History

of the

U. S. Food and Drug Administration

Interviewee:	Sharon Smith Holston
Interviewer:	Robert A. Tucker Ronald T. Ottes
Date:	November 27, 2001
Place:	Rockville, MD

INTRODUCTION

This is a transcript of a taped oral history interview, one of a series conducted by the Food and Drug Administration's History Office. The transcript is prepared following the *Chicago Manual of Style* (references to names and terms are capitalized, or not, accordingly.)

The interviews are with persons, whose recollections may serve to augment the written record. It is hoped that these narratives of things past will serve as one source, along with written and pictorial source materials, for present and future researchers. The tapes and transcripts are a part of the collection of the National Library of Medicine.

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Sharon Smith Holston

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

CASSETTE NUMBERS: 1,2

GENERAL TOPIC OF INTERVIEW: History of the Food & Drug Administration

DATE: Nov. 27, 2001 PLACE: Rockville, MD LENGTH: 110 Min.

INTERVIEWEE:

NAME: Sharon Smith Holston

ADDRESS: [redacted]

INTERVIEWER(S):

NAME: Robert A. Tucker
Ronald T. Ottes

ADDRESS: Food & Drug Adm.
Rockville, MD 20857

FDA SERVICE DATES: FROM: 1972 TO: 2001

TITLE: Deputy Commissioner For International & Constuent Relations
(Last FDA Position)

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RO: This is another in a series of FDA oral history recordings. Today we are interviewing Sharon Smith Holston, retired Deputy Commissioner for International and Constituent Relations. The interview is being conducted in the Parklawn Building in Rockville, Maryland. The date is November 27, 2001. Ms. Holston is being interviewed by Robert Tucker and Ronald Ottes.

The transcription of this interview, together with the tapes, will be placed in the National Archives of Medicine and become a part of FDA oral history recordings.

Sharon, to start this interview, we'd like to have you give a brief biographical sketch of where you were born, raised, educated, and any relevant work experience prior to FDA.

SSH: Okay. Well, I was born in Cleveland, Ohio, in 1945, went to public school all through high school in Cleveland, and after graduation, thanks to a scholarship, I went off to Barnard College in New York City. Barnard is the woman's college at Columbia University, and that's where I was an undergrad for four years. I graduated as a French major.

RO: French?

SSH: French. French language and literature, in 1967. At that time I had visions of living in New York City. However, my father had other visions of me returning home to Cleveland, which I did, reluctantly. But I only stayed there for a summer, and I came to Washington, D.C., in September of 1967.

I started out originally in graduate school at Howard University, again in French, but that was very short-lived, mostly because I really had no desire to be in graduate school. I only had a

desire not to be in Cleveland. And as a result of a friendship from a longtime friend of mine, who was working at the U.S. Commission on Civil Rights, I was able to get a part-time position there.

RT: What was the interest in French?

SSH: It was not an overwhelming or a compelling interest. It was that, as a child, I had been selected for a program for what they called gifted and talented children, when I was in the fourth grade. I left my neighborhood school to go to a special school for these gifted children, and French was a part of our regular curriculum. So from fourth grade on, I had French all the time through junior high school and high school.

So when I got to Barnard, I played around with, you know, what do I want to major in. At one point it was math, at another point it was psychology, but that was just sort of going through my mind. Well, by the end of your sophomore year, you have to declare yourself. You have to say what you are going to major in. And I just chose French. It was something that I liked, I was familiar with, and I just decided I wanted to major in it. I mean, Barnard is a liberal arts college for women, so nothing that you actually major in is actually going to prepare you for much of anything. It's just the well-rounded education that is supposed to prepare you for whatever you're going to do in life, and so the choice of a major wasn't that significant. I suppose if I were a science student going on to medical school or something like that, obviously I would have chosen biology or zoology or something like that. But not having any of those interests, it was just pure choice. It could have been art history; it could have been anything. But I liked French, so I chose French.

When I graduated from Barnard, of course, I was not prepared to do much of anything, and so I thought, if I go on to graduate school, I might either end up teaching or something like that. But again, I didn't have the right desire to go to graduate school.

RT: When you went to Howard, did you have a different major or a different study?

SSH: Still French. Still in French., right, in the Department of Romance Languages at Howard University. But I literally was there for less than a semester, because I had this part-time job at the Commission on Civil Rights, working, really, in a clerical position in their personnel office. This was, to me, really coincidental, because when I decided I wanted to stay in New York originally, personnel was a field that I thought I was interested in. I had gone about trying to begin looking for positions in that area, until my father sort of rudely brought me home to Cleveland. So I ended up, just by happenstance, in the personnel office at the Commission on Civil Rights, working part-time and going to graduate school full time.

Then, unfortunately, there was a woman who did work there full time who, I believe had a stroke. The personnel officer for whom I was working indicated that they were very pleased with my work, I was bright, etc., and asked me was I in any way interested in a full-time position in the personnel office. He didn't have to ask me twice. He offered me a full-time position when this woman became ill and couldn't come back to work, and, as I said, he didn't have to ask me twice. I mean, I just immediately said, "Yes, I'd love to work here full time," and learn to become a personnel management specialist. So I never went back to school. I never even quit. I just never went back. [Laughs] And that was the start of my federal government career, as a personnel management specialist.

I started out briefly as a Grade 5, but I took the Federal Service Entrance Exam, which was the way you got into an entry-level position at that time. Plus, I had a very high score on the graduate record exam, and if you had a high score on the test and you had the graduate record exam, they could make you a seven. And so within about three months, I became a Grade 7, personnel management specialist, and that was sort of the start.

I stayed at the Commission for two and a half years, and I think I was an eleven when the Department of Health, Education and Welfare was given the responsibility to try to put together this new agency that was going to administer President Nixon's welfare reform program. Now, the legislation was still in play. Nothing had actually been enacted. But there was going to be a complete and comprehensive overhaul of the welfare system. So a planning staff was put together—it was called the Family Assistance Planning Staff—to do the fundamental groundwork for this new agency that was going to administer this legislation once it was passed. And so in 1970, I left the Commission and I became an employee of HEW.

Now, what they did was, they brought people in from anywhere, different agencies, and we all became employees of HEW. We were put on the rolls of one of five different HEW agencies, even though we never worked in those agencies. That was just an employer. My employer was the Office of Education, within HEW, and I was hired to be the personnel officer for the planning staff, which at that time—eventually, I think, it numbered about 250 or so people. I did all of the personnel work for that staff. It really required me to interface with the employing agencies, because they were the ones that actually had the people on the rolls. But I did all of the personnel work for the people, and I had a staff, eventually, of about three, I think. So I did that, again for another two and a half years.

But the legislation went nowhere, and so finally in 1972, when it was apparent that this was never going to happen, the planning staff was disbanded. Each of us had a job in our employing agency, but we were also given the option to look elsewhere if we wanted to. My supervisor at that time on the planning staff, a woman who had hired me on the planning staff, was Mary McBride, and Mary McBride came to FDA. She was here as the executive officer for the Office of the Commissioner. I think she was the first executive officer the Office of the Commissioner had.

She told me about a position here in FDA that was vacant, and it was going to be the first-ever equal employment officer for the Office of the Commissioner. There was an agency equal employment officer, and that was Voyce Whitley at that time. Each of the bureaus at that time had an equal employment officer, but the Office of the Commissioner did not, and never had had one, and so this was a brand-new position.

So Mary told me about it, told me to apply for it. She thought that with my personnel background, it might be something that I could qualify for, and it was a Grade 13 position. By this time, I was a twelve. I had gone from an eleven to a twelve on the planning staff. So I applied for that position. I was interviewed by Voyce Whitley, by John Droke, who was the Deputy Associate Commissioner for Administration (I think that was the title), and by Mickey Moure, and was ultimately offered the position, and that is how I ended up in FDA.

I reported to John and Mickey, but I worked in a very small suite on the fourteenth floor, 1490, with Mary McBride. So it was me, Mary, and we had a secretary. I can't remember who that was at that time. So that was my first position.

RO: This was in 1972?

SSH: December of 1972. Charlie Edwards was the commissioner at that time, and not long after that, Dr. Edwards went to become the Assistant Secretary for Health, and he took Mickey and John with him. Gerry Meyer, who had been, I guess, Assistant or Associate Commissioner for Legislative Affairs, became the new Associate Commissioner for Administration, which then made him my new boss. We knew each other, because as the equal opportunity officer for the Office of the Commissioner, I was servicing all of the associate commissioners and assistant commissioners at that time. So I knew Gerry, but not all that well. I don't exactly remember the time frame, but it happened fairly quickly, so that I didn't have very long, really, working with John and Mickey.

So Gerry came, and he and I started working together, and there were some serious concerns that employees had about equal opportunity in the Office of the Commissioner. Predominantly the concerns surrounded our operations downtown at FOB 8 [Federal Office Building 8], where we had people who did all of the support services for the Bureau of Foods. They worked in the basement of FOB 8, and it was pretty awful working conditions down there. Then we had some people who worked at a place called Half and L Street, which was another one of our locations, and again, the condition, it was a warehouse kind of place, and the conditions there were pretty bad, too. It shared space with a place that was like automobile maintenance or automobile, something like that. But there were fumes all the time in that enclosed space, and employees were concerned about that. Most of these employees were low-grade minority employees, both in that facility, as well as in the support services for the Bureau of Foods. So they had a lot of issues about their working conditions, their grade levels, and they never got opportunities for advancement, that kind of thing. So some of the most difficult issues I had to

deal with when I was an equal opportunity officer were trying to sort out what was going on and what was fair and what was not fair in how they were being handled.

There was a particular supervisor who, as it turned out, was running the place. My words were, he was running it like a plantation, basically, and he would very often bring in very new, inexperienced, non-minority employees and put them in positions over the longtime minority employees who had been working there. This was a pattern, and it just got to the point where it was pretty egregious. After looking into it, I talked with Gerry about it, and I said, "This is a problem. I've tried to look at this as objectively as I can, but this isn't right." Gerry took me very seriously.

RO: The supervisor was non-minority?

SSH: Right. So as a result of my investigation and my trying to work with the supervisor and him being very reluctant to change his ways, I recommended to Gerry, and Gerry concurred, sort of withdrawing from him his authority to take any personnel actions affecting the employees in that organization. They had to be signed by Gerry, and I think there was a letter of reprimand. Well, that was considered sort of a monumental first in the history of the agency for that to happen.

I know I digress, but there was one employee in particular who had been there for a long time and only wanted an opportunity to show that he could do more than he was being allowed to do. As a result of this action, he was given a chance. He ended up being promoted. He's still here at the agency. When I had my retirement party, he was there, and he never comes to Parklawn [Building] for anything, and yet he came out to Bethesda [Maryland] for the retirement

party. It really made me feel good to think that, all these years later, he still remembered what had happened and that I had helped him, so I really felt good about that.

That was my EEO career, and it didn't last very long, because that's a very stressful job. It really is. If you take it very seriously, if you try to do what you think is right, sometimes you end up taking on the world's problems, and I found out after about two years that that just wasn't how I wanted to spend the rest of my career. I knew going in that that wasn't how I wanted to spend the rest of my career, but it came to me even sooner than I had anticipated, that I needed to do something different. Gerry and I had developed a really good working relationship, and I was able to say to him, "I'd like to try other things. I'd like other opportunities." I didn't know exactly what. But he was very supportive of me and gave me opportunities to go on details to do other things.

In this building, we had, I think, five different agencies and five different computer centers. A decision was made that all of those computer centers were going to be consolidated into one, and it would be the Parklawn Computer Center; someone had to pull all that together. So Harold Heiser, who at that time was head of the accounting branch in our Division of Financial Management, was given the lead responsibility, and I was to help him pull together the new Parklawn Computer Center.

Harold and I both left our positions and went down to the second floor of the building and began the process of trying to pull together this new computer center. So he and I worked together for, I think, maybe about four to six months, something like that, on this detail, and at the end of that period, he and I became fast friends, too, as a result of that.

We came back and a decision had to be made about who was going to actually head up the new computer center on a permanent basis. Harold decided he was interested in the job, and

we sort of offered ourselves up as a team to head up the new computer center. Unfortunately, someone else was selected over Harold for the position, and he went back to financial management. I went back to the EEO office.

By this time, it's 1974, I think. I had been married in '73, and my husband, a struggling artist, was just sort of getting started, and I decided that I was going to work full time and help him. So I left FDA in, I believe, August of 1974, to work with him in his business. Things weren't going as well as we would have liked, so the following spring, I think, I came back part-time. When I left, I had a letter from Sherwin Gardner, who was the deputy commissioner at that time, that said that I'd done really well at FDA and that if I ever wanted to come back, I was always welcome. So I took the agency up on that a short seven months later, I think. I came back part-time initially, and again worked in personnel and also worked with Mary McBride, and eventually just came back full time.

RT: You came back in what capacity?

SSH: I started out working in the personnel office. There were people, Don Owens and some others, who worked in personnel, and I just did a variety of different projects in personnel. But eventually, Mary McBride, who was still the executive officer for the Office of the Commissioner, asked me to come work in the executive office with her, and so that's what I ended up doing, coming back to that same office, working with Mary in administration. So I was doing general administrative things, as opposed to EEO or anything like that, because a new EEO officer had been hired.

RT: Who was that person?

SSH: His name was Phillip Rushing, and he was a double amputee. He didn't have arms; he had two prostheses. So he was the new EEO officer for the Office of the Commissioner after me. Unfortunately, he ended up slipping downstairs on the fourth floor one day on some rug or carpet or something, and it badly injured the muscles in one of his shoulders. As a result he wasn't even able to use one of his arms, his prosthesis, and he ended up retiring, I think, on a disability or something like that.

I worked with Mary in administration, and Mary eventually went on a detail to the personnel office to become the personnel officer, and someone else came in acting for her. I think initially Ron Chesemore may have become acting executive officer while Mary was on detail. Then Mary asked me to come back to personnel and work, and I did that, on detail again for a while.

During that time, my son was born in 1977, and so I was on detail in personnel in 1977 when he was born. I had agreed that I would go back to personnel and work, but I didn't want to stay in personnel. I really liked general administration. I liked working in the executive office. So I asked if I could go back to the executive office. Mary stayed in personnel. I went back to the executive office. By this time, Gerry Elder was the acting executive officer. All of these people were still on detail, because it was technically still Mary's job. She was sort of on this long-term detail being personnel officer, but her job was the executive officer, so everyone who came in was always acting in her position.

Ron went on to become head of financial management. Gerry left the agency and went on to ADAMHA [Alcohol, Drug Abuse and Mental Health Administration] at that time, and Gerry

Meyer asked me if I would come back and be the acting executive officer, and I agreed. So I came back, and now I was acting in Mary's job.

In 1978, I had another child. Gerry left to go to private industry, and Ron Chesemore was the acting associate commissioner, and Mary stayed in personnel. Ron was interested in the job of permanent associate commissioner. Mary was interested in the job of permanent associate commissioner, and we were conducting this search to replace Gerry when Gerry came back. What he did was to call back and say he'd like to come back, and he didn't care what kind of job it was, he just needed to come back. He wanted to come back into the federal service. As I recall, it was something along the lines of, "Well, Gerry, we didn't fill your job, so you might as well come back to this one." [Laughs] And so he did; he came back.

He asked me if I would come and be his special assistant. He wasn't going to have a deputy this time. He'd had two deputies, not terribly successfully. First, Ed Steffee. Ed Steffee had left and gone to, I think, HRSA [Health Resources and Services Administration] before his tragic motorcycle accident. Then Jack Patterson came, and Jack Patterson was Gerry's very best friend in the whole world. I think the lesson from that is, never hire your best friend to work for you, because it significantly strained the relationship. Gerry was a very hands-on, take-charge kind of person. He didn't really need a deputy, necessarily, because he never wanted the deputy to make any decisions. He wanted to do everything. People like Ed and Jack wanted more of a role than just doing certain grunt work, in essence. So when he left and came back, he decided that he wasn't going to make that mistake again, and said he was going to hire a special assistant and not a deputy, and he wanted me. I couldn't exactly figure out why, but it was obviously a wonderful opportunity, and so I went to work for Gerry as his special assistant.

I stayed his special assistant for one year, at which time he decided he wanted me to be his deputy. I guess he assumed he wouldn't have the same problems with me that he had with Ed and Jack, because I was so overwhelmed by the opportunity, and it was such a great learning experience for me, that I certainly wasn't going to fight him for his role and responsibility. I never even occurred to me to want to do that. So I worked as Gerry Meyer's deputy from 1980 until he was sent to the Center for Drugs [Center for Drug Evaluation and Research] in 1986. We had, I think, a very, very good working relationship. I learned just an enormous amount from working with him and just watching him.

He was very instrumental in trying to get a new consolidated campus for FDA. He worked on that a lot. I worked with him, but it was something that he was very much committed to and got started.

RO: Through this time, there had been a number of commissioners.

SSH: Yes.

RO: I think when Gerry came—

[Begin Tape 1, Side B]

SSH: He was commissioner. And then after Dr. [Donald] Kennedy, was it Dr. [Arthur Hull] Hayes after that? Right. Or was it Dr. [Jere] Goyan?

RO: Goyan was in there for a short period of time.

SSH: He was after Kennedy.

RO: Yes.

SSH: Dr. Goyan came. All right, Dr. Goyan came.

RT: Jere Goyan.

SSH: Yes. Dr. Goyan was the one who came and built—I remember a couple of things. One, he fired David Link, who was head of the Bureau of Medical Devices at that time, and he made Alex Grant an associate commissioner. The Office of Consumer Affairs had really come into its own. It was a model for the entire federal government. There was no agency that I know of in the government that had an Office of Consumer Affairs like ours. All of the consumers used to tell other agencies, "You should do it the way FDA's doing it." We involved consumers in everything, gave them a voice, gave them an opportunity to participate, and they loved it.

Alex was the one who really built that office, when he was a Special Assistant to the Commissioner for Consumer Affairs, and Jere Goyan surprised him by making him an associate commissioner. Dr. Goyan came to me and wanted to know how he could do it and what do we have to do, but he didn't want Alex to know anything about it. So we put through all the paperwork. He announced it at a consumer meeting, and it came as a total surprise to Alex that he was being elevated to the position of associate commissioner.

But Dr. Goyan was here for a very short time because of the change in administration when President [Ronald] Reagan came in. The other thing I recall is that he was given very short notice that he had to vacate his office by noon on Inauguration Day. He was living in an apartment off Georgia Avenue. Peppertree Farms. So a group of people helped him to pack up his truck with trailer with his belongings, and he drove back home. We were without a commissioner for a while, and I believe it was Mark Novitch was acting, until eventually Dr. Hayes came. Dr. Hayes was someone that—I never really got to know him that well. I think that the one thing that remains in my mind is that despite the fact that we had many commissioners over that time, a lot of them really didn't get that involved in the running of the agency, the management aspects of the agency. They pretty much left that to Gerry.

The order of succession at that time was commissioner, deputy commissioner, associate commissioner for regulatory affairs, and then Gerry. Gerry took that fourth-in-line-of-succession role very seriously and pretty much stayed in complete charge of the workings of the agency, and let the commissioners run the programs, and they were happy with that, pretty much. So Gerry and I learned to sort of manage our part of the world without a lot of interference, if you will, from the commissioners, because they didn't get involved. Now, I'm not sure center directors or bureau directors were particularly happy with that system, because it meant that Gerry pretty much controlled their finances, and he just knew the total ins and outs of the budget. He had been on the Hill. He'd been an administrative officer at NIH [National Institutes of Health]. So he had a background in this kind of thing, and he knew it inside out. I think that things went along relatively smoothly until, quite frankly, until Dr. [Frank E.] Young came.

RT: What about the department? Through all of these years, there were some changes in administration, changes in secretaries.

SSH: Yes, there were changes in secretaries. I'll have to say that I'm not feeling as if we felt that that much, and it may be because of the role I played, that I didn't feel as if that a significant impact on what we were doing, the administrative part of what we were doing. There were a lot of issues that kept coming up. There was always the drug lag. That was a big problem. There were different issues like that that came and went, but the rhythm of what we were doing, managing the agency's support services, the money and the space and the computers and that kind of thing, that didn't change that much.

RT: When Dr. Young came, I think you indicated there was a change. What was the nature of the change that Dr. Young implemented?

SSH: The nature of the change was that Dr. Young was more of a hands-on commissioner than we'd ever seen, and he wanted to be very, very closely involved in managing the agency's resources.

RO: His deputy, John Norris, who he brought in, was Norris also involved in that hands-on style?

SSH: Absolutely. John wanted to control the resources. Their theory was that whoever controlled the money, controls the agency, and that was Gerry's theory, too. [Laughter] So we had a little bit of a clash there about who was actually controlling the resources of the agency.

RO: Dr. Young, I think, was known for his presence of walking halls and dropping in, particularly with regard to emergency situations. He was very interested in keeping close touch with those.

SSH: Dr. Young wanted to be everything and everywhere. He was totally immersed in being the Commissioner of Food and Drug, and to him that meant being commissioner over everything. We had gotten into a pattern sort of like year in and year out with the budgets, where Gerry would sort of work with the centers a little bit, or the bureaus, as they were called, work with them a little bit, come up with some numbers, present them to the commissioner, tell him what we were going to do, get the commissioner's blessing, and then just go off and manage.

RT: Commissioner Young, I believe, implemented the action plan concept?

SSH: He certainly did. That was one of the first things he did when he came in, this action planning process.

RT: How did that impinge on this—

SSH: Well, in fact, it probably affected planning and evaluation more than it affected administration, because it superimposed itself on Jake Barkdoll's very thoughtful planning process, and this came out of left field from nowhere. So there was a little bit of a clash there in terms of which plan are we working with, how does this action plan fit in with our overall planning process. So there was a little bit of tension there.

The biggest tension, from Gerry's perspective, was that the commissioner wanted to control the budget and the resources. John Norris was his person for making that happen, and John and Gerry sometimes had times when they didn't quite see eye to eye.

RO: Norris didn't stay very long.

SSH: He didn't stay very long. Let's see. There was a period there, now, from January of '85 to January of '86 when I was not here, because that was my year away at Harvard. As I recall, Dr. Young came probably in '85. I think I was away when he came, and so I missed some of the back and forth between him and Gerry. When I came home for the summer—most of the students in the master's program at Harvard started in August and went through to May. I decided I couldn't do that, because I had small children and didn't want to be gone that length of time, so I started in January.

RT: Sharon, what was the nature of the Harvard experience? Was that in management?

SSH: It was a master's in public administration, under FDA's long-term training program. I should back up a little bit. By this time, I had been working for Gerry as his deputy for about five

years, and my earlier attitude was, this is all I could ever want from life. I certainly could never aspire to more. But after about five years, I said, "I can run this shop myself." [Laughs] So I was looking for an opportunity to do more. I applied for the department's SES [Senior Executive Service] Candidate Development Program and was unsuccessful.

Around the same time, Harvard was sending around their recruiter for their master's program, and a friend of mine had referred the recruiter to me. I thought at the time that it was impossible for me to do a full-year program at Harvard, and Gerry said, "No, it's not impossible. If you can work your family part out, the agency can work the other part out." So my husband was very supportive, so I went away. So I did miss Dr. Young and Mr. Norris coming on board.

I lived in Cambridge from January to January, '85 to '86, but I did come home that summer, and that's the reason I did it, so that I would have that break and could come home and be with my children over the summer. It was sometime during that period while I was gone that whatever tension there was between Gerry and Dr. Young and John Norris was developing. When I came back, John Norris asked me about acting for Gerry for the summer, while Gerry went to CDER [Center for Drug Evaluation and Research] on detail. Obviously, as his deputy, it was expected that I would do that. But I was concerned about what appeared to be happening, and Gerry was concerned because why would you all of a sudden ask the associate commissioner to go to CDER to be something?

Gerry was, I think, one of the best managers ever. I really do believe that. I think that Dr. Young sensed that CDER was in trouble and needed help and someone with Gerry's skill could help bring some order to some management issues in CDER, and that part, I think, is quite valid and quite legitimate. The concern on Gerry's part was that he was being sort of exiled. But since

I was only going to be there for the summer, we understood that when I went back to school, Gerry was coming back from his detail, and that's what happened.

I went back to Harvard and I finished up the following January, and I came back again. Then John Norris started talking to me again, and those were some uncomfortable conversations, because it seemed as if they were not happy with Gerry, and had heard from Dr. Hayes that some of Dr. Hayes' problems, as far as his travel were concerned, were Gerry's fault, which was totally untrue, but he was a convenient scapegoat.

RT: Wasn't Dr. Hayes kind of marginal on following the ethics of travel?

SSH: Well, there were some issues about him being reimbursed from more than one source for the same trip. For some reason, he seemed to feel as if, or at least he said, I'm told he said, that it was Gerry's fault that he got into that trouble, and he apparently had indicated to Dr. Young and to John Norris that they needed to be very careful in their interactions with Gerry, because he might "do them in" or something like that. For whatever reason, they were very cautious in dealing with him.

When I came back from Harvard the second time, it seemed to be pretty obvious that they wanted to do something different with Gerry. My level of discomfort was that I was going to be—

RO: In the middle.

SSH: Yes, literally caught in the middle of this, and I didn't want to be in the middle of this, because Gerry was responsible for all the good things that had happened to me in my career. But I was also not in a position to say, "I refuse to be acting if you send Gerry away." So ultimately they did send him to CDER, and ultimately I did become the acting associate commissioner, and that was a very difficult time for my personal relationship with Gerry.

RO: He surely didn't suspect that you were involved in this?

SSH: I think, Ron, when something that traumatic happens, everyone is suspect. I think that Gerry felt that not just me, but other people, may have had a hand in undermining him, and I think he was hurt more than anything else. It was a very, very bad time.

They sent him to CDER again and said it's only temporary, but then when he decided he really wanted to come back, they said that was not in the cards for him to come back. They actually reassigned him and advertised the job. I had been acting in the job now for over two years, and so, obviously, I applied for the job. I became the associate commissioner in 1988.

RO: Through this time and the changes in commissioners, there were some internal reorganizations in the agency, including the Office of Management and Operations. At least the people who were involved in structuring some of those reorganizations were on your staff, weren't they?

SSH: Right, people like Michael Brannon, who was head of the Organization Planning Branch. We organized and reorganized numerous times. Obviously, we went from the bureaus to the

centers. For a brief moment they were called national centers, until we were told that we couldn't do that. So for a very short period, we had a National Center for Drug Evaluation and a National Center for Biologics, and then we switched them back to just the centers.

Then we had the time when we merged, of course, the Center for Drugs and the Center for Biologics into the Center for Drugs and Biologics, and then we merged medical devices and radiological health. That one stuck, under John Villforth, whereas the other one, under Dr. Henry Meyer, was less successful. I think it was less successful because the whole corporate cultures of those two organizations were so very different, with CBER [Center for Biological Evaluation and Research] being a very NIH research-oriented center, as opposed to CDER, which had a research program, but it was not a strong one, by any measure. CDER was under the gun for not getting drugs out fast enough. Those two cultures never could merge, and when it became obvious that simply wasn't going to work; we had to split them apart again. Some of that happened under Gerry, when I was still his deputy, and then by the time he went to CDER, they had split again and become two separate centers.

RO: You were Gerry's deputy, when the generic drug problem broke?

SSH: The generic problem broke in 1989, and I was actually the associate commissioner at that time, and Dr. Young was the commissioner, and that was pretty hard on everyone. Now, what we did learn, of course, there were two things that happened. We learned that employees who were going—I'm sorry, I need to back up a little bit.

The whole issue of what we were and were not allowed to accept was unclear for a long time. I do remember that it was common agency practice, if an employee was going to a meeting

or a conference or something like that, where the costs were higher than the government per diem, that the employee's additional expenses, it was okay for them to be subsidized by the sponsoring organization. That was okay. Nobody questioned that. I can remember Gerry saying that was fine, that was allowed. But that was supposed to be just like your hotel expenses. It wasn't supposed to be everything. If the room cost more than the government per diem, the difference could be subsidized. That was the accepted.

I'm not going to claim to have a purely accurate memory on this, but what happened is that we learned that there was a particular meeting sponsored by the National Association of Pharmaceutical Manufacturers, or something like that, but it was a generic trade group, where they subsidized not only the rooms, but they subsidized everything. The employee went to the meeting, paid for their little share of the room, but room charges, tennis games, golf lessons, everything was paid for. When that came out, that was really bad. Employees were disciplined for that, and in some ways one could argue they had gone too far, maybe, but it hadn't been unheard of for employees' rooms to be subsidized, their hotel expenses.

The department issued very stern guidance to us that from this point forward there would be no subsidies of any kind. We could accept nothing of any kind from trade associations. This subsidy was limited to trade associations, I should clarify. It wasn't the drug industry, per se. We had drawn a distinction between a trade association and the industry itself, and so these subsidies were coming from trade associations, which we had felt was acceptable. The department, you know, clarified for us that that was not acceptable, and so the line was drawn. We couldn't do that at all.

So we had this issue, and then we had the issue of employees, we were learning, who were taking money to rearrange the queue of generic drug applications. So you had, really, two things

almost coming around the same time; the one which affected employees who were otherwise quite straight-up, honest employees, in my mind got commingled with employees who were actually accepting money to influence the outcome of the generic drug process. So there was a period there from '89 on where the agency was pretty demoralized about what kept coming out in the media all the time, because we felt we were all being tarnished by that.

I remember so clearly all of us going down to a hearing called by Mr. [Congressman John] Dingell, where he had the world's longest witness table, because they had strung together enough tables for—my mind keeps saying sixteen, but it may have been even more people, all to sit at the same time in front of him, and we were all sworn in. We had to swear that we would tell the truth, the whole truth, and nothing but the truth. It was a very, very difficult time, and Dr. Young ended up paying the price for that, because it was on his watch.

RO: Do you think that the department felt that they had to do something and Dr. Young was the scapegoat?

SSH: Yes, I really do. I think they had to do something. Dr. [Louis] Sullivan was the Secretary at that time, and we found out that the generic industry itself was pretty—I shouldn't blanket the whole industry, but there were some pretty devious things going on, on the part of the generics in terms of substituting. They would substitute samples. They'd send us one sample to say this is the sample for us to look at to do bioequivalence or something. It might have been the brand-name drug, actually, that had actually been tampered with to make it appear as the generic industry's product, when it wasn't. It was the actual product that they were being compared against.

It was decided we simply didn't have the capacity to investigate that kind of thing, and that was when Dr. Sullivan decided that we were going to hire criminal investigators.

RO: He was the one that decided that?

SSH: Yes.

RO: To satisfy Dingell?

SSH: Right, because we simply didn't have anyone they felt was qualified to look into that kind of activity, that kind of criminal activity, and what we needed were criminal investigators to do that.

RO: I thought that at one time that the department's inspector general was willing to—

SSH: Absolutely, and there was a bit of a fight over who was actually going to do this. The Inspector General's office clearly wanted, and said, "We are the ones who should be responsible for this," but the agency felt very strongly that "We have the capacity. It should be an agency function. It should not be an Inspector General function."

Between Dr. Young and Dr. [David A.] Kessler, Jim Benson was the acting commissioner, and Joe Levitt, who was serving in a quasi-deputy role, although he was never actually given the title of acting deputy commissioner, had to deal with the whole generic situation. Then by the time David actually came in as commissioner, the whole idea of the

criminal investigators had pretty much gotten to the point where it was decided to move with that. I apologize now if my chronology is not 100 percent on this.

At that time we had our own little internal affairs staff. We had our ethics investigators, who investigated employee misconduct and things like that. They were not criminal investigators, and they were considered not at the level necessary to do this. So we established these new positions in what is called the 1811 Series, the Criminal Investigation Series, and hired Terry Vermillion, who had been with the Secret Service, and he started to build that staff. Something in my mind says that the Secretary told us we would have forty positions for criminal investigators. So we started building the criminal investigations staff, and it was a direct result of the generic drug scandal.

RO: On the budget, usually you got rather involved as the deputy or as the acting. You were more than an acting.

SSH: I became associate commissioner in '88.

RO: So you got involved in presenting that to the congressional budget committee, didn't you?

SSH: Yes. We put together the budget. The commissioner, obviously, was the chief witness for the agency.

[Begin Tape 2, Side A]

SSH: The commissioner did most of the talking, but the associate commissioner was there as a resource, if necessary, as were all the center directors, and clearly the person who was head of financial management was there on the other side of the commissioner, or right behind, handing information up to the commissioner, keeping them informed with the information they needed to respond to questions. That process pretty much was run by the associate commissioner and the head of financial management.

When I inherited the job from Gerry, Frank Claunts was the head of financial management. Frank Claunts was the head of financial management, and Frank had very good relations with his counterparts on the Hill, the people who were our liaisons with the committee chairs, and always used to get intelligence for us about what kinds of questions might be coming up, what issues were important to all of the various members of the committee. We would constantly try to call them and find out what things they were going to be asking questions about, what was on their minds, what were their top priorities, what we needed to make sure the commissioner was prepared to handle the hearing.

RO: Who was the chairman?

SSH: At one point, Jamie Whitten was the chairman in the House. I remember Thad Cochran in the Senate. It changed. It would take me a while to remember everyone. There were so many members of the committee. We had people like Dale Bumpers on the committee, who was always looking out for NCTR, and we always had to watch NCTR because they could always go directly to Bumpers to get him to pay attention to their issues, and we'd find some odd language in our appropriation that pertained specifically to NCTR, thanks to the people down at the center.

RT: In the budget process with the Congress, that was your responsibility and did not involve the Office of Legislative Affairs, is that correct?

SSH: At that time, it did not. The people who did the liaison with the appropriations committees were the staff in the Office of Financial Management. There was always this tension, because the Office of Legislative Affairs handled every other relationship on the Hill except that one, and it was jealously guarded, I mean jealously guarded by the Office of Financial Management.

As a supporter of my staff, I used to have to knock heads from time to time with whoever was head of legislative affairs about the fact that we handle this part, and Frank used to get very exercised if he thought that the people from OLA were interfering in his relationship with the appropriation staffers. And that pretty much went that way.

RO: One thing we haven't talked about yet is GAO [General Accounting Office] and all of their studies. The liaison—

SSH: Was in the Office of Management and Operations. We had the GAO liaison and the IG [Inspector General] liaison. At one point we had so many GAO studies going on that, for all practical purposes, the person needed to be residing here in the Parklawn Building. Lois Adams handled the GAO liaison, and the IG liaison was in the Division of Ethics and Program Integrity, which at that time was headed up by Delores Willis. When I came into the job, I selected Delores

for that position not long after I assumed the Office of Management and Operations. It was like a constant. They were always investigating us for something.

We also had that layer of the Public Health Service over us, as well, so you would have the GAO looking in. You would have the PHS overlooking you and the GAO. Whenever reports came back from the GAO, they came to the PHS, not directly to us. It went to the PHS. There was a person at PHS who was a GAO liaison, who then would send us the report. We had to turn around our results and send it back through PHS, who sent it back to the department before it got to GAO, which meant that we had like six seconds to respond to the reports because of all the layers that had to review it before it actually went back to GAO. We had a very adversarial relationship with both GAO and the IG.

RT: Were there time constraints imposed by GAO on response time?

SSH: Yes. It was our opinion that they had it for like six years and then they'd give us six days to respond. I think we usually had something like a ten-day turnaround time, but sometimes part of that ten days was taken up by PHS, as well. So we never had enough time to adequately respond to whatever findings they had on the subject. There literally was a GAO office across the street in the Park Building, and that's where they resided, because they were here so often that they just needed a full-time office here.

RT: How about the Inspector General, the IG? Was there any difference in their expectations on response time, or was there a response time? Maybe that was more of an investigator scene.

SSH: The IG used to have, at least, three different staffs, so they looked at things differently, depending on which staff was doing it. If it was an actual investigation, they would give us the time to look at it, but you didn't usually respond to an IG investigation. That was looking into some wrongdoing.

They also had a staff that was very much like the GAO, which was almost like a management staff, and they looked into administrative things, and then they would give you time to review their recommendations and findings and respond back, and then they'd come out with a final report. So it really depended on who was doing it. This is my recollection.

The GAO process was very controlled in that Lois was the point person. They had to come through Lois, and Lois decided how it was going to play itself out. They were never to go directly to staff without coming through Lois and clearing and making appointments and everything. We structured it that way. We did not want GAO coming in and just kind of willy-nilly going throughout the agency, asking anybody they saw anything they wanted, and then having the agency not prepared for what might come through in their report. So we tried to very tightly control that process.

RT: In my own experience, I recall when GAO was in on some kind of an oversight thing, and their attention had been drawn to the state contract program, and they wanted to do that simultaneously, however Lois adamantly said that it would be only one investigation at a time.

SSH: One at a time. Right. She was good at doing that.

RO: Did GAO get involved in the facilities? You had been up to your eyebrows in facilities. Did GAO ever get involved in our looking, or FDA looking, for other facilities?

SSH: It seems to me that they did. My recollection's a little hazy, but I do recall that at one point we talked about the fact that we had badly outdated, antiquated labs that were falling apart and we needed more space, and at one point Congress wanted us to justify, I think, our need for space. There were some who were skeptical that we actually needed everything we were asking for. I seem to recall that GAO was asked to look into what were our real space needs as opposed to this sort of pie in the sky.

RT: What about White Oak? Where does the agency stand on White Oak? I realize you've been out of it for the last couple of years.

SSH: Right now, White Oak is designated as the new location for FDA, but it will only include the Office of the Commissioner, ORA, the Center for Drugs, and the Center for Biologics and the Center for Medical Devices. CVM [Center for Veterinary Medicine] will not be there. As you know, CFSAN [Center for Food Safety and Applied Nutrition] is not there. So it's not, quote, "the consolidation" that we would have wanted. David Kessler and I, together worked on this.

You had two congressional districts in Prince Georges County and Montgomery County, both of whom wanted FDA. So we worked out a compromise—we would go for consolidation, but part of it would be in PG and part of it would be in Montgomery. That was the deal that was made and sort of blessed by everyone who was involved, including all the senators from the state, as well as the representatives. So we gave up the idea of having one consolidated location.

We started out with Clarksburg as the site for the Montgomery County piece, and I think we had 400-and-some acres in Clarksburg that GSA [General Services Administration] selected for us. Around that time, Congress was mad at us about tobacco, and we had an environment where there were some who felt that FDA shouldn't even exist any longer, that it had outlived its usefulness. That was when we were called the "number one job killer in America," we were "stifling the pharmaceutical industry," we were "keeping promising therapies from being made available to people," on and on and on.

The Citizens for a Sound Economy was one of these lobbying groups that came out very forcefully attacking the agency, and they would do these full-page ads about people who had died because FDA had not approved a particular drug that was available in Europe or somewhere else, but not available here. So they pretty much targeted us and went after our consolidation. Every time we had a public meeting about our consolidation, someone from the Citizens for a Sound Economy would come and speak against it and say we didn't need the space, that we were trying to build a Taj Mahal, and that in view of the fact, in their minds, that the agency was probably going to cease to exist, it made no sense to go out and get all this land for this agency that was going to be so tightly reduced in size that it wouldn't need all this space.

RT: Was there some discussion at that time about separating food safety from other parts of FDA?

SSH: Well, that wasn't an integral part of this discussion. There had been, even when President Clinton came in and they had had their National Performance Review, one of the recommendations had been for a single food safety agency. We didn't know where that was

necessarily going to be, but it did seem that that was on their agenda to create a single agency for foods, and it might have been that it would have left FDA.

But when we talk about the consolidation issue, there were some people who believed that, as I said, FDA was harming the interests of the industries that it regulated, and that it needed to be cut back, it needed to be cut down in size, and so we didn't need all of this "new campus" talk. That made no sense, because we weren't going to exist. So the money that we had earmarked for the consolidation was taken away from us. It was wiped out, and we had to start all over again from scratch.

So then the new plan came up with White Oak, after the base closings. They closed the Naval Surface Weapons Center, and the community of White Oak was desperate to have another federal facility occupy that site. They knew about our search for a location, and GSA talked literally with the White Oak community, and they began their own almost grassroots effort to get FDA to that site. Relentless, they were. They had formed a committee called Lab Quest, which meant they were seeking a federal laboratory research center to come to their site. The Lab Quest movement interviewed, if you will, FDA to see if they thought that we would be compatible with what they were seeking for their community, and they liked us, and then got behind us 100 percent, lobbying Congress, relentless in their efforts to bring FDA to White Oak.

[Congressman] Steny [H.] Hoyer was successful in getting us the CFSAN part and the remainder of the new CVM lab building, and Representative Hoyer has always been a strong supporter of the agency, although most of it wasn't in his district. After they redrew the lines, even White Oak was no longer in his district. I think College Park is still in his district. White Oak wasn't in his district, but he still fought for us on White Oak. A small part of White Oak is in Prince Georges, but the majority of White Oak is in Montgomery County, and so

[Congresswoman Constance A.] Connie Morella has always fought for us, but then when White Oak was decided as the site, it was no longer in her district. It's in [Albert R.] Al Wynn's district now. But Connie Morella, Al Wynn, and Steny Hoyer banded together with the White Oak community to fight for FDA to come to White Oak, and so that is the designated location now for the consolidation. We had the groundbreaking, and so the construction has already started for the laboratory for the Center for Drugs to go up at White Oak.

RT: Was the user fee proposition anything you had to deal with?

SSH: By the time user fees became a viable issue, David Kessler had come and had restructured the Office of the Commissioner again, and that's when he created the five deputy positions. So those of us who were associate commissioners reporting directly to the commissioner found ourselves reporting to, instead, a deputy commissioner. Mary Jo Veverka was the Deputy Commissioner for Management and Systems, so the Office of Management, the Office of Planning and Evaluation, etc., reported to the new Deputy Commissioner for Management and Systems, and Mary Jo played the key role on user fees. She had come from a consulting firm. I can't remember which one. But she'd come from a consulting firm. She had been a consultant with the pharmaceutical industry. She had contacts in the industry, so she was able to negotiate and draw up that user fee plan, working both with people in the agency and with people in the industry. She really, I think, is the key person who's responsible for the user fee program.

As I said, I was still the Associate Commissioner for Management, but the role had changed dramatically once the deputy structure was put into place. All of us who were associate

commissioners felt very much sort of diminished by that new structure. I think it was a difficult time for all of us, really. It was hard to get used to being subordinated that way.

RO: Imagine how the center directors felt.

SSH: Right. They were under the Deputy Commissioner for Operations. Although Jane was a great person to be working for, it still made a big difference to them. But the facilities part, the consolidation part, was one of the things that David still expected me to handle. That was between him and me; it was not between him and Mary Jo and me. So I reported directly to him on the consolidation issues.

Carol Scheman, who was the Deputy Commissioner for External Affairs, came in and she was hired, among other things, to do the PR part of consolidation. We had taken a black eye over our consolidation project, and we needed to build a community of support out there. David felt that Carol had contacts that could change some of the noise around FDA's consolidation project.

So I worked with David and Carol both on consolidation, but I spent hours working with people at GSA, with people at OMB [Office of Management and Budget]. OMB was not convinced at all that we needed everything that we were asking for, and it was days and days and hours of working with OMB to sell our project to them. I did that, working with my staff. Voyce Whitley was a key player on that, too. Many very unpleasant, nasty meetings with OMB staff about consolidation.

RT: In the other phase of your responsibilities, there was an international aspect. What were some of the salient experiences in that realm?

RO: In discussing that, would you cover FDA's increased interest in international activities?

SSH: What happened was that, when Carol Scheman left as the Deputy Commissioner for External Affairs, I was still working for Mary Jo Veverka, and I had let David know that I wasn't exactly happy in that role. [Laughs] I had a very good relationship with Dr. Kessler, and as a result of the fact that I had a good relationship with him, I tried to be a good trooper, even though it wasn't always pleasant.

When Carol left, he came to me. It was the funniest thing. Oh, I know what happened. Jane left first. Jane [E.] Henney left. Margaret Porter approached me and said, out of the blue, "You would be a great person to be the Deputy Commissioner for Operations," which had never even crossed my mind. I couldn't figure out why Margaret thought I would be great in that job, but she did. We talked about it, and I couldn't quite get myself really believing that I would be good in that job, but I also was so unhappy in my current job that I was willing to even consider it.

I talked to David about it. I remember he said, "Why don't we talk about it. Can you meet me at my house?" one morning. David was not an early riser.

So I remember going to his house one morning, having his wife come down and meet me. She still had her bathrobe on. We talked for a long time. David wasn't convinced that was the job for me, either, but he was willing to at least explore it. I think he had something else in mind, but he was willing to at least explore it. So we talked about it and we talked about it.

Then finally what happened is, Carol announced that she was leaving, and David came to me one day and he said, "Pauline and I were talking (Pauline was his wife), and we think that's the job for you."

I thought, "Well, thank you, Pauline." [Laughs]

I wasn't even convinced that that was the job for me, because it had public affairs, legislative affairs, consumer affairs, health affairs, and all these other offices. I had been a person who, my entire career, had been doing administration and internal management stuff, and all of a sudden, there are all these external-looking offices. It was August of 1993, I think. I can't remember. It was, I think, '94 that David approached me about this. I was getting ready to go on vacation, and I said, "David, I'm going on vacation for three weeks. Let me just think about it."

I came back from vacation and I told him yes, and I went into the Office of External Affairs as the Deputy Commissioner for External Affairs.

International affairs was part of the Office of Health Affairs, but there had been a big fight between the Office of Policy and the Office of External Affairs about who was actually going to do international. Linda Horton had gone to the Office of Policy as head of a small international policy staff, but still in external affairs there was the international affairs staff, and the centers were getting beat up between the two of them about who's doing what. And so Carol left and Mike Taylor left, and so there were two key vacancies: Deputy Commissioners for External Affairs and Policy.

Bill Schultz and I came in very much around the same time, so one of the first things we had to decide was how we were going to resolve this problem about international, because it didn't make sense the way it was running. And David tried, he really did. He tried to come to some Solomon-like decision about this, and what he said to me is that he really felt that it

belonged in external affairs. But Linda Horton was not at all happy about that, and Bill supported her, as he should have, I think. So we stayed split for the longest time. We couldn't resolve it. We stayed split.

But I felt that international was assuming enough importance that it deserved to be an office on its own and not subsumed under health affairs. So what I did was take the international affairs staff out from under Stuart Nightingale in health affairs and make it a standalone Office of International Affairs under Walter Batts.

And because I had done that, it sent a signal that FDA is acknowledging that international affairs is becoming a critical component of how we function, and it really was. We were being bounced back and forth on so many trade-related issues because of the administration policy about breaking down all trade barriers between the U.S. and Europe. There was the Transatlantic Partnership, there was the Transatlantic Business Dialogue. There were all these things they were saying in trying to eradicate trade barriers between Europe and the United States. But here we are, we're a public health agency. We have to maintain the public health standards. So the only way that we can get in there and protect public health, while still supporting the administration's trade agenda, was to get in there and be full partners in the international arena, so that we would be on the scene when all of these discussions and negotiations were happening, so that we could protect our public health interests. They just became a bigger and bigger part of everything we were doing. What was happening in Europe was affecting us, and we needed to be full players at the table.

So I got very closely involved, because some of these things, you have to have a "title." You don't send just any person to these White House meetings that were constantly happening on

international trade issues that affected our regulatory responsibilities. So I found myself doing more and more international work.

David, ostensibly, as the head of the agency, was the person that they wanted, but David wouldn't play. So whenever he was asked to go to this meeting or that meeting, he would say, "Sharon, I want you to go."

But he and I would do things where it was absolutely critical for him to be a part, like the health minister from Israel was coming to Blair House and wanted to meet with the commissioner, and so David and I would go and participate in the meeting.

I remember the health minister asking David to please to come to Israel to help them with some issues involving clinical trials and David saying, "Okay, I'll do it," and everyone telling me, "David's never going to Israel."

I said, "Yes, he did. He told the health minister he was coming," and the next thing I knew, I was on a plane to Israel.

Or Ron Brown, who was our Secretary of Commerce, asking David to please come to Spain for the Transatlantic Business Dialogue, the very first—

[Begin Tape 2, Side B]

SSH: David told Secretary Brown he would do that, and everyone said, "You might as well start packing. You're going to Spain." And sure enough, he never went to Spain. He asked me to take a message to the secretary and explain why he couldn't be there. He just never traveled, and so I found myself doing a lot of the things that the commissioner should have been doing internationally.

But it was important to me because I saw how the whole horizon was changing and how so many decisions that were taking place in foreign countries were affecting how we regulated. They would negotiate a trade agreement that said we will find equivalence, for instance, and they would want us just to kind of go along with it, and FDA had to fight for its ability to continue to regulate. So my staff ended up being involved in very tense negotiations with the Europeans on things like equivalence, because we wanted to protect our ability to do our job, but we didn't want to appear to be standing in the way of what the administration wanted to accomplish as far as removing trade barriers.

RO: When you talk equivalence, you mean equivalent inspections of their manufacturing plants?

SSH: Right. For instance, when they decided that they were going to have this comprehensive mutual recognition agreement with the Europeans, where the ideal would be that we each would recognize each other's actions, whether they be approvals or inspections or whatever, FDA had to get in there and fight long and hard to circumscribe narrowly what mutual recognition meant. To us, what we finally got agreement on from the Department of Commerce, the Department of State, and from the Office of the U.S. Trade Representative was that in the area of pharmaceuticals, biologics, and devices, we would negotiate an agreement that provided for mutual recognition of inspections, once we determined that they were equivalent in the way that they did inspections. Furthermore, what the Europeans wanted was for us to find that Europe, as a single entity, was equivalent, but we insisted that we would have to go country by country. We

But all of these activities started taking more and more of our time, because as they were off negotiating various trade agreements, they were negotiating away, if you will, our ability to do our job, and we had to be there to fight and protect, in the interest of public health, for our ability to maintain our standards.

I think more and more we will see that global standards are what—well, let me just say this. I don't know what September 11th may have done for any of this, I really don't know, but I do think that global standards will be what happens in the future and that it's important for FDA to be a full player at the table every time there's a global meeting. If there's going to be one set of standards, we want to make sure they're the kind of standards that we would want, that they're not a set of standards which end up lowering public health protection.

My staff ended up going to negotiations in South America and all over Latin America, all over Asia, all over Europe, everywhere, because that's where the meetings were happening. That's where the trade meetings were happening. Why does the FDA need to be at a meeting of the World Trade Organization? Because we never know when they may be negotiating something that affects our ability to regulate.

David didn't want to play, but he understood the stakes; he really did. He understood what was at stake, so it was his desire that we be players in all of these places. We didn't have the department involved at all. FDA would go to the White House as FDA, and I would sit there at the table representing FDA, and no one thought that was unusual or strange or anything like that. I was in meetings all over the world where FDA was looked to as the single-most important agency for public health protection in the world, where I would be representing FDA, and people from all over the world would be listening to what we had to say because we were considered the world leaders.

It started changing as Europe began to flex its muscles more, and we started having to fight for our standards versus somebody else's standards, because the European Union was established mostly as a trade entity, and so their main concern is trade. Our main concern is public health. We would find ourselves at meetings where we were fighting public health issues with people who were only interested in trade issues, and that's why it's important for us to be there.

RO: Normalization has been kicked around. What is it?

SSH: That's a new term. I'm not sure I know exactly what it means. I developed a lot of good friends in the European Union, but it was always good friends knowing that we were approaching things from different perspectives. I think it's critical for FDA to be able to stand up for its standards in these different world meetings.

What I noticed after this change of administration is that FDA was given significantly less freedom to go and speak independently on its issues. The department has assumed a much more substantive role. In fact, they will go to meetings where FDA issues are being discussed and not have a FDA person with them, and I think that may be problematic for the agency.

RO: In your new role, you have, what, three or four different staffs?

SSH: When Jane came, the one thing she did was finally consolidate the international responsibilities. She took the international policy staff that had been in the Office of Policy and gave it to me, and I merged it with the other Office of International Affairs, and created the Office

of International Programs. That office had four staffs: the international affairs staff, international trade policy staff, international scientific activities and standards staff, and international resource management staff. So those were the four staffs within the Office of International Programs. But in addition to those, the Office of International and Constituent Relations included the Office of Women's Health, the Office of Consumer Affairs, the Office of Special Health Issues. I think those were the four. So it was International Programs, Women's Health, Consumer Affairs, and Special Health Issues. I think that was it. But the one that clearly took up most of my time was the international.

RO: Since you are leaving, who is replacing you? We realize you can't be replaced.

SSH: Well, they decided not to replace me. They split the office up. So the international part now reports to Mac Lumpkin. He's the acting deputy commissioner. Mac was one of Janet Woodcock's deputies at CDER, and then about a year and a half ago, he came to the Office of the Commissioner as a senior medical advisor.

Jane had decided, when she came, that she didn't like five deputies. Jane had decided the five-deputy concept that David had put in place, she didn't think much of, even though she had been one of them before. But she didn't think much of it. So she decided that they were going back to the old model of only one deputy, but those of us who were deputies were allowed to remain as deputies as long as we were here.

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As they left, each new one became a senior associate commissioner instead of a deputy. So Jane's model was, senior associate commissioners and one deputy commissioner. So that meant that when Bill Schultz left, Bill Hubbard became Senior Associate Commissioner for Policy. When Bob Byrd left, Jeff Weber became Senior Associate Commissioner for Management Systems. And when I left, they didn't replace the Deputy for International Constituent Relations. Mac Lumpkin became Senior Associate Commissioner for International and Strategic something. But he's also the acting single Deputy Commissioner. Originally, when Jane advertised for a deputy commissioner, a single deputy commissioner, I was on the search committee and I interviewed the candidates, and it was decided that none of them was what she was looking for. That's when she asked Dr. Schwetz to be the acting deputy commissioner while she was here.

So when Jane left, Bern Schwetz, who was the acting deputy commissioner, sort of became the acting principal deputy commissioner. Eventually they started calling him the acting commissioner, but now I don't think they call him that anymore. I think he's still the acting principal deputy commissioner. But Mac Lumpkin is the acting deputy commissioner in that "one deputy" role.

After I left my office was split up so the people that were the constituent outreach offices, like consumer affairs, women's health, and special health issues, report to Linda Suydam, who is now the Senior Associate Commissioner for Community and Constituent Relations, or something like that, and the international people report to Mac. So I was not replaced.

RO: What do you think of the future of the agency?

country leaves gaps, because you're coordinating with too many different agencies: the Department of Agriculture, FDA, National Marine Fisheries Services, CDC. I mean, there are too many people who have a finger in it, and maybe there does need to be a single food safety agency. And so that may happen. But as for the rest of the agency, I think it will continue to exist and continue to do what it does.

As I said, I believe that what happens internationally plays a more important role every day in what we do. The whole issue about genetically modified food was not an issue at all for this country until the Europeans got up in arms about it, and then it became a big issue because it was a trade issue. Our corn-growers couldn't export their genetically modified corn to Europe because the Europeans were suspicious of genetically modified products. Once it became a significant trade issue, it became a significant regulatory issue for FDA.

I felt that that was going to happen more and more, that some other countries' perceptions of an issue were going to impact upon how we have to regulate here. You can't grow this bunch of corn for the American population, and grow this bunch of corn for the European population, because then the Americans are going to say, "What's that? Why is it okay for us, but it's not okay for them?" I mean, people will question those kinds of things. And that's why I say we're going to have to work hard on coming up with some kind of global standards that everyone can live with, or else everyone will be affected by what goes on in any corner of the world.

RO: FDA has said there's really no problem with genetically altered foods. So you're telling us that it's the trade as far as the European community is concerned and not a health issue.

SSH: Well, the European people feel that, for some reason, that it may be a health issue, even though the leading scientists are now saying this is not a health issue. But farmers in Europe have a vested interest in perpetuating this as a health issue in order to keep our products off the market. And it's the same thing with beef. They didn't want any hormone-fed beef. They perceive that as a health issue. But basically these are trade issues. At the end of the day, they're trade issues. And our concern is because it has had, in some senses, a devastating impact on our ability to export products.

RT: How about irradiated food? Is there any difference in perception in European countries?

SSH: They don't want that, either. They don't want anybody tampering with their food. As long as we want to be able to send these products abroad, then we have to figure out some way to accommodate some of these concerns. They want us to get involved in certifying things, that things are good enough for the European market, and that's another issue. FDA has enough problem keeping track of what's going on domestically. We don't have time or staff to be able to certify that a product meets some standards in some other country. But this is becoming, again, more and more of a part of what consumes a lot of people's time, how to reconcile public health and commerce, basically.

RO: What I'm hearing is, you thoroughly enjoyed your last assignment.

SSH: Absolutely.

RO: Probably more so than any other assignment in FDA.

SSH: I think that's true. I think I enjoyed it thoroughly, and even though I had trepidation at the beginning about doing external affairs-type work, I think I did it probably better than almost anything that I had done previously.

RT: Was there any particular reason for your decision to retire at this time or did you just feel sort of burned out?

SSH: I think that I was just burned out, really, more than anything.

RO: Have you had withdrawal symptoms yet?

SSH: Not really.

RO: No, I don't mean just from the FDA, but with all the travel and all.

SSH: Well, the truth of the matter is, I traveled far and wide. I saw places I never dreamed I would see. But I had gotten to the point where I didn't want to get on another plane to go anywhere. My last trip was Singapore last August, and I was glad for the opportunity, but I could have easily passed it up, too. So I have not had withdrawal from travel at all.

RO: Did it ever bother you, when you were over in those countries, to stop and think that you were really the spokesman for the agency?

SSH: Truthfully, Ron, I think that was getting to me more than anything. It wasn't that I was just a spokesman for the agency; I felt I was the spokesman, in some issues, for the whole United States Government. After a while, you think, "I'm not sure I want to do this anymore."

I think, again, that the whole environment was changing. Previously, as I said, FDA could pretty much say what it felt was in the best interest of the American people, because we were the leaders, we were the experts at what we did. I think more and more it was becoming obvious that what I consider more political concerns were influencing what we were permitted to say, and I found that difficult sometimes; I really did.

It's like the people at this level, between the U.S. and the EU, could work together very well. But once it got into this rarefied political atmosphere, you had to fight battles that you didn't necessarily think were necessary or that you agreed with. It just got harder and harder to do that; it really did. I'm not saying that I couldn't do it, but it wasn't nearly as much fun to do.

RO: Did you say that with the change of administration now in the last year, you felt there was a different role that the agency played than you did before?

SSH: Clearly. Absolutely. We used to be able to decide for ourselves what was important for us to do, where it was important for us to be, and we would send people. The first thing the new administration did in the department was to require that all foreign travel be approved in advance by the department, which is a cumbersome process, at best, sending all the trips downtown to get their okay before people go places. Obviously, in an emergency you can send someone to go do inspections and things like that, but it was just another way of controlling. Then requiring that

by the department, which is a cumbersome process, at best, sending all the trips downtown to get their okay before people go places. Obviously, in an emergency you can send someone to go do inspections and things like that, but it was just another way of controlling. Then requiring that people go and report back about all the meetings, what went on, and everything like that, and we were not allowed anymore to go to meetings at the White House without—

RT: Was the role inside the department also minimized with regard to the agency's presence and input? You mentioned the White House was not a free place to go anymore except through the department. Is the agency still actively heard in the department, do you feel?

SSH: I think it's gotten better over time as they've gotten to better understand the agency. I was just talking with Linda Suydam last week, and she was saying she had to go downtown for a meeting on user fees with the deputy secretary, and clearly they know that the agency has to be full players in these kinds of discussions, but in some of the trade issues or some of the international issues, what I was feeling is that we were being held in check, and the discussions would take place at the White House and other places without even involving us, even though they were our issues, and I think that's a difficult way to have to try to do business.

RO: Sharon, this has been most interesting.

RT: You've given us a lot of insights for the historical record that haven't been there before.

SSH: I hope it's been helpful.

SSH: No, not really. I just hope it's been useful for you guys.

RO: It has been.

RT: Thank you very much for giving us this interview.

SSH: Thank you for asking me.

[End of interview]