

**History**  
of the  
**U.S. Food and Drug Administration**

**Interviewee:** Stephanie Gray

**Interviewer:** Suzanne Junod, Ph.D.  
Ronald T. Ottes  
Robert A. Tucker

**Date:** April 11, 2000

**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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PLACE: Rockville, MD

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INTERVIEWEE:

NAME: Stephanie Gray

INTERVIEWER(S):

NAME: Suzanne Junod, Ph.D.  
Ronald T. Ottes  
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FROM: August 1972

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TITLE: Director of Compliance, Center for Drug Evaluation & Research (CDER)  
(Last FDA Position)

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RT: This is another in the series of FDA oral history taped interviews. Today, the interview is being held with Ms. Stephanie Gray, Director of Compliance in the Center for Drug Evaluation and Research (CDER). The date is April 11, 2000, and present with Ms. Gray are Dr. Suzanne Junod, Ronald Ottes, and Bob Tucker.

Stephanie, as we begin these interviews, we like to have a brief history of where you were born, raised, educated, and any work experience prior to your joining the Food and Drug Administration. So would you please begin in that way.

SG: I was born in Kansas during the second World War. I only lived there about six months or less, but the important thing is that my parents are both Kansans, so no matter where in the world we lived I probably had that Midwestern influence.

When I was three, we--we meaning my mother, father, and younger sister at eighteen months--flew down to Brazil.

SG: I may be the only FDA employee who was under house arrest at the age of three, because my mother forgot our joint passport, and so the moment we landed in Belém, Brazil, and this was back in the late forties, we were all three--my mother, sister, and I, and nobody knew any Portuguese--put under house arrest for failure to have the proper paperwork.

Now that wasn't too bad for me because they had these mosquito nettings over the bed that made it look like I should be a little princess, and I was treated like a little princess, so it wasn't a bad start in Brazil.

So we lived there for five years and came back here and lived in the Midwest a few years, and then in Boston a few years, and I graduated from high school in Boston. I went to college, first to the University of Arizona for a year in Tucson; then Simmons College in Boston, a women's college that specializes in the sciences; and then the University of Kansas. I graduated with a bachelor of science from the University of

Kansas, went on to a dietetic internship at the University of Kansas Medical Center, and a master of science degree there in nutrition.

I'm smiling because I'm coming up on a decision of how many secrets to tell.

SJ: Why nutrition?

SG: Why nutrition? They were all personal decisions, and my change from one school to another was always a personal decision. I went to Arizona because I was tired of the snow in Boston. I came back to Simmons because I got homesick. I went back to Kansas because that's where my parents went to school and really wanted me to go there, and I didn't enjoy Simmons that much, partly because I was living at home for part of the time and so on.

And nutrition because I thought that was more challenging because of the chemistry, and I liked chemistry more than teaching—my mother had been a teacher—or being a nurse. The nurses were screaming, “We don't want to be handmaidens to the doctors,” and that was a little too stereotypical for me; so I went into what was really at that time a more scientific thing, nutrition.

My secrets are that during that time at the University of Kansas Medical Center, I dated Carl Peck briefly, and we're going to have to keep this closed for five years if I tell you the next thing. I dated Bob Graham once or twice. I'm sure that he doesn't remember me, and I feel certain that our commissioner has no knowledge of this.

Let's see. So at the University of Kansas Medical Center, I met and married my husband. He was a medical student who eventually became an orthopedic surgeon. When he finished school and I had finished school . . . Let's see, my first . . . I won't say my first job, but a preliminary job was as a dietician at the Children's Hospital in Kansas City in the Endocrine Clinic for the kids. So it was the PKU babies, the diabetic kids, the juvenile diabetics, and so on.

When I married, we moved to San Francisco, where my husband did his internship, and I first went to work for the Solano County Public Health Department. They were--probably still are--a mostly Roman Catholic county, but they had an extremely high maternal and infant mortality rate. So they applied for and got federal funds for family planning, so called, and what it really meant was the whole family. Looking after the newborn babies, the children, and so on. They had a nutritionist slot, and so I started part time and eventually became full time.

That was fascinating because I got to know the population subgroups. I got to know California as a newcomer and also the population subgroups. The Filipinos coming in who had bought their x-rays to get in and had TB; the American Indians or Native Americans now. I remember one woman who was an American Indian woman who had married a Spanish man, and he wouldn't let her out of the house. And she was accustomed to the great outdoors and at home in the great outdoors, and she was really sad and also got TB, and I thought had she been able to go out and be healthy and be in the sunshine, this wouldn't have happened. And the reason I was there was for the nutrition education for this woman and others like her. Also the migrant workers at the migrant camps around Solano County, and the poor black people, the kids who were having too many babies at thirteen or fourteen years of age. So it was a real education for me.

From that I went to the University of California at Berkeley and got a master's in public health, and did an independent study in food law with a lawyer who argued against FDA. He said, "If you are going to understand food law, you have to interview the folks over at FDA."

So I went over and interviewed Ron Fisher and Bill Hill and found out they were hiring, and in March I applied for a job. They were hiring women inspectors, but Bill pointed me toward consumer affairs work, which I really enjoyed.

So in August I started with FDA as a Consumer Affairs Officer (CAO).

SJ: What was that, early seventies?

SG: Yes.

RT: When did you join FDA?

SG: In 1972--Project Hire.

RT: You came in as a Consumer Affairs Officer?

SG: Yes, one of three.

RT: Right. The first complement of three Consumer Affairs Officers.

SG: And I rinsed my hair red at that time, so we had a blonde, a brunette, and a redhead. (Laughter)

RT: I guess at that time was Bill Hill the District Director?

SG: Bill Hill was the district director. Ron Fisher was the director of compliance. Irv Berch was the regional director. Jim Nakada I think was there, but I'm not sure whether he was there then or when I came back to San Francisco the second time. Actually I'm not sure of when Irv Berch was there. I think maybe he was there the first time actually.

RT: As a CAO, what kind of activities were you assigned initially?



SG: Well, having just come out of Berkeley, I could speak counterculture, and there was a strong counterculture at Berkeley then, and the big issues were limiting the amount of vitamins you could get before they became OTC, food labeling, and what FDA was doing to limit what we fondly know as health fraud which is now called nontraditional medicine or whatever.

So my part in that area was northern California and Hawaii. And, of course, it was getting in touch with the educators, the press, and the professional health people. I mean that was my primary mission. My interests were the people that I thought carried the most weight in the community, and those were health professionals, universities, not so much the high schools and the press. I can remember going over the Berkeley to talk about food labeling and what we were proposing to do with vitamins and minerals, and it was the first time I was in real fear for my personal safety. You know, how a room full of heavy-breathing people can just exude hatred. Well, luckily I could speak their language, which included the way you breath and the intonation. So I think in a kind of a subliminal way that de . . . What do I want to say?

SJ: Diffused?

SG: Diffused, thank you, that situation.

RT: At that time, you were dealing with the media. Did you get exposure through television appearances, as well as these seminars?

SG: Yes, a lot of TV work. One of the things that, you know, when you're first starting out in work and you've come from Berkeley where there's a certain dress code, and you go to work for FDA where there's another certain dress code, so you have to make some decisions. My decision was that dressing the way I wanted to dress was a

luxury. I'd better dress to fit in at FDA, because things were different there; and I better dress appropriately every day, because if I got up feeling tired, that would be the day that the TV cameras would roll in unexpectedly. So that was a good discipline to learn early on.

RO: How long were you in San Francisco then?

SG: I was there just short of two years, I think, because then we moved to Boston because of my husband's training. I was very grateful to Bill Hill for calling Boston and arranging a transfer at my expense, but at least I had a job. I transferred to Boston and met Jim Beebe and Richard Davis and spent two years there as a CAO. And maybe this is interesting . . .

RO: Who were the CAOs . . . ?

SG: I was afraid you would ask that. Yolani Harsani was the senior CAO, and there were two others, whose names I don't remember. I could describe them to you, but I don't remember them.

But at any rate, the dynamics in the Consumer Affairs Office were such that I had retained that title but was assigned compliance work, and I did compliance work for a year. The people in Boston would say, "You should demand a promotion. You should demand a temporary promotion." And I said, "No, if I make any demands, they'll just give me CAO work, and as long as I'm doing compliance work I'm getting the experience," I thought to myself, "to be competitive to apply for other jobs."

RT: What grade level were you at that time?

SG: I think I was a twelve. I started as an eleven. Of course, that made investigators starting as fives and sevens jealous. But I had two master's degrees and work experience, so I didn't think I was getting any special deal.

So . . . What?

RT: Being one of the earlier professional level women in the agency, was there any particular burden or difficulty you experienced because of your gender?

SG: Oh, I think so. I don't know how candid to be. There certainly were stereotypes in FDA that I was unaccustomed to coming from Berkeley, and there were stereotypes in FDA I was unaccustomed to coming from a family with two children and being the oldest child and only daughters. People have been asking me what are my achievements, and I have been right now reluctant to name firms that I'm glad we got our hands around the necks of or other kinds of things. So I've tried to be diplomatic publicly, but to myself I'm thinking, "You know, what are the things that I accomplished?" And one of the things is being a woman and surviving and prospering. And that's not all because of me, because the people who gave me a break were the men at FDA. They gave me a break, they supported me, they counseled me. I think they did their best to be fair as they understood fair to be at that time, and we've all changed in what we consider fair and appropriate behavior.

But I went to a talk not too long ago, and an off-color story was told from the podium, and the people in that man's agency were ready to hang him, and I thought, you know, in FDA we don't have to worry about this anymore. The guys don't do that anymore, because our standards and what we think is right has changed.

So when I talk about being a woman and some of the trials and tribulations, I don't link that with criticisms of the men. I've admired most of the men, and the men I haven't admired, you know, are for other reasons.

But one of the things I was thinking to myself is that I managed to stay out of bed and make the guys friends, and I think that's important. I think it's really foolish to do that with the people you work with.

RT: When you got into the investigational role, were there any particular cases or incidents that you were involved in that resulted in significant regulatory action?

SG: Well, you see, I was never an investigator. I had a two-month detail as an investigator and got sent back to a warehouse three times because I didn't collect the sample right. But my first experience along those lines was as a compliance officer, and I did lead an investigation . . . I mean, the investigators went as far as they could, and then they couldn't anymore. That was Camomile which was a so-called nutritional formula for kids. This guy was just as slippery as could be. He went up into the woods north of San Francisco, and I made an appointment with him, which he then called to cancel. I got on the line and talked him into keeping the appointment. We went up and met him, and I didn't want him to get away. So I offered to ride with him while he took us to his so-called manufacturing site, with the rest of the investigators trailing behind in another car. They all thought I was a hero because I would get in the car with him. And he was funny. I mean, he was . . . He'd say, "How am I doing so far?" What he was doing was telling us this big long lie, and then he'd turn to me and say, "How am I doing so far?" I had a hard time keeping from laughing.

RO: So what was this?

SG: Camomile. And it was . . . You know, it was in a time when the Infant Formula Act was just new and, of course, that came about because of problems, and so-called natural food was big, especially in northern California, so this guy had a good

idea, a natural infant formula. But he was making it in a deserted house, and when we asked him to show us his manufacturing technique, how did he crimp the cans closed, he sat down on the floor, held the can between his knees like this, and crimped it closed. It was all a setup. You know, it was just a big setup.

RT: What was the town? I didn't quite catch the place.

SG: I said northern California because I can't remember the nearest town. But it was out in the woods. It was like in the Russian River Valley, and he was tricky. He was tricky enough to double back if we were following him and, you know, he had eluded us for five weeks.

RT: How did the agency first become aware of him? Was it an interstate shipment situation?

SG: You know, I don't remember. I might be able to remember, and if you ever get a hold of Wayne Blondell, he could probably remember better than I can. He is in San Francisco the last I heard.

SJ: So he took you to a nonexistent manufacturing plant?

SG: Well, we wanted to see his manufacturing plant. He had rented what was basically a deserted hotel, and he had one little room or two where he claimed he manufactured. But it wasn't a manufacturing facility. And, you know, I don't remember the rest of it, but we did get our hands around his neck somehow. Wayne could tell you.

RT: This was when you were in the role of a compliance officer at San Francisco.

SG: At San Francisco, so we've skipped a whole trip around the country. But when you asked about interesting cases, that's the one that came to mind.

So maybe I should go back and say . . . OK. So I was in San Francisco. We moved to Boston, where I did the compliance work. At that time, I guess one of the interesting things that happened is, I can't remember the case, but the man in question came in with his lawyer. It was the first time I was having a 305 hearing, column hearing or whatever it was, as a noncompliance officer. Of course, Jack Hamilton was there, and everybody was like, "How would Stephanie do?" There were probably another couple of real compliance officers there.

So there was this back and forth. The guy was supposed to be deaf. So we weren't to ask him any questions; we were only to talk to his lawyer. So the compliance officers were talking to his lawyer. Finally we got to sort of the high point of the hearing, and I asked him a direct question, and he answered me. (Laughter) He wasn't deaf. But, you know, when things like that happen, it sort of turns to . . .

And back to women's issues, there were probably some advantages being a woman at that time, because the fellows didn't know how to deal with us, and you could pull little surprises.

RO: Oh, come on now.

SG: You don't think? (Laughter)

RO: Before you mentioned that from Boston you went to Puerto Rico.

SG: Puerto Rico, yes, and that was again because my husband was activated by the navy. So we went down to the Navy base, Rosy Roads at Puerto Rico, and I think Jim Beebe was instrumental in my transfer there.

You know, that's why I mean, all these men were instrumental in keeping me in FDA, and by doing that, by, you know, making the request to transfer, again at my expense, but they did that, and I think Bill Hill also, as an ex-navy man, had put his weight into that--so Cliff Shane was the regional director there--that builds loyalty in people. You know, I felt the agency had helped me out and responded when I asked for something. So it really built a lot of loyalty in me.

RO: Were you a Consumer Affairs Officer then?

SG: I went to Puerto Rico as a program analyst. That was when POVAC started. One of the first things that happened was that you, Ron Ottes, and Paul Hile called all the Program Analysts in to straighten us out on POVAC. That was my start.

SJ: POVAC?

SG: Yes, POVAC, which was Operations Versus Accomplishments. It was the first kind of computerized system of accomplishments and stuff, and it was pretty good.

SJ: Predecessor to PODS (Program Operations Data System), I guess.

SG: Yes. PODS was part of it. How much do you want to hear about that?

Well, in Puerto Rico, I was a program analyst. Everybody knew or figured that I reported to Cliff Shane, and that's where my loyalties were, and Puerto Rico was pretty much telling stories and being uncooperative, telling big stories.

Delbert . . . What was his name? He'd tell these huge stories to me with a straight face, and I knew he was telling me a story. But I was so naive, I didn't figure out how to hit him between the eyes with it.

RO: Who was the district director in Puerto Rico?

SG: Max Crandel.

RO: Max Crandel?

SG: Yes. I could tell a lot of stories, but maybe I'll not.

Anyway, I was on this navy base. It was fifty miles away from the downtown location of the district office, and it took two hours each way on the road, and it was dangerous driving. So my friends at the navy base said, "Why don't you learn how to fly? It'll be so much faster." So I did learn how to fly. It was a great place to learn how to fly because the mechanics on the Cessnas were the navy mechanics, and the instructors were the carrier pilots. There are no better pilots in the world, and they loved flying, and it was fun. And I did learn how to fly, and I did occasionally fly to and from work, but not very often.

RT: Were you ever contracted or asked to fly in behalf of the work for the agency?

SG: No, no. I don't think women's lib had gone that far yet. (Laughter)

SJ: Did you have an actual license?



SG: Yes, I had a license, and I learned not only to fly single-engine land, but a glider, because a CO (Commanding Officer) at the base was a glider pilot. And then when I came back to California I got rated in single-engine sea planes. But I did it as a hobby, and I wanted to do it for fun. Nobody ever asked me to fly for work.

RT: Well, there have been a few occasions where persons who had private planes and licenses have done some couriering of samples, and I just wondered if that ever had happened in your case.

SG: I think maybe when Three-Mile Island blew, one of their investigators was a pilot.

RT: Bob (Robert) Brands at Baltimore did some of that.

SG: Yes. No, I never did.

SJ: Jerry Halperin tells the story of getting, upon his retirement, presented with a certificate for the most expensive, unauthorized procurement in the history of HHS for commandeering a navy aircraft, I believe, to pilot some sort of aircraft to transport what they needed at Three-Mile Island. Anyway.

SG: Well, TMI was a big deal. It probably was a good thing to do.

OK. So from Puerto Rico, after two years, we moved back to San Francisco because my husband was going into private practice there. And Bill Hill was there, and I went back there as a CAO. Let's see. One of the things that was happening then is food labeling. So one of the fun things I had to take charge of, almost immediately after getting back, was setting up the food labeling hearings with Don Kennedy. Those

hearings were so popular that from a schedule of two days' testimony, we had to extend him to three days. You know, I thought of all kinds of things like, what if we have an earthquake, we've got to train our folks to get the people out of the hearing and so on. But what I didn't think of, because we didn't think so much about it in those days, is security, other kinds of security. One of the men testifying, who looked a little strange, walked in with a briefcase, sat down at the table, put the briefcase down, and opened it up, and by then you could see fear on the faces of the whole panel, Don Kennedy and whoever the other folks were. People were literally looking over their shoulder for where the door was. And I was thinking, "Oh, my God. Why didn't I think of that?"

But he opened it up, and he pulled out a green banana to complain about the quality of bananas. (Laughter) So that was kind of funny.

RO: These were the regional hearings that they were holding.

SG: Yes.

SJ: What was the major feedback the agency was getting, at least in your interpretation, on that coast as far as the food label? Did consumers have an idea of what they wanted?

SG: Consumers wanted food labeling, and I think they were not organized about what they wanted because there were all different kinds. But they wanted food labeling, they distrusted food, and industry was unilaterally opposed to food labeling. But, you know, that's one of the differences in the agency then and now to me. Don Kennedy said, "We're going to have food labeling," and we had food labeling. It turned out to be I think a very good thing for food industry now, because people are interested, they're more sophisticated, and so on.

SJ: Were there any particular foods that people were concerned about?

SG: I don't remember. I don't remember that.

SJ: None of them stuck out in your mind.

SG: No. What other story was I going to tell about San Francisco?

Oh, yes! We had this hearing set up at someplace that didn't have a telephone, so we knew that Don Kennedy would need to have a telephone nearby, and this is where it pays to know your folks.

Bill Hill and I really knew that a fellow named Tony--and I can't remember his last name--in the lab could jigger walk and rig things up. (Laughter) So I asked Bill Hill for permission to ask Tony to rig an illegal telephone, and he gave it. So Tony appears with this big brown grocery bag at the site of the hearing and rigs this illegal telephone so Don Kennedy could have a telephone in case anything came up.

So from San Francisco--

RO: Wait now, before you left San Francisco, you went from being a CAO into the compliance branch.

SG: I did.

SJ: Formally.

SG: Yes. I applied for the position when it opened up, and I had more than a year's experience because of the time I had worked at compliance in Boston. I think there was more pressure to select women. You know, I think that's true. And I got selected.

Ron Fisher was the director of compliance and Bill Hill was the district director and Irv Berch was the regional director, and the other compliance officers were Rod Shu and Alex McCormick and Lou Edmonson and Steve Gross. Lou Edmonson was just wonderful teaching me over and over again what to do. Alex McCormick I think was the backbone of the whole operation. I remember those two with particular fondness. Alex was real capable, and Lou could diffuse the situation with his funny . . . He's so funny.

RO: Any interesting cases that you worked on?

SG: Well, that was the camomile. I did a lot of import work, and so I had developed some opinions about imports. What else was interesting? I did some medical device work. I don't remember any particular cases. I could probably go look if it mattered.

I got divorced and entered a mid-level program. By that time Ron Johnson was the district director. When Ron Fisher left, and the position was open, I applied for compliance branch chief. Steve Kendall was selected, and I did not admire Steve Kendall at all.

SG: OK. So Steve was selected branch chief, and I didn't admire him. So I applied for the mid-level program, and Ron Johnson wrote me a nice recommendation, and I got into the mid-level program. Of course, that was career changing. I thought in the mid-level program what I needed was to do real work and get known by people in the field so that there wouldn't be a worry about me as a woman, but they would know me and my chances of getting selected would be better.

So my first detail was as DIB (Director of Investigations Branch) in Los Angeles with George Gerstenberg, and the big case then was the counterfeit Naprosyn made by Syntex at the time. This turned out to be a huge case because there was money

laundering involved, millions of dollars, the guy was Iranian, he skipped to London. It was really an interesting case, and this was before OCI (Office of Criminal Investigation), so we could do the whole thing. I remember being, you know, a brand new, on detail DIB at that time, sending folks out to do what was basically undercover work without training, without protection, without communication, and I thought, "God help us." We're sending people in to do something where they're going to have to rely on their wits, and we're not backing them up, and it really is unwise of the agency and not fair. I worried quite a bit about the safety of the investigators going out to do the work.

RT: What period of time was that?

SG: Nineteen eighty-six, eighty-seven.

RT: The undercover work wasn't necessarily drug related? Is that correct?

SG: It was counterfeit drug. See, these guys had gotten smart, and they figured out that they could make more money by counterfeiting one of the top four legitimate drugs than by doing street drugs. So they were crooks, they were big-time crooks. But they were just counterfeiting Naprosyn which is a big seller, and they could have gone on for years had not a pharmacist noticed that it didn't dissolve properly, and we got a complaint from the pharmacist, who also complained to Syntex, which was in San Francisco District at that time, and that's how that started. It was sort of one step at a time, and we found the people doing it. We found the equipment, the presses, and so on, and we found the bulk raw materials.

But you know what was very difficult and why I think we were not as successful is once it got into the distribution claim, it was impossible to track, and that's maybe

where PDMA (Prescription Drug Marketing Act) can help or it wasn't long after that that we got that Prescription Drug Marketing Act which was intended to make the chain or the integrity of the drug clearer.

RT: Ron, do you recall when the office of criminal investigation was organized? That was after the period that Stephanie is speaking of?

RO: That was about in '87 or '88 when it came along.

RT: So it was kind of concomitant with this.

SG: Just shortly after that.

RO: Right after that, yes.

SG: But it is no fun to be responsible for sending somebody out onto the streets at night up against serious crooks.

RO: Of course, by that time, a lot of the fellows who had worked on, you know, the old OTC program weren't available. I suppose they had probably left.

SG: Yes. What's the word for serious crime that I can't recall right now?

SJ: Felony?

SG: No, not felony, but . . . The people we think of as the Mafia and tax evaders and so on. These were real criminals, and real criminals change their method of

operating over time, and we were sending people not only who had no previous experience, but they couldn't even draw on the experience of the people who had, because the crooks they were dealing with were so much more sophisticated. We used some computer printouts and printouts of telephone calls and stuff. So we were starting to use more sophisticated documentation of crimes than before.

RO: But you were successful.

SG: We were successful.

RO: But not as totally successful as you would have liked.

SG: That's right. And with a lot of concern, you know, for the safety of the folks on the front lines.

RT: So not only were you successful in the undercover investigation, but this presumably then led to some regulatory or penal action against the perpetrators?

SG: Yes, it did. But I think they had to pick him up in London.

You see, I was only there one month, and during that month we did get the raw materials, and I can remember having to arrange for the trucks and going out there myself and looking at it and, you know, these fifty-five pound drums of powder that wasn't what it was supposed to be.

I'm trying to think of who was involved in that. Tom Sawyer could tell you a lot about that. And Debbie . . . What was Debbie's name? She's left Los Angeles and gone someplace else. Cincinnati the last thing I remember.

RO: So this was all part of the mid-level program?

SG: This was part of the mid-level program.

RO: And then you went from being a DIB to a . . .

SG: Well, at the end of the mid-level program, I got selected to be a real DIB in New Orleans.

RO: No, but I mean some of the other times that you had as a midlevel.

SG: San Juan had a vacancy, I think it was maybe right after Lynn Campbell left, and I called Jim Beebe and said, "I know this is skipping a grade," because I was only a thirteen, "but if you need somebody, I'd love to go there, I've been there before, kind of know how it is, and I'd be happy to go in the middle of summer when it might be harder to get other people." And he was nice enough to send me there for thirty days and extend me for nearly another thirty days.

RO: As lab director?

SG: As director of the whole thing, district director.

RO: Oh, as district director?

SG: See, so that was a big thing to go from . . . I was a compliance officer, I was in the mid-level program, and Jim Beebe put me in there as district director, and that's what I mean by the men in FDA gave me a break, gave me a chance, supported me.



RT: What was the year that you served as director there? Do you recall?

SG: As acting? I think it was 1987, but I'm not sure. And you know who followed me--the tall guy who got killed in Chile. What's his name?

SJ: Pat Pouzar.

SG: Yes, I never met him, but we'd talk on the phone before he came, and eventually we started comparing our sizes, and, you know, I'm not real tall and he was real tall.

SJ: Mutt and Jeff. (Laughter)

SG: Yes, yes.

RO: So then when you got out of the mid-level program, you went in as a real DIB in New Orleans. Bob Bartz.

SG: Bob Bartz. Best boss I ever had.

RT: Nice guy.

SG: Nice guy. And you know what? He took time to be my friend, and I learned a lot from him about people. That was really my first supervisory job. So he took a chance on me. My first supervisory job, he puts me in as a DIB? He had been there for something like fourteen years, and this was the only branch chief selection he had a chance to make, and he selected a woman? The only thing that could've been worse is if I'd been a black woman.

And, you know, I'd heard the stories about blacks in New Orleans. So when I left San Francisco, I told the only person I thought could do anything, I was this concerned, I said, "If an accident . . . If anything happens to me, don't believe it was an accident." Yes. There were some not nice people in New Orleans. And you don't believe me, but that is, you know . . . There were some not nice people in New Orleans. And I could tell you stories.

I told one story to two men who are not in FDA, because I worried about what if a similar thing would happen on my shift. How would I handle it? And as I told the story, I could see the muscles in their jaws harden. The one who'd never worked in government said, "I'd kill that guy." And he, you know, he was only partly kidding, he was just that infuriated over the action. And the one who had worked in government said, "I'd find a way to get rid of him." But those things didn't happen.

One of my triumphs in New Orleans was the day this guy came into my office, having convinced Bob Bartz that we should participate in a raid on an abortion clinic. I knew when I went there that there would be some tough times. And I had to talk him out of it. So some of my triumphs are what we didn't do.

RO: You mean that these people actually worked for FDA that weren't nice guys? Or just the people?

SG: No, sir. That's the director of compliance there, the former director of compliance there, in New Orleans.

SJ: On what grounds would they be raiding an abortion clinic?

SG: Well, that's exactly it.

SJ: There weren't any.

SG: They came in at about ten o'clock and the raid was going to be at eleven or something. The state had called him up supposedly. I mean, this was all stories coming from Jim . . . What's his name? What's his name? It begins with an 'M.' And I thought to myself, "If the state really wanted us to participate, wouldn't they call us before one hour ahead of time? What's going on here?" And Bob was, you know, Bob was all excited. "We're going to do this raid." And I said, "On what grounds? And how do you suppose I'm going to explain this to Ron Chesemore when he calls me in there?"

So, you know, sort of one step at a time we talked through it, and that was where I learned the value of body language when people come in and confront you. You lean back in your chair and you start asking questions. Pretty soon Bob could see the handwriting on the wall, and we did not participate in that raid, and I believe the raid never took place. But it could have been a mess for FDA. I mean, there's no reason. We didn't have any justification for doing that.

SJ: So what else? How long were you in New Orleans?

SG: For three years I think, and I enjoyed my time there, and I think Bob Bartz was a really good boss. And Bob got selected to go to Atlanta when Kinslow left, Maurice Kinslow. So that was the time when we had the magnificent seven, who'd been through this special force to be district directors and there were eight DD slots. So the magnificent seven--some of them, not all of them--went to DD positions, and there was San Juan left over, and I applied for that, and Bob Bartz selected me, I think because he knew me, and that was going to be isolated. When I went to San Juan, he said,

"Your job is to bring that district into the Southeast Region." So that's when I went to San Juan.

SJ: And you did.

SG: Yes. It was kind of putting it back together again after Lynn Campbell had been there.

RO: Then you came into headquarters.

SG: Yes. When Dan Michels left, Gerry Meyer supposedly wrote fifty letters asking those people to apply for the job, and I was one of the people who got the letter. So I applied for the job, and I think Gerry . . . I had known Gerry Meyer sort of distantly, just because he'd come to San Francisco every once in a while when I was there and give a talk, and I think he was instrumental in my selection and I think I was an acceptable candidate to Gerry and to Richard Davis and to probably Ron Chesemore because there was friction between ORA headquarters, Philadelphia, and the center.

RT: No!

SJ: Which center?

SG: The Center for Drugs. You know, I had experience in drugs in Puerto Rico, and that was the limit on my experience in drugs really. But I was known to all those folks, and they thought I'd be an okay person.

RT: What year did you actually come into that assignment?

SG: In '93 I came to Washington.

RT: You've worked there since that time to the present?

SG: Yes. Six and a half years which is the second longest thing I've done in FDA.

RT: During this particular phase of your career, were there some highlights that might be worth mentioning here?

SG: Well, in Puerto Rico, Warner Lambert . . . Warner Lambert managed their side of it very deftly, because every process we looked at had a major GMP problem. They ended up . . . And we didn't have the resources to look at the processes for every drug they manufactured there. They ended up taking fourteen to sixteen drugs off the market, claiming business reasons, but it was really the pressure we had put on them, and they didn't want or were not able to clean up the processes and all. But they announced that and somehow had a more important announcement, so it got almost no press coverage.

It took--as Mary Mason said--it took a lot of my knocking on doors up here to get the case taken. I mean, people were just ignoring it. I don't know if it was because they ignored Puerto Rico or they didn't want to deal with Warner Lambert because they were a big Capitol Hill player. I mean Gerry Meyer was worried about it; that they were a big Hill player. But they were the maker of Dilantin. They had product drift in Dilantin you wouldn't believe, and we thought it was so that they could manage to avoid having a generic drug made. They can't copy it right because they keep changing it, and, you know, you can avoid the competition.

So that was a big case. And one of the funny things that happened there--only partly funny--the Pink Sheet did a pretty full and complete and accurate article on what

was going on with Warner Lambert. There was a reporter at *The San Juan Star* who took that Pink Sheet article, reworked it minimally, sprinkled it with "Stephanie Gray said" in quotation marks, ran it in *The Star* attributed to me, and I ended up on the carpet with Ron Chesemore. I never told him this; he just bawled me out. And I said, "Yes sir," and went back. I figured I was pretty dumb not to tell the reporter not to quote me, because she did come in and talk to me, but I knew better than to say the things that were in the Pink Sheet. So that was one of my lessons.

RO: In headquarters, any big major compliance accomplishments?

SG: This is just between us for at least five years? The accomplishments are that things aren't worse than they are. There's just no support for compliance, there's no support for regulation, there's no real support for the mission.

RO: Is this due to the center? Or is it due to the agency?

SG: I think it's first due to the center and second due to the agency.

RO: Because you've had several center directors.

SG: No, I have not. I have had one center director who came on six months after I started and is still there.

RO: Oh, I thought you came under Dr. Peck.

SG: I did come under Peck, but I came in October, and I believe he left in November, December, or January. Gerry Meyer left about the same time, and Janet Woodcock came in February. So that's the major influence.

SJ: You also came in the hay day of, the aftermath of AIDS, I call it. Is part of the reason that they were not looking as interested in compliance having more to do with the drug effort, the massive effort to speed up the drug approval process? Did you get tangled up in that? There was no PDUFA (Prescription Drug User Fee Act) yet, but they were getting there.

SG: I don't think that's the primary thing. PDUFA did result in very uneven budgeting, and even more than it appears, because you have to put a certain amount of the budget, the appropriate budget, toward PDUFA issues before it triggers PDUFA. So the have-nots were even more disadvantaged than it looks like they would be.

But I think while money is important, what's more important is the philosophical support for the GMPs, the protecting and promoting the health of the American public. And I think there was complete disdain for compliance as part of that in the center, and it was a pitched battle the whole time. It was not just a pitched battle with the senior people there, but there was a pitched battle with the Office of Pharmaceutical Sciences and that leadership to take over the quality issues. It was a total encroachment.

The GMPs, the regulations. I mean, they proposed things that were specifically counter to the GMPs, and they didn't address we've got to change the GMPs, they were making end runs. It's a serious, serious problem in my view. It might be mitigated a little bit because the person leading that charge has left the agency, but I don't think it's mitigated enough. I think there is real troublesome erosion of the GMPs within the agency, within the center, and if you think that doesn't have something to do with why I'm leaving . . .

RO: What about the quick approval process? The agency has always been criticized for not approving drugs soon enough. Then in the last year, there's been several instances where drugs that have been on the market, are going to have to be taken off. Do you think if they'd had a little slower approval process it would have prevented that? Or is it that we don't have enough population involved in the premarketing testing?

SG: I think that the approval process is not just too fast, but it allows for absolutely no dissension, no disagreement. Any of the reviewers who disagree are ostracized, and that's not a way to make good decisions. So maybe they could do it as quickly as they do if they would give some time to the people who are troubled by something they find, and that is a more serious thing to me.

SJ: It was heard that Kessler had said that he was happy to speed up the drugs if the companies were willing to take them off the market just as fast if there was a problem. Have you seen that being upheld?

SG: I'm not close enough to that to make a judgment, because I'm not on the reviewing side, I'm on the compliance side which is post-approval manufacturing, and so on.

SJ: Were you responsible for implementing the GMP checks before the drugs, the final approval was given?

SG: Yes, the pre-approval instruction program.

SJ: The pre-approval . . . ?



SG: Yes.

SJ: Would you like to speak a little about the evolution of that and the implementation?

SG: Actually that was in place. It started about 1991, when I was a DD in Puerto Rico, and I remember the drug committee coming in and Richard Davis talking about it. So it was really his concept, and I see him as a man with a lot of vision and a lot of powerful thinking capacity in behalf of the agency, and I'm sorry that things got the way they did.

So I was dealing with that in Puerto Rico as a DD, and Puerto Rico's main business is drugs, so we have some experience with it. I came into the center, and like anything new, it needed to evolve, it needed to be more controlled, more timely, more dependable, the results available faster, and so on. We worked a lot on those kinds of things, getting the assignments faster, sort of projecting what they might be, communicating with the industry, making sure what we could put into a computer program so that there would be immediate access to whatever information was known would get known, the EES system, the Establishment Evaluation System, providing for, if a request for an inspection came in within a two-year period, and there no problems, the district evaluation to be made without actually making an inspection, and some flexibility that way.

SJ: To bring up a less than wonderful topic probably from your perspective, but we try to anticipate the kinds of questions people are going to have in the future, and I think one of the questions they may have is about the investigation of Robert Feddes and the Southern California Research Institute. FDA was supposedly apprised at irregularities about seventeen months allegedly before we actually did some investigation and follow

up and found another incident. Do you recall if that time frame is about accurate?  
What do you recall about that response?

SG: I recall very, very little about the Feddes case, and what I would need to do is go back and look at the documentation, and it's partly because there were so many issues and so many cases that I didn't try to keep them in my head because I was afraid I'd get something crossed over and I wanted to depend on the paperwork, which I learned as a compliance officer is a lot more dependable than what somebody is telling me. So usually when a question comes up, I said, "I need to look at it," and it's because I haven't made an effort to remember the details.

SJ: Yes. Did you have any interactions with Amanda Peterson's office and the Office of Ombudsman?

SG: Yes, very much.

SJ: And you've mentioned something about how compliance seems to be strengthened. Is there any . . . ? Is that money that's still being . . . ? That's not coming under PDUFA, am I correct? There's no way . . .

SG: Only minimally. There are some FTEs (full-time equivalents), PDUFA FTEs in the Division of Manufacturing Product Quality that manages the preapproval inspection program.

SJ: Has industry, has HACCP, has any of the quality control programs . . . ?

SG: HACCP.

SJ: That's in the food industry.

SG: Oh, HACCP. H-A-C-C-P? Hazard Analysis and Critical Control Points, yes.

SJ: Hazard Analysis and Critical Control Points, right. Sorry. Has that made any difference? Are the companies themselves taking this initiative? Is there less of a need for compliance programs, which is I think what industry would want us to believe?

SG: In the foods area?

SJ: No, obviously in drugs.

SG: In drugs? Oh. We don't talk HACCP in drugs. We talk controlling critical processing, controlling all processes and validating the critical processes, and it's the same concept I think that you need to have a reasonable amount of control according to what the process is and where it is in the greater order of the manufacturer of the drug, and you need to identify the critical points and validate those critical points. But that's the way it's usually described in drugs rather than Hazard Analysis and Critical Control Points. They're the same concept, wouldn't you say?

SJ: But is industry taking responsibility for that thing in a way that they haven't in the past so that they can justify less resources?

SG: I think good industry understands that that's important.

SJ: Are there growing inequities between the good companies and the ones who are sliding back?

SG: In drugs. See, drugs is real different from devices and real different from foods. I was going to say we have a growing inequity, but I think our lack of oversight has resulted in the Pfizers, the Scherings, and similar firms are not just out of line on manufacturing, they're out of line on the reviewing side. I mean, it's just major, major, and it takes a long time to get that way, and they're not getting squared away very fast either.

So for me to say there are not many problems isn't true; there are problems. But I think the concept of validation is accepted, which it wasn't in the beginning. There was a lot of arguing against it. And I think companies in general, when they have their processes controlled, can do a very dependable job. Does that answer your question? Maybe you should ask actually the question again.

RO: Is the agency going to get back to making the mandatory biennial inspections? Or is this a thing of the past?

SG: No. Our biennial twenty-four month is now at four and a half years, and whether it gets back or not, I don't know. It's in ORA, which isn't getting them done.

RO: You should have programs in the Center to accomplish this.

SG: We do have programs over there. But there's only so much resources. And I think we've gotten our fair share, or more than our fair share, of inspectional resources, ORA resources, because they've done preapproval inspections, because, you know, that was really a critical thing to do. And it is. It's the best program we've ever had, and I give Dick Davis credit for that, because it is at the pivotal point where the company is most interested. I mean, they need to get past this inspection in order to get their drug approved, so they'd better get it right.

And they didn't do that before. Before they'd still be basically trial and error on the first several batches that went out. So this is good for the industry, and it's good for people taking the medications. And it's good for FDA, because it gives us a good control point and a good point of reference.

RT: Has there been any congressional oversight over the CDER during the time that you've been in compliance that relates to compliance rates? Any hearings or congressional interest?

SG: Well, when I came to the center, that was the time where the Dingell Committee was meeting with generic drugs once a month or once a quarter, and their staff people were frequently coming out to FDA. That changed when the administration changed or, as you know, the Republicans took over the house, and so there wasn't as much oversight or interest. I don't know that I have a good overall sense of that. You know, I can tell some again little stories.

At a DIA (Drug Information Association) conference in Boston . . . Now that's six thousand people come to this conference, and mostly it's the CROs (Clinical Research Organizations) who are contract organizations to review the clinical studies to develop drugs. So there's just a little . . .

RT: We're recording again now.

SG: OK. You let me know when. Yes. I've got the story back in my head.

At DIA meeting in Boston a couple of years ago, there was a session on counterfeit drugs. So I was on the panel and Bill Gross from Eli Lilly was on the panel. It wasn't particularly well attended, the group, but I looked at the back of the room and I could see one of the fellows from GAO and two of the fellows from the congressional

staff. When Bill Gross started in on his stories about counterfeit drugs, I knew that he didn't know who those people were, because he was telling about Lilly's problems with counterfeit drugs and really being quite complaining--I don't mean that in a bad sense of the word--but, you know, being very vehement about the problems and the issues dealing with counterfeit drugs.

So when he was done, he said he had to make a plane, and shot out of the room, and these three guys shot out of the room after him I'm sure to ask him for details. Of course, he will complain about what happens and what FDA does and mostly what FDA fails to do, but what he does not want to do is be specific about Lilly's problems because he wants not to have Lilly's name in the press or likely to be leaked to the press. You know, they have a certain protective feeling, and I can understand that. But I'm sure he would not have been as candid had he known who was in the room.

So your question was about congressional oversight. That was one time when the GAO and the congressional staffers got more than they might have expected. I think maybe they have those DIA meetings on their list now, which is a good idea because if they go to the trade meetings, DIA, ISPE, PDA (Proprietary Drug Association), they'll hear what the issues really are, and I think the better educated they are the better job they can do. So it's in all of our interests for them to know more about the issues.

RT: Thank you.

SG: You're welcome.

RO: I think you've told us why you are leaving the agency, but would you care to expand on that?

SG: Yes. It's also time. It's time. The longer I wait, the harder it's going to be to do the next thing, and I want to do the next thing and I'm looking forward to my next job.

SJ: Can you tell us anything about it?

SG: Yes. My next job is as vice president Worldwide Regulatory Policy and Quality Strategy with Glaxo Wellcome which is merging with Smith Kline Beecham and will probably be the largest drug firm in the world. My work is going to be again in the manufacturing--not the clinical side or not the reviewing side, but the manufacturing side. I think I'll be doing similar things to what I'm doing now. In other words, I intend to be an ally to FDA, and I believe Glaxo intends me to be an ally. I'm delighted to be joining them because I think they're a preeminent firm and in the time that I've been in compliance they have always, always intended to do the right thing. I did not want to join a problem firm. So I'll be preparing then to be receiving the results of the MRA (Mutual Recognition Agreement) and smoothing their product across borders because each little country has a different set of regulations and some of them are in conflict.

SG: Sort of a Mary Pendergast . . .

RO: Glaxo Wellcome also has a domestic regulatory side. You're the international side. Is that right? Or is this all one?

SG: Well, you know, I don't know their structure. I haven't started with them yet. I'll start in about a month, and I don't know their structure well enough to know that. I believe that what they have is a manufacturing quality organization that doesn't

distinguish between domestic and international, because they are a UK company and it's a multinational company, so it would, you know. But that's the way I think it is.

RO: It's very interesting.

SG: If we're coming to a close, I have one or two things that I would like to say. Did I say that I thought it was good that things weren't worse than they were? That's my accomplishment in compliance? Did I say that?

RO: Yes.

SG: OK. The other thing I wanted to address is being a woman. A lot of times I've been the only woman or been the first woman, and that means not having a role model, which people see as a difficulty. But the flip side of that is you're free to develop your own style and set your own standards, and I appreciated that. I really liked that kind of freedom. I'm not sure I would have wanted a role model unless I thought it was very, very good, and I didn't think that they always were very good. So everything I guess has two sides.

RT: Well, Stephanie, we appreciate very much this interview, and we'll look forward to getting it back to you for your review and finalization. Does anyone else have anything they wish to add? We'll get your address and so forth.

RO: Yes, get your address where you're going to be, because it'll probably be a month and a half before we get this back to you.

SG: OK. I'll be in the same place for now.