physicians groups, but the ones that did the work were the nurses groups, right? Etc., etc. So it was a month. We would do this for a whole month. The campaign was a month, often in October. And then we'd be exhausted, and they'd be saying, "Okay, so what's our next thing." And so what we learned was we shifted it to be more ongoing. Our, you know, view was this is year-round. People need to know about safe medication, diabetes, menopause, mammography, whatever, throughout the year, and that we would make these things available continuously.

So we'd do a lot of exhibiting at these conferences, so they know about it. So we've got a college campaign, so a lot of colleges and universities use our material for their health centers. We had a relationship with HRSA's community and migrant health centers, and they use it in their clinics. Again, we have a lot of nurses organizations that use it. Minority-serving organizations use it. It's, you know, for people who've got, you know, things they want to do for their churches or their synagogue or their social group. You know, all are welcome. We did a

video, Spanish-language. We have a lot of Spanish-language materials, and we did a video in Spanish, speaking about that, and we made that available to 5,000 large hospital networks to put into their broadcast system, sort of on a loop, about safe medication use.

So our goal has become let's make this available on a permanent basis, and now we use a lot more social media, as well, to inform people, as we're up on Twitter. We were the maiden voyage when FDA started Twitter. They came to us and said, "We need somebody to start doing Twitter. Would you all like to engage?" And, of course, we said yes. And I said, "Why did you pick us?" (laughter) And I always remember: she said, "You're edge-runners." I said, "Yes, we are, and that's what we will do." So our office started as, like, the first office to tweet for FDA getting messages out.

And that, too, has morphed in a very interesting way, because here, again, we've always been open to the public, and patient, engagement-focused. And two concrete examples related to this -- and I've told this story before -- our first engagement was with bisphosphonates. I get, you know, emails all the time. This one says, "We've got a problem. We think we've got a problem with your product line, bisphosphonates for osteoporosis. And there are a lot of us online who are talking about our adverse experiences, and we would like to come in and -- excuse me -- talk to CDER about it. And can you help us have an audience with CDER?" And so we engaged with CDER, identified what the concern was, and went to a local -- this is before we were out here, I guess -- hotel.

And about 22 of them came in, at their own expense, women from around the country. These women had had atypical femur breaks that they believed were associated with bisphosphonate, and they came with two physicians who had treated some of them, but, as I said,

they were from around the country so these physicians had just on their own collected information, because they had a couple of hundred online that they were talking with. And, you know, something that I've mentioned to the Agency is people now are looking for what I call virtual communities. I have a condition. I have a problem. I'm going to go online and see who else has my problem, what their experience has been, what they've been doing about it, who they use for their, you know, physician, etc. And that's what these women had done.

And they came in, and Dr. Woodcock was there, as well as her division directors and staff related to that particular division. What I later learned was that when the products were approved they knew that it had the potential for brittling of the bone that could cause damage, but they didn't know how long it would take, or how it would present itself, or if it would in your lifetime, right? They just knew it had that potential. So when this came in, and they reviewed the history of the approval, it was credible. So there was a full lineup from CDER, and we simply hosted. We just said, you know, "Welcome. (laughs) Now it's your turn." And the women went around the room. They had little cards, three-by-five cards, and they would say, "I'm Susie Q. I'm 65. I started taking Fosamax 11 years ago. I was standing at my china closet and I fell to the floor. An ambulance came and got me, and I had an atypical femur break, and I now have pins." Next person: "Marylou. I was walking across the street, and I fell in the middle of the road. Went to the hospital. Atypical femur break. I've been taking, you know, whatever for X amount of time." They went around the room. The story was very consistent.

And the two physicians that were there said, "This is what we're seeing, and this is what we have learned from some of our colleagues: that we think that these are good products, that they have a bone strengthening capability, but that for some patients at a certain point there may be a tipping point where it causes these atypical femur breaks, and this is what we suggest: we

suggest that you set a date, maybe seven or eight years, that it could probably be safely used, and that needs to be in the label. The second thing is that many times prescribers start prescribing it before you have osteoporosis, when you have osteopenia, and even though FDA has never approved it for osteopenia, that's the way it's being used. So you should caution -- you should assert this should not be used too early, because that shortens your window, right?" And then the last thing they suggested was if a woman complains of discomfort in these areas, they should be rigorously screened, that some of these women have reported discomfort and it was ignored.

And it was a listening session, and they were very pleased to have the audience, meaning the women. They were very pleased that this happened. They also for the first time got to meet each other, and had a lunch or whatever afterwards. And then several months later virtually all three of those things became the case for FDA.

VB: Were there labeling changes and guidance?

MH: Yes, yes, yes, new guidance. And it speaks to evolving in different directions. We have MedWatch. MedWatch has been around for a long time. Actually, our "My Medicines" brochure was the first time the public was introduced to a phone number they could call. That number had previously been advertised to providers, and we put it on our brochure with the statement, "If you have a problem with any of these things you can call this number or whatever."

So we had another experience with Essure. Essure was brought to our attention because we were tweeting, and my social media person at the time would do things like, "Are you pleased with your current method of birth control? Learn more," or "There are many options." And you would hit the link. And what we typically tweet about sends you to our material, or to a website at FDA. And she started getting (laughs) this blowback of "Why aren't you taking this off the market? It's a terrible product," on and on. And she's like, whoa, I don't know anything about this Essure. And so she googled it, and she found there were two -- here again, what I call -- virtual communities online, and they had hundreds of women. And one of them was sponsored by Erin Brockovich, which is an a-ha moment. And she invited people to tell their story, and send their picture, so all these photographs of women who believe they have been adversely affected by this product. So I said, "Well, we've got to tell CDRH. And, more importantly, we want to be able to respond, and we don't make it up. So we want CDRH to craft something that we can then refer them to."

CDRH said no. They told us they had received eight letters through MedWatch, and they had responded to all eight, and there was nothing wrong with the product. So we said, "Well, you know, we've got hundreds, and we think you should do a page that says what you've just told us. You know, that's what you think, fine, but you need to put it on, like, a webpage." "No, we're not going to do that." So I directed my Medical Director to go to the FDA ombudsman and negotiated. I didn't think that that was a satisfactory response. The ombudsman sided with us, and they put online this webpage, which we referred people to.

Well, it became a thing, and the next thing we knew there was going to be a big public meeting where people would come in and talk about this product. And who was invited to open

the meeting and welcome everyone? Me. And, you know, I always tell the truth. I got this from someone who had been reluctant to engage with us on this.

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And I sent back, "Well, let's talk about it. I will be available on this day at this time." Do you know how far CDRH is from this office? It's a walk. So I invited him to take that walk, if he wanted me to open the meeting. And he did, and, you know, we had a lovely discussion, and I opened the meeting. And from that time there have been a number of internal meetings with stakeholders and the company, etc. And fast forward, you do know that it's being withdrawn from the market, as of the end of this year, any day now.

So that was an interesting experience, and I use that experience to say I think that FDA needs to be more rigorous with social media, because why would you use an approach that wasn't that effective 20 years ago? Okay, now you know better. You should be doing better, and there needs to be more surveillance, in my opinion, related to social media, and seeing what people are saying about our products.

And that leads me to the birth control guide, another one of my favorite topics. When I got here, as I said, I didn't have anything to work with, so I would get things that the centers did. And they used to have a magazine called *FDA Consumer*, and it didn't go to any consumers. (laughter) It was a lovely magazine. It was glossy, and it was very professional, and it was very expensive. And I think industry used it, and maybe they gave it out, or something, but it was not something that was on the newsstand or whatever. But anyway, I would look at it every time it came out, and it was talk to the scientist. So that was the other thing: it was a little... It wasn't easy reading. And I was looking through it one day, and I say, you know, this thing about

contraception, and effectiveness rates, and they had this chart, and I said, "Wow, this..." You know, it was, like, three pages, and the last page was this chart, and I said, "Oh, this is great, but we don't need all that. We just want the chart." So we took the chart, and we kind of, you know, made it look a little easier to understand, and we then sent it through, as we do with all of our products, sent it through every division in the centers responsible for those labels. So, as you can imagine, it was drugs and devices, and we sent it through to make sure that we were being accurate.

And so it became a popular tool, because it's got the effectiveness rates in a very easy to understand, with an arrow, so you can just see as you go further down the products become less and less effective. And, of course, we've had to modify it. As every new contraceptive either comes on or off the market, we make those changes. Well, lo and behold, unbeknownst to us, there became something called an IOM report, for the first time, on preventive services for women, because when the Affordable Care Act was being considered, it was going to encourage direct insurance companies to provide services in the prevention area, and there had never been a document about what constitutes preventive services across the life cycle of a woman. And so the report came out, and in the report it says that contraception should be paid for, at no cost to the patient, and that the things that should be covered are the FDA-approved methods.

Well, where is the one and only place that there is a list of all FDA-approved methods? Our chart. And we have a booklet that complements it. It's a little more detailed, but basically it's the chart. So our chart became very, very visible and controversial. There are some people that consider birth control of any kind something obviously that shouldn't be paid for, but, more importantly, things like IUDs and Plan B as products that cause abortion. So it was a little tough getting it reprinted at the early phase of the ACA, but it was always online. We always posted it.

And now we've continued to print it, and now we actually have companies -- a company -- sending us information, since they've now been approved, "This is how it should go on the chart. This is the language you should use. This is where you should position it," with their suggestions. So that has taken an interesting turn.

So we have things that have what I call unintended consequences, hopefully, you know, moving in a positive direction, but the birth control guide has been one of our more controversial experiences.

VB: I know we need to break in a little bit, and I don't want to go too far forward before we talk about some of the early work that the Office of Women's Health did in the '90s, particularly concerning clinical trials and MQSA, so two different directions.

MH: Right, right, right, but related. MQSA, the Mammography Quality Standards Act, had a number of components. One, it was the first time that all of the equipment had to be standardized, calibrated, based on regulations from FDA, as well as the training for those that were actually using the equipment. So, to inform women about that, this office established 1-800-4CANCER, and that was a call-in number, because as facilities became certified women wanted to know where the certified locations were in their communities. Well, obviously, over time all of them have been certified, and so we no longer needed that number. So NCI has now taken -- we gave our number to NCI, which they use for all kinds of cancer-related consumer call-in. So that was something that we modeled and then passed on to others.

We did a variety of things with MQSA. We targeted African American and Hispanic communities particularly, because their use of that service was low, has been identified as being very low. And so we worked with churches to get information out, and we developed a guide called Pink Ribbon Sunday. And the PASs, again, used that and distributed that and had groups of churches around the country, and we now work with a group called Healthy Churches 2020, which has over 100,000 African American churches that use it routinely as training for churches to do the mammography-related information, and something that we learned by doing and making mistakes. We realized that a lot of people didn't understand that it didn't matter whether you got your assessment in a hospital or in a moving van; all of the equipment and training is standardized so that you could be comfortable with the results, whether it's in... It didn't matter what kind of facility. It didn't have to be bricks and mortar, and on and on, and encouraging women to go for mammography. And we did radio talk shows and all kinds of things during that period.

And the other question was related to clinical trials, and sort of the same kind of thing that we're noticing with people: they have to become comfortable, whether it's with mammography or clinical trials. And our clinical trials approach, which we will get more into a little later, has been to start internally. You know, we started internally with the regulations and guidelines, and then we then started tracking the trends related to it. The women's groups have sort of stayed in that 1990s mode, which has been a very difficult impression to change. They still believe there are not enough women in clinical trials. Their view is 50/50 minimum. And, you know, I try to explain the three P's of the approach: population, which is percentage... The three P's... Population, prevalence, and power. Okay?

Population approach is 50/50. They think if you've got 50/50, all is right with the world. And we say all we need is enough, and enough may not mean 50/50. When you go to prevalence, we don't have, in most cases, enough research that can specifically identify prevalence of a condition in women versus men. So, for example, when we do products, they are not just to lower your blood pressure, so everybody who's got high blood pressure is in that category. There are often people who have high blood pressure who also have high cholesterol, are diabetic, and may also be taking an antidepressant. I mean, how do you find prevalence for these kinds of conditions, even, you know, AFib versus hypertension? We don't have good ways to determine what the prevalence is, although we do take a look at that. And the other is power. They always want to go to power. It would be many, many thousands and thousands that would greatly delay our ability to approve these products in a timely manner. And, you know, FDA, by Congressional directive, is on a timeline. We have to make these reviews in a timely manner and get them out the door, and we can't stop them unless we have evidence that they have done something wrong. And so that's our challenge.

So one of the things that we've done is try to bridge the gap of what they know about us and what we know about them. Many of our reviewers that don't have much exposure to the public don't understand the conversations that we're in, so we recently had the great debate conversation, because we say we only need enough. It may be 30% women, which might be just fine, or 80% women. We need enough of that particular application. And so we brought in a very noted physician, Dr. Rita Redberg, who's also the editor of *JAMA Internal Medicine*, to debate -- she's a cardiologist -- to debate with our Head of Cardio-Renal, Dr. Ellis Unger, the issue of what's enough. That's what we called it: "What is Enough?" There was obviously no agreement, but the discussion was there. People need to know that we are under very different

guidelines. And, you know, one of the things that we are always challenged about with NIH versus FDA -- NIH is the theory. They're the research protocol that's rather standard, with the hypothesis, etc. We're the application. And there is a big difference between the theoretical approach and the application approach. They both integrate with each other, but they're very different, very different. And we don't do our own research. We only accept (knock on door) applications...

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VB: Okay, so this is our second session of the oral history interview with Marsha Henderson, Associate Commissioner for Women's Health. And I forgot to mention in the first taping that Rashetta Fairnot is also joining us for the interview. And so when we closed our conversation earlier, we were talking about clinical trials. And I'd like to go back to that, but while Rashetta's still with us perhaps we could talk about the incident in the mid-2000s, when Barr Laboratories, I believe it was, filed an amended NDA to make the Plan B emergency contraceptive an over-the-counter drug, and I was wondering if you could tell us a little about that.

MH: Well, that was a very controversial time, again, in this office. Actually, it was not quite as heated as RU486, mifepristone, which was the "abortion pill," and to some degree they had a similar level of energy, but different. With RU486, which preceded Plan B, the "abortion pill," that was a top-secret experience where people were aware that there were deliberations, but it

was not acknowledged as to when there would be the so-called public advisory committee meeting. We had a medical director here named Debra Smith, an OB/GYN, who was our representative for that effort. It is my understanding from her that those who were invited to participate were told to come to a secret location that was actually a parking lot, fenced. They drove in. Guards were there that checked their credentials. They parked their car on this lot. They got onto buses that had darkened windows, and they were driven to a Defense Department underground location, and during that time they deliberated about the safety and effectiveness of that product, and the committee approved that product.

Our office became involved in it yet again when it was time to do the announcement about the approval. I got a list of questions that had been approved for the Commissioner, at the time Jane Henney, to use for her Q&A with press and Congress. I took one look at the list and said, "This is ridiculous." They were all scientific questions. And I said, "The first question's going to be: why have you approved something that's going to kill babies?" Nothing like that was on this list, nothing that was what I would call real-world questions. So I made a list of things that I thought some of the religious groups, conservative advocates would ask. And so I got rounded up to be part of the prep for the then Commissioner, because she was going to get some hard-hitting questions.

Ironically, at that same time, I was leaving to go to a one-month experience at the Federal Executive Institute in Charleston. And I knew the announcement was coming. And the day that the announcement was made I was asked to give a presentation about this product, and why it was approved, before all of these federal executives. Luckily for me, I had read and helped draft the responses, and that was very enlightening for me because one of the things that had occurred -- there was a lot of publicity around this, and who would be able to prescribe, etc. And as you

can imagine, nurses and physician assistants were asking that the prescribing would be available for them. And our language at that time was very restrictive to physicians only. And from my FEI experience and training, I learned that's what the law said, that the law as it related to performing abortions said "physician." And so with the expertise of our FDA general counsel, they held it very closely to the law. And as a result of that, when another administration came in it was my understanding that the new general counsel was directed to find a way to take it off the market. And when he reviewed FDA's language with the law, he had to go back to the White House and say, "Can't do it. They followed the script, and there is no loophole here."

And during that time we had public access to the Parklawn Building, which is where we were located, and all of a sudden I saw these guards that were stationed. This was right before all of the approvals, and we had a big sign out in front of our door, "Welcome to the Office of Women's Health," which, of course, we got rid of (laughs) for a time, because, you know, there were threats and all kinds of things related to that.

Now, fast forward to Plan B. We had a Director, Susan Wood, who became rather well-known because of Plan B. Susan's talents were that in some circles where there was controversy -- for example, around menopause and hormones, and the then recent Women's Health Initiative decision that caused hormone products to come off the market, she was very good at working through issues with that. As it relates to setting direction for the Office of Women's Health, we never quite knew what that direction was. So she became very popular as a director, not for directing the office but for stepping out of the Agency when they would not approve the product, when they would not release it. Apparently, there was a big controversy internally with the reviewers, who felt it should go on the market, and some of leadership was not pleased. It was actually, in something I read, quoted that if we put Plan B on the market it would encourage

child sex rings, so that they would use this if the children became pregnant. You know, a lot of hysterical comments, from my perspective, were made, but...

And I was out of town, yet again, presenting somewhere, and I received a call from Susan indicating that she would be leaving, and that I would probably see her at lunchtime on CNN. She had, it's my understanding, lined up an arrangement with a speaking organization and some women's groups, and she was going to be on a media tour related to her concern that this product was not being made available to women. And some of that money has led to her being an endowed chair in George Washington. It was an opportunity for her to create that seat at George Washington, which is where she currently serves.

That caused a lot of problems within the Agency. It was viewed as the Women's Office was not part of FDA, that we were a leper in the midst of the Agency, and it took a lot to gain a relationship. The view during that time was that there was a Director of the Women's Office that was hostile to industry. Now, what you need to know is that Susan's background was that her family was -- and this is very public; she is a noted person, spokesperson on this -- was dramatically affected by DES. Her mother died. Her sister died. Both she and her brother had reproductive complications. So her worldview was very different from mine, and it made the assumption that industry needed to be watched at all times, and was abusive to the public, my words not hers, but that was the consensus within the Agency. And so when she stepped away from...

Oh, and also we had some legislation that said we were to develop a data reporting system on women's health. This was being forced on the Agency. We got money, and in essence the staff that were here at the time went to particularly the Center for Drugs, and

basically said, "We're creating a methodology, and you're going to use it." That did not go over well. It was called DITR. I've forgotten what the acronym stands for, but I have it. I could, you know, tell you later. But so there was this atmosphere. I was rather, and intentionally so, separate from that. That was considered the science side of the office. I was the outreach side of the office. We were much more popular. (laughter) Well, we didn't tell anyone in the Center what to do, and we were basically very complimentary about the things they were doing, and we didn't, quote, "get in their way" of their reviews.

So when she left, under this public, internal fight, it was very tense for the office. Norris Alderson, who I think was, like, Head of the Office of the Chief Scientist, a very nice guy, but he knew nothing about women's health, and he asked -- I was the Deputy at the time -- asked if I would be the acting director, and I said, "No, thank you," (laughter) because I felt that it was too poisonous. And I said, "If I'm to continue to have a good relationship with the outside, I have to appear to not be in any camp." So for a very short time, he was the Acting Director. So then the word got out a man is now doing it, and he came from CVM, so they claimed he was a veterinarian, which wasn't accurate, but he ended up on *Saturday Night Live* being mocked as the veterinarian that they put in charge of Women's Health. So FDA just was looking very badly all the way around. I think we got a temporary person, lovely, Terry Toigo, who, you know, was running her own unit, so basically she wasn't very engaged, but then we got Cook Uhl, Kathleen Uhl, who currently runs the Generics office. Fabulous woman. And, you know, with each director we have had certain growth capability. So with Ruth, the original director, she brought about a change in regulations and guidances. Audrey Sheppard, who came next, a political appointee, who worked for the White House and saw women and decided she wanted to come over, actually had no background in science or in public health, but she knew a lot about

interacting with women's groups. She's the one that hired me, and that's when we started our "Take Time to Care" campaign.

After Audrey was Susan Wood, and Susan was helpful in getting us a little more money, because she had worked for the Women's Congressional Caucus as their Science and Medicine Director. And from there she went to the Department's Women's Office, where she was the Director. So she came from the Department's Women's Health Office here, but she knew the Hill very well, and that was helpful to our office. And we had just had the Women's Health Initiative, and we got a Congressional mandate to educate women about hormone therapy, because so many women were afraid from the outcome of the Women's Health Initiative. And basically we stuck to the FDA message, which was lowest dose, shortest duration. That had never changed. It's my understanding that the company -- and the product was Premarin -- gave free Premarin to NIH for this huge study. And their goal was to get a new indication for FDA, in a variety of areas, because the theory was it would prevent heart disease. It would help with dementia, like Alzheimer's. It would help with osteoporosis. I mean, hormones being added was going to be like the greatest remedy on Earth. And so they gave it to them free.

One of the issues now is they only focused on older women, and they did that because they were looking for those indications that present in an older population, and they didn't want to wait with people in their forties or fifties. They started with people that were older, and it backfired. And when it backfired, we got money to educate women, and this is when we brought in all of these women's groups that had different opinions about hormone therapy. And Susan was very good at sort of getting them to accept our lowest dose, shortest duration, you know, approach for a while. But she did leave us in a shambles, frankly.

Fast forward, we got Kathleen Uhl -- we call her Cook -- and she had another view. She had worked in the Center. She had worked for Janet Woodcock. And her view was we should not be outliers; we should be part of the Agency, and we needed to work with the Agency. And she wanted to do training and that kind of thing of reviewers. Great idea. Here was the difficulty: she didn't have the staff that knew how to do it. They were grants managers, from the days of doing grants, internal grants. And so she had a few people that had challenges, and I just loved working with her. Actually, she made me her deputy, and we worked well together, but she, like most physicians, believes you have skills, and I say "Scalpel," and you put the scalpel there. Well, they couldn't do that, and it became a bit frustrating for her, and Janet gave her the opportunity to go over to Generics, which was going to be a big deal, that whole movement of branded products going off-label to be, you know, eligible for generic conversion.

So she left, and I was asked to take the position. But I learned a lot from all of them, and what I learned from Cook was we didn't have the team to move to the next level. And I put together a list of some things in '09, I want to say, that I presented to Dr. Hamburg, and said, "This is the direction in which I want to go, so you're going to start seeing some staff changes." And the big thing was I wanted an agenda for the Office of Women's Health. We did not have a real, defined focus. We just gave out grants that said "Woman" on them. And I thought the priorities should be set internally, across the Agency. So I hired an epidemiologist who had worked in both CDER and CDRH, and she led this effort. She put together what she called the Research Roadmap, where we had senior division directors from all of the human product centers, and we tried to attach our priorities to theirs. They had already established their individual priorities, but we tried to identify commonalities, so that our seven priority areas include things like adaptive clinical trial design, new technologies, etc. And so those were

common themes, and we said, "We will, you know, take these, and we will look at your resources, and we will give you money to add to your priorities for the benefit of Women's Health." And we introduced this to the center directors, and they liked it, and we said, "We'll do multiyear funding, rather than a year or two. We might fund a project for five years, so that it'll be a more in-depth, richer experience." They liked that.

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One of the other things we did was with the roadmap. We defined who was a woman. And I remember introduce that to the center directors; they kind of looked at me. I said, "First, we have to define who's a woman." So the different centers have different ages, because they have different legislative backgrounds, so one had 18, one had 17, one had 21. But for the Office of the Commissioner, and the Office of Women's Health, we've defined it as 17 and above. We also said you are who you say you are, and as the science evolves FDA will evolve with it. You know, that's sort of our little secret. Maybe it isn't now, but that's what we've said as to who a woman is.

Fast forward. We've had the opportunity to work in that arena in the area of REMS, Risk Evaluation and Mitigation. There are products that are under REMS because they can dramatically affect the fetus, and we were approached by the transgender community, because you have to sign something called iPLEDGE, and you pledge when you are taking these products that you are not going to be a woman of childbearing potential or whatever it is. You have to sign something, and you declare yourself a woman in this process. And they felt it was not culturally comfortable for them to do this, and they felt that their physician, who was certifying this, was being put in an awkward place if they... For example, if I'm a trans man and I'm... Oh,

and that was part of the problem: trans men who are born female, trans-ing to male, often take testosterone. That can apparently cause a lot of acne, and the remedy for it is Accutane. So Accutane is under REMS, so that when they would go in for this product they would have to sign this. And some of them will say, "No, I'm not a woman of child-bearing..." And the doctor certifies that.

Anyway, so we did a whole series of training around the spectrum of sexuality, and on and on, in the office. The Agency appears to be comfortable with making changes. The problem is you can't do it just for one product; you have to change the language. And we have been working with the Center for Drugs to draft that language. That's Erin South. She was leading part of that. She's now on our staff. So I just rated her and I recruited her, (laughter) so she's a senior pharmacist here.

Now, why would I tell you all that? So the agenda that we created is the Research Roadmap. It was published in January of 2016, but it was almost two years to get that created. We had to get a lot of buy-in, and ups and downs in reviewing every center's general priorities going forward. We also said that that will direct our funding. And actually, we presented it to Senator Mikulski when she made her rounds to say goodbye as she was leaving, because she was one of the big supporters of not just this office but women's health over the years.

So the things that I wanted to do was to, one, have an agenda, a Women's Health Research Roadmap. I wanted to also have a staff that would be what I called value-added. Our office would often come to you for help, right? So we have publications, consumer publications, and we, you know, need your help. Well, do you want to see somebody coming who always wants something? (laughter) So, you know, I said, "We need a team that will be viewed as

value-added, that can be helpful." Our first opportunity to do that was actually right before the Roadmap, right after I hired Dr. Pamela Scott, because we had a directive in Section 907 of the law to do a data review. We were required to do two things. First, we were to do an assessment of all products, drugs, biologics, devices, as it related to women, minorities -- sex, race, and age. And we led that data effort. So we pulled in all of the centers to put together the report. The report was a one-year report, because we didn't have time to do a lot of additional years, because it had to be done manually across all of these centers. So everybody had to get onboard. We had to make up the charts, everything, go back and forth. It was a heavy, heavy lift, but we got that report out to show the level of inclusion by product categories, and race, age, and sex, and a narrative around what we thought we were seeing.

And, in essence, we said we were pretty comfortable with the level of women in clinical trials, with some outliers: cardiovascular disease, HIV, and dementia. Those, of course, happen to be the big killers. (laughs) But that aside, we were concerned about that. And for Minority Health it was an issue, because often we cannot distinguish at the levels that one might like. So the data report was out there. That was part one.

Part two, though, was the action plan. And I think this is when we really came back into alignment with the Agency. The action plan said, in essence, "What are you going to do about it? The problems that have been identified, what are you going to do?" We were not responsible for that. We said that the centers needed to be responsible, because these are regulatory decisions that they have to make. And there was a draft that was done, and it came through here to get clearance. I did not clear it. Not only did I not clear it, I had it marked up by my staff, and I wrote a cover letter that said, "One, it's filled with inaccuracies. It does not meet the intent of the directive. And it's not an action plan. There are no actions with timetables. I cannot

approve it." Because, you know, something like that that went out of here, because the women's groups were the ones that pushed for this, would look at our office and say, "This is junk," and they would blame our office.

So, fast forward, it did not get cleared, but that meant it's got to be rewritten. Luckily for us, fantastic writer in the Comms Office, who was then the Deputy Director, Karen Riley, and I sat down, and we talked about what should be there, and we said there were three areas: transparency, quality, and something; I want to say maybe innovation. There were three key areas, themes, that it was based around, and it was to have specifics and a timeframe. And we had listed all the things advocates said they wanted, just a whole list. And there was this committee, and I think I went to the committee twice, and on that second time I said to myself, I am not coming back, because they said the same thing over and over, meaning internally. It was, you know, yes, and it was just a debate, and it was theoretical. And this is when I sat and wrote a note to Janet Woodcock, and I said, you know, "Janet, we have this Congressional mandate, and we have a whole list of things that they're asking for, and, as you say, no one speaks for you but you. And, you know, so I would really like to sit and talk with you about what you think is realistic." And I signed my name, and then I put under it, "P.S., I am not Susan Wood. I support industry." (laughter)

So Janet is someone who, like, (snaps) in a nanosecond responds. If you've ever had dealings with her, it's like one word, two words, but it's like nanoseconds. Two days, I got nothing. I was like, whoa. And I was putting my coat up on the hanger one morning, like the third morning, and there was Janet at my door, and said, "Let's talk." I said, "Well, great. Come on in." And she sat right there. And I said, "Okay, I'll get my list. They want X." "No." They want Y." "No." (laughter) I said, "Okay." I turned my paper over. I said, "I think their big

issue is they want to see the decisions that we've made by these categories, and you've said we can't put it on the label. They want it on the label. We know you can't put it on the label because it's too much, and we'd have to go through regs, and on and on." She said, "I'll do a data dump. If they want the data, it's public. I'll put it out there, data dump. But we have to do that manually." And I said, "Well, okay. I'll give you an ORISE fellow, and if you put in an ORISE fellow, the two can work for your people, and they can do the website that will have this." And that's the drug trial snapshots. That's how that came about. That, to me, was the most significant thing in the action plan. There were some other things, but that was really a new piece, where people could really look. As the product gets approved, once a month, Center for Drugs posts the drugs that have been approved, with all the demographic information in there, and information from the reviewer's notes. And she did that. That was her brainchild. She's a very brilliant woman.

So from that point on, we've started working much more internally with the centers, and we now have, you know, the capabilities of... We had data capability, which they learned from doing the data report and the action plan. I had a pharmacist at the time who was a PharmD/PhD who would do a lot of internal training and accepting preceptors that were pharmacy students trying to finish, and, you know, we've just done -- we've now got, what, three -- we'll have three physicians, and one pharmacist, and three PhDs. It's a very different component on that side. We've maintained, I think, a very strong -- small, but strong -- comms and outreach group that has done very well with Twitter and with our contacts database. We have over 100,000 contacts in our database that are predominantly from national organizations, our stakeholder groups, that we've collected over the years. And so we work a lot internally.

We're now on a lot of FDA committees. I'm very proud of that. The science group is there when they're talking about demographic changes to the database, or talking about new regs and guidances. We are actually on these committees, so we have a voice internally, and they have invited us. That's the way we have become members: through invitation. And we still do a lot of sponsoring of intramural proposals. We are part of the Office of the Chief Science annual intramural proposal process, and I believe last year they had 59 applications, and 54 of them identified us as either the first or second level funder. So, you know, we've really, I think, integrated our things with the Agency rather well.

We have a lot of major publications. When we talk about women in clinical trials, we step back and look collectively, not at a product by product but as a category that focuses on a condition or a disease. This past year, 2018, we had published in *JACC*, the journal of cardiology. That was the largest sex analysis of products that have been approved for cardiovascular disease, so 224,000 participants in clinical trials for these products, and we looked to see whether... The question was: are the industry's exclusionary criteria keeping women out? About a third of these clinical trial participants are women, one third, and so we wanted to know why they're one third when we have other products where the numbers, the percentages are higher. And it had been suggested that women were lower because they were being excluded, often by things like age or weight or certain diagnostic tests that it has been claimed were developed for men; therefore, the outcome would have had, perhaps, a bias. We did not find that.

Actually, what we found was the pool that they go to appears to be cardiac rehab. There are data that indicate women are not being referred as frequently to cardiac rehab, or they're not ending up in cardiac rehab, for whatever reason. Once they get there, and that's the pool, you

have as much likelihood of being referred to a trial as a man, but the issue is you've got to get in that pool. So that's part of the messaging to providers: you know that this works, cardiac rehab works, and you need to encourage more women to be there, just as a standard of practice. So, you know, some have tried to dispute that, but that's what our analysis has said.

And, you know, we look for emerging issues. So, obviously, opioids are a big issue for us. Last year, we started meeting in 2017. We started with an internal meeting, focusing on women in pain, because women present differently with pain. We are often thought of having more chronic pain, because of things like mastectomies, C-sections, chronic illnesses like autoimmune, arthritis, lupus, etc. predispose us to long-term chronic pain. And, you know, what does that mean in terms of pain relief, and that kind of thing, and also, of course, looking at the opioid issue. So we moved from that to a major conference this year with about 40 speakers from across government and academia, focusing on opioid use treatment and sobriety, as well as tobacco, nicotine. So that was a joint, two-day meeting. And, you know, these are things that we wouldn't necessarily have thought of ten years ago, or maybe even five years ago, but we always want to be focusing on what's the current, you know, most recent concern of the moment.

We do a lot with NIH, because they are often feeders for industry to us, and, you know, we're always doing activities with them, particularly with the Organization for the Science of Sex Differences. OSSD is one of the leaders in the area of sex differences in this arena, so we do a lot with them, but, you know, also with other groups.

VB: You know, one thing that stands out to me, especially -- I just joined the Agency recently, so it was in my time here -- is how well integrated your outreach strategy is with your research plan, and I imagine that's an outcome of putting together the roadmap.

MH: Absolutely.

VB: But even just looking at the roadmap, outreach is part of its one leg of this model that is heavily science-oriented. And with the conferences, and I know there's already outreach materials on the website about sex differences in pain, that there is a very coherent strategy. And along those lines, I know you have this really robust intramural program with the centers for research, but you also do collaborative outreach programs with them, too, and in particular with ORA. And I'd love to hear more about how some of those programs developed, or how you --

MH: ORA, and also with NCTR. And I'll step back just a little bit with... So one of the robust things -- we have a training series that we do quarterly, and it's with internal reviewers. And we have a steering committee now of senior people from across the centers that helped us work on the roadmap, right? And they're our intelligence. They tell us what's going on in the centers, what's important to them, their new directions, because we want to be there to support that internally. So we had a training. You know, number one killer of women: heart disease. We have over 370 published articles in national journals that we've sponsored from this office, and

earlier on one of the things that was one of our most impressive ones was related to QT prolongation, heart disease, and arrhythmia.

[00:40:24]

And, in essence, if you take certain products, like antihistamines, certain antidepressants, they will affect the rhythm of your heartbeat. And in lay language, there is a point where there's a flatline, and that is called *torsades de pointes*. If it extends too long it's really a flatline, (laughs) which means you'll have a heart attack or stroke, you're out. Women are disproportionately affected by that.

That was discovered in some funding that we provided to a center that worked with Georgetown. A man named Ray Woosley was responsible for that, and that's when we first started seeing signs of this, also in the '90s. Our money was very small. We made that -- you know, he did publishing, etc. Cedar then funded him more greatly. Guess what product came off the market. It was withdrawn. You could not get those products that typically now have a D behind them, like, you know, Claritin or Zyrtec. That came off the market, because women could easily have a problem with that. So it was analyzed and determined with those particular products what was causing it, and it was eliminated from the products, so they went back on the market but, as you know, behind the counter.

Well, I call that our 360 approach. And so regulations have been, or guidances have been, promulgated so that industry has to prove that that will not happen with certain products. So when you come in with your application, you have to have a supplement that basically says, "This is not going to happen." And this may cost a company a couple million extra dollars to run these tests. So our goal has been to look at two approaches that we are funding now to see

whether a methodology can predict it accurately, or if adding a certain compound can minimize it. Because the goal would be not just we know there's a problem; fix the problem with the products that are on the market, and also do guidance, but to see if we can eliminate that extra step that would allow for products to go to market sooner, and to minimize costs. That is one of the great outcomes of our money.

I was in a training about four years ago that we were doing with a person from CDRH, who was talking about defibrillators. As you know, with devices, there are many fewer people in the trials. You know, they may have 30 people in a trial. And so this application we received as an intramural grant was there are all these defibrillators internal that are on the market now. They weren't tested in women. I want to go back now and look and see how women fared that are now actually living with these defibrillators. And so we, of course, gave him this money, and he found women fare better, actually fare better, than men when they receive these defibrillators, which is a story you want to tell, right? So he's presenting his data internally, and someone from the Center for Drugs says, "Oh, I work in XYZ. I get applications all the time, talking about QT prolongation. I didn't know women were disproportionately affected." We had known it for 20 years.

For me, that was an a-ha moment, because I said we haven't done enough internally, right? People are busy, people here in the centers. We have brilliant scientists. They work hard; they do their job; they go home. They're not necessarily reading a journal article that we just put out there. And so anything we do internally needs to be informed within the Agency, and repeatedly, because I don't know when this woman came. She may have come last week or something. But we need to have an infrastructure that allows for continuous knowledge of things that we are aware of. So that's when we really started a more rigorous training. And in our

training we do not just continuing education credit -- which is important, because we do that -- we do pre- and post-test. So we do pre- and post-test on certain things, you know, at the beginning and at the end, and then we provide that to the division directors so they know that, you know, their staff may need some more training in a particular area. So that's relatively new. And what was your other question? Sorry, I just wanted to get to that issue why we do that.

VB: Well, since you brought it up, I think it's fantastic, and I think it's probably unusual. I don't know of many other offices that offer such a thorough training, and so frequently.

MH: And we get people from all over, so that, you know, we don't assume we have internal capability. Sometime it is internal, and sometimes we bring people from universities or whatever, researchers that come. And, you know, we've done that, for example, to also do crosspollination. So we did one related to breast cancer, and metastatic breast cancer, and we brought in someone from, I want to say, Cedars-Sinai, but anyway, came in from California. Had a discussion first with the oncology unit in FDA, before the training, so that they could ask the questions they wanted. So they had an hour session where there were two of them that talked about their issues. And then they did the training, and then they went and talked to Dr. Woodcock, to have some conversation, because they had some theories that they wanted to share. And she enjoyed it. She indicated that, you know, she didn't often get to do theoretical discussions of that nature. So, you know, that was another kind of bonus. So we're trying to develop a reputation of high-quality, cutting-edge opportunity that we are offering with our resources.

VB: If I can backtrack just a little bit, since you were talking about sex differences in cardiovascular disease, and also talking about devices, I believe -- and maybe I'm wrong, but -- that OWH sponsored research about heart valves and sex differences. And I was wondering if you could say a little bit about that, and heart physiology.

MH: Well, since I'm not a scientist I'm not the best to speak on that, (laughter) but that's an example of the kinds of things that we get across the board. So heart valve issues apparently are one of the major -- not just valves, but devices for cardiovascular disease, you know, the sizing of them, they often emit various medications, etc., and apparently in women this is a huge issue that's not well understood. And we actually sat down with the American College of Cardiology and CDRH some time ago, talking about their concerns, which was another opportunity where physicians came in, represented by this cardiology association, to say, you know, "We're using your devices, but we have a lot of questions and concerns, and we want you, as you are considering future products, or even current ones, that you look into these concerns that we have." And we do that kind of thing periodically, but, you know, here again, the number of people involved in these device approvals is relatively low.

And so I think that CDRH is working on a lot of now what they're calling patient engagement, because they're going to be more dependent on registries, and on post-market review, to make determinations about these products. One of the coups that we had is because there's so many concerns over there, I got a phone call from Jeff Shuren maybe two years ago,

saying, “I think I need in my office a Director of Women’s Health. What do you think of that?” I think it’s great.

VB: It’s wonderful.

MH: I think it’s wonderful. Own your responsibility. And I made a recommendation, months later. Someone self-identified from NIH and said, “I’m looking for another opportunity,” and I said, “Hmm.” So I called Jeff, and I said, “Are you still considering that?” He said, “Yeah, it’s sort of in the works.” I said, “Well, I’m going to send you a résumé of somebody I think you should consider.” Didn’t hear anything, and then apparently an announcement went out, and she is now the Director of Health of Women, Dr. Terri Cornelison, and she’ll be terrific. She just launched stage one of her new initiative there.

I have been -- and most people don’t know this -- I’ve been asked what would be the ultimate for women’s health, and I said, “There’d be no Office of Women’s Health at FDA. There wouldn’t be a need for it. If everything went perfectly and smoothly and on and on, there would be no need for it.” And as we see new offices emerging that do the things that we used to do, that’s a good sign to me, you know, to have a Patient Engagement Office, to have a Director of Women’s Health within a center, to have, you know, the things that many of our advocates want, like drug trial snapshots. Many people don’t know that that was a women’s health initiative, right? And so, you know, as the Agency evolves over time, I think the future prognosis would be positive.

My concern is these women's groups are lagging behind in their worldview, and they're still sort of in a '90s view of things, when we know clinical trials are going to change drastically. We just had a big initiative from the Department around pregnant and lactating women. I would project that we're going to start putting pregnant women in clinical trials. Pregnant women, contrary to popular belief, take medication. They have to. Many, with chronic illnesses, whether it is diabetes or a seizure disorder or whatever, they have to take medication, and we don't know enough about that, and our registries are not rigorous enough for us to really know that well. But we will also be using technology. We're funding a project called Placenta on a Chip, so that computerization is being used with human cell lines, and they're exposing those cell lines to different medications to see if they will cross the placenta, and what the absorption looks like. So, you know, to have a big trial with a lot of people may not be necessary in the future. We're going to be using information from insurance companies about outcomes for people who are taking certain medications, and they'll be doing methods development to predict whether this could have been identified if we knew certain things in advance, and that will probably be applied to other products in the future. So where we've been is not where we're going, and I can't seem to get that across to my advocacy groups. Where we've been is not where we're going. I remember that, because I have a presentation on that.

VB: Does seem like two different conversations are going on at the same time.

MH: Yes.

VB: If we can return to talking about the collaboration with other offices in the Agency for second, I'm curious to know if you have ever worked with the Office of Special Health Population, or Risk Communication.

MH: We do that all the time.

VB: I would imagine.

MH: Because we have such a strong contact database, we are always part of that grouping, so that whenever the Agency's rolling something out we always have a lead responsibility in that arena. With special health needs, the one that's gone, like OSHI?

VB: Yeah.

MH: Yeah, because many of the things that OSHI did, we sort of did in a very different way, because we typically talk to the national organizations. They deal with individuals. So we've always stayed at the national level with representatives from the national organizations, and that's a bit different. And so we try to maintain ourselves at a policy level, and general information level, but we don't typically do a lot of interacting with individual patients, as such. So, you know, we have the HIV guide, which all of the HIV groups use, because we're the only

ones that list every product, and the side effects related to that. And that was true for, you know, a number of the chronic illness groups that they worked with. We didn't work with them, but we worked with the national organizations.

With Health Comms, we do a monthly e-update, and we tell people from a women's health perspective what's going on at FDA. So that includes the things our office is doing, as well as public meetings that the Agency may be holding, new publications they should be aware of, that kind of thing. We can certainly show you that, to get a sense of it. We also do what we call e-blasts. That is an urgent newsflash: tampering; recall; an announcement of any kind that is going to hit the press that day. We send it to, generally, our full group of stakeholders. Sometimes we have for some of the centers -- for example, for Biologics, when they were getting ready to approve the HPV vaccine, they asked us to develop a factsheet for them so that they would have a consumer product that would inform consumers about the product they were getting ready to approve. They knew that there would be a lot of mythology, (laughs) probably, around it, or marketing that might not be that accurate, so they wanted what I would call an FDA-speak tool that consumers would have, so when the announcement for approval went up, so did our factsheet. And so we developed that, and, of course, ran it through them to make sure that it was consistent with FDA's position on that particular vaccine.

So we've worked, you know, in that arena, as well, helping to develop things. We worked with ORA to do a piece on fraud. Fraud was a big issue, health fraud. And they had it drafted by lawyers, (laughter) and I said, "Well, this is not going to be something that will be successful, but I'll take it to focus group, and I'm going to invite you, in ORA, to witness what the focus group says about it." And so we had our contractor that does the moderators' guide, and sets up the meetings, and on and on. We invited them to come and witness the experience,

and it was just what we anticipated. One, they don't know what health fraud is from an FDA perspective. They thought health fraud meant your doctor is double billing, or someone has stolen your Medicare card. And so then the moderator asked, "Well, what do you call this?" And it was the FDA things. They said, "Oh, those are scams. That's not fraud; that's a scam." So the new brochure we created says "health scams." And then we said, "Where would you get this? Where are you exposed to these scams?" And they gave us a list. And so, basically, the focus group in that case was used to actually craft the new document, which we then produced for ORA to give to the PASs, and we duplicated it in very large quantities so they would have it available.

So we did that for ORA. We did, you know, some things for CDER, and... But usually the things that we do now are mostly training about sex differences, and how to analyze the data that you do have, and what questions you should be asking the sponsor.

VB: I have to say, I didn't know "scam" was the new word. We still use "quackery" in the History Office, so we've got a long way to go. (laughter)

MH: I don't know, maybe they would have liked that, but that's the word they used. These are scams.

VB: Yeah, makes sense.

MH: Yeah, you know I like "quackery" better than "health fraud."

VB: Right. I mean, it makes sense why people think of Medicare and...

MH: Right.

VB: Yeah. So I feel like we're coming to a conclusion, and I'd love to ask you: if you were going to stay another year or two, what would be your priorities?

MH: It's interesting you should say that. This is a good way to know when it's time for you to go. I've checked my boxes. I laid out a plan. I structured what I wanted to do over the last three years or so. I've laid it on the table. I have selected people that I think will end up being the director and the deputy director. They will have new ideas, and I'm going to get out of their way.

[01:00:03]

That's the thing for me to do. I was lucky that the people that were the directors before me got out of the way and let me do my thing. I think that I've established a core group of good people who know what they're doing. They're experienced. They're well-trained. They're capable. They're going to have all kinds of new ideas, and I'm very comfortable with that.

So as they move forward, I had a big closing strategic planning meeting with the staff, and they know me. She doesn't even know this yet, because she wasn't here. (laughter) And there are three things that I told them to always remember. And the first thing I said to them is, "What's my favorite expression?" And they will all yell in unison, my staff will yell in unison, "Save yourself." So the first thing is: whatever you do, be balanced, and try to pick good opportunities to move to the next level, but have a balance when you go into whatever. The second theme is orange is not the new black. Everything we do is legal, and so we learn all the rules. We master the rules, because they will help us, just like going to the Ethics Office for our "Take Time to Care." We learned the rules. The other people that weren't successful didn't know the rules, so they didn't know how to use the rules. So we stick to the rules.

But my last one, which I think is the most important, is lead with the need and not the process. In government, process is so important, you can often lose sight of the need, and the need evolves. We've been going through years of strategic planning, and, you know, all of it's about the mission. And I said, "What's our mission?" And we had been going over it, but it had all this stuff, and they were talking about changing the mission. We don't change the mission. FDA has had a mission for over 100 years, and it is to protect and advance public health. Consumer safety: that is our number one thing. So we don't change that; we change how we address it, and that will evolve. But we often focus a lot on process.

I was very disturbed -- and I'll close with this -- I was doing awards, as I always do, at the end of the year, and I asked people to draft awards. And I was a little discouraged, because I'm reading these -- I changed all of them, but I'm reading all of this -- and it would say things like, "We've worked across centers, and we've brought in all these people, and da-da-da." No. We have an epidemic called opioid addiction. That's the need. You always lead with the need.

The needs will change. Some will remain the same. But always focus on the need. I focused on the needs that I perceived at the time, and those needs are going to change. And I had a list, and I went through my list, and now I'm ready to drop the mic.

VB: (laughs) Is there anything else you'd like to...?

MH: I don't think so. Any question you might have?

VB: Well, I'm going to close the record, then, right now.

MH: Oh, oh, oh, oh, one thing. One thing.

VB: Okay, we're going.

MH: Leadership matters. Leadership matters. We've not talked about the FDA Commissioners.

VB: That was in my mind, too. (laughter)

MH: The FDA Commissioners. It makes a big difference as to what you're able to do. You can always go forward, but having support in various ways makes a big difference. You know, and as I've said, I started with Dr. Kessler. He's always my number one, because he set a path for so many things that are happening now, whether it's tobacco, or our office, or, you know, not being able to own things that would cause you to have conflicts of interest financially, to, you know, tobacco. He set that agenda, and I think that the Agency's in very good hands with Dr. Gottlieb. To a great extent he's been courageous. I've teased him about following Dr. Kessler's lead, but I think there's certain things that we do that are important, and then there'll be things that eclipse it. So as much as we want to focus on sex differences, if we can get menthol to not be in cigarettes, that has a women's health impact unlike any other in the foreseeable future. So I always say focus on what's the most important and what the greatest need is, and don't get caught up in process. And hopefully, you know, with good leadership -- and I think we have it now -- it opens the door to do a lot of really good things.

And to have the support of the women's groups. We have always had... One reason we communicate constantly -- newsletters, emails, tweets, etc. -- is because we want them to know that their investment has paid off. And if they don't hear from you, they won't know that. So we never have to worry about them coming to our rescue, and we've had to have them approach various commissioners about how they perceive our office.

VB: Is it similar -- not as much with private stakeholders -- but keeping a relationship with Congressional women, as well?

MH: I'm talking about Congressional women. I'm sorry.

VB: Oh, that's who you're talking about. Okay.

MH: When I pointed to that, those are all the women in Congress.

VB: Oh, I'm sorry.

MH: That's what that is. No, the Congressional women, and the stakeholders educate the Congresswomen. So when they perceive we have a problem, they go to the women on the Hill, on our behalf. And, unfortunately, they've had to do that a few times.

VB: Mm-hmm. Hopefully not again any time soon.

MH: They were just here. (laughter) I didn't want to close out without having their influence brought to the attention of the Commissioner, and they were very pleased with the meeting that we had.

VB: Good.

MH: It was a good one.

VB: Good. Well, I, like so many other people in the Agency, are really sorry to see you go, and celebrate the influence you've had here, and just hope you know how much you're going to be missed.

MH: Well, you know they will go forward. They can do more and better. It will be great.

END OF AUDIO FILE

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[The following came as an addendum immediately after the close of the interview].

MH: Okay. As I've said before, our stakeholders are groups that have an interest in the health of women. I was invited to speak at what was the Washington Business Group on Health. They're now the National Business Group on Health, but they represent Fortune 500 companies that self-insure. So this is all the big, big companies that it's cheaper for them to have their own

private insurance for their international employee groups. And so I went to this meeting, and they were talking about things that they needed, and this gentleman said, "I represent Caesars International," which was then about nine casinos, in Las Vegas and in Atlantic City, and some international ones. And he said, "We have a major problem. Our workers come in from high school, and they stay until they retire. They're on their feet 18, 20 hours every day. They smoke. They have free fast food in the employee lounge. And we pay 100% of their healthcare. They don't even have copay." He said, "I'm looking at them aging and getting fatter, and we're about to have a huge financial problem." And he said, "I don't know what to do, but we need help and I have money." And I said, "I am so there for you." (laughter) Because he was starting wellness centers. Not health centers, because they had health employees, onsite health. He wanted to start wellness centers, where he would take people's blood pressure, and help them do blood sticks and, you know, weigh them, and, you know, refer them to free exercise classes, etc. And I said, "We've got all this free information. We've got information on diabetes and the importance of sleep and hypertension, and on and on, and it's all free. And, you know, I could give you a disc, and you can print it, since you have money."

And so I went to Las Vegas a couple times, and we sat and talked, and he said, "I want to do a big thing." He invited in their big union. Their big union, actually, for all of the people from the croupiers to the doormen, are the... They're the restaurant union, is for all of them, but it doesn't matter. They decided they needed a big thing, and it was going to be for English-speaking and Hispanic-speaking families, because they wanted to do a whole family thing. And Gladys Knight is an advocate for diabetes intervention, and they said, "Oh, she's here at our Flamingo Hotel, but we'll bring her over to Caesar's for a one-night-only spectacular, and we'll broadcast it, and we'll have a concert, and it'll be focused on the importance of maintaining your

diabetes whatever. And so the American Diabetes Association literally stationed someone in Las Vegas for two months to work on this project, and the Chain Drug Stores were going to do a rollout across Las Vegas, the city of Las Vegas. The casino was bought. The whole conglomerate was bought by... Harrah's? Harrah?

RF: Oh, Harrah's.

MH: Harrah? Harrah's. H-A-R-R-A-H.

RF: A-H-S, yeah.

MH: All of them. So all of the executive team was replaced in a nanosecond. So that was that. But we did a bunch of things while there. I mean, they did a lot of rollout. All of their employees became aware. They had dances in the park where people came and got food and dancing, and our material was there.

And one of the other nontraditional folks we used over many years was Dear Abby. And she would only take launches, so it had to be a new initiative. So we've done caregivers. We've done cosmetics. We've done safe medication use. And it was always a question. You write a letter. It's all pre-done, but you write a letter to Dear Abby, and she responds, and her response is to get our material. So we would do kits. We would package our material in a way that you

would write Dear Abby, and she would send you to this link, and it would flood out. Dear Abby, as of three years ago, four years ago, was reaching 101 million readers a day.

VB: Wow.

MH: So whenever we did Dear Abby, we knew that at least they were reading our message in a very large way, and she was always one of our good nontraditional... We've been in airports; as I said, Las Vegas Casinos; we've done executive women's groups. And the Pharmacy Association did a *USA Today* event that I think I mentioned to you earlier. So, you know, we've had a lot of fun doing a variety of things.

VB: Where'd you guys come up with the idea to do Dear Abby?

MH: They had a relationship with the GSA, what I called Pueblo Clearinghouse. We had done something with mammography. Remember everybody was learning that these sites were getting converted, and so people needed to know this information. So, somehow, before I got here, someone thought, let's get Dear Abby to say that things are changing for women, and the diagnosis of breast cancer, they're now going to be certified. So it was a question-and-answer, and that's when she put a picture of the 1-800-4CANCER number there, and that's how people knew to call this number. So that relationship with Dear Abby was there, and her people knew us from that. But they are very picky. You don't just go to Dear Abby. Nothing political. If it

even has a hint of political, she will not accept it, and it has to be original. She only wants things from government that are a first, like an announcement. So that's how we got Dear Abby.

VB: But she did a lot of women's health issues, so she must have been really receptive to helping.

MH: She only took certain things. Cosmetics, it was the 75th anniversary, so that we could announce that there were big changes from the days of Lash Lure, and that things were now sterile and safe, and that things were now sterile and safe, and that there was a website that would show you the ingredients that have been approved, and you could go to that. That was new information. She did mammography, because it was a first. She did our safe medication campaign, because you could... Also, it was national, right?

VB: Mm-hmm.

MH: So, you know, she can't just limit herself to certain communities. So that was nationwide. Diabetes, big epidemic. Talked about how many women were affected by this disease, and the trend. So she was willing to do those. You don't just do something that's limited, as it relates to her, or very controversial. So we've always been very picky about presenting to her. And you provide her every piece in advance, and they review every piece, and question you about it. So it may take six months to get something into Dear Abby.

RF: Oh, wow.

VB: Wow.

MH: Yeah. And our materials take about two years. An original booklet of ours takes about two years, because we have to go through that many reviews and drafts and literacy and focus group tests, and on and on, and get approvals through OMB, and on and on.

VB: Does every translation have to go through clearance, too?

MH: No, not the translations, just the English original. They trust us. (laughter)

END OF INTERVIEW

Deed of Gift