

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

**Interviewee:** Steven M. Niedelman

**Interviewer:** John P. Swann, Ph.D  
Robert A. Tucker

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Interview with Steven M. Neidelman

November 13, 2007

TAPE 1, SIDE A

RT: This is another in the series of FDA oral history interviews. Today, November 13, 2007, the interview is with Steven M. Neidelman. Participating in the interview are Dr. John Swann and Bob Tucker of the FDA History Office.

Steve, if you'd begin with a brief overview of your personal history and education; then we can move into your regulatory career with FDA.

SMN: Gladly.

I grew up in New York City, and, surprisingly, went to college in Kansas, in the Midwest, to learn what a different lifestyle could be outside the city. I went to a college, what was a small college, that is since defunct, as many of them are out there, the College of Emporia, which was a private college, which had been established for quite a number of years. I graduated with degrees in biology and chemistry.

Upon graduating, based upon the economy situation of the times, there wasn't an awful lot going on, and I was approached by the government, by FDA, to come in for an interview. Back then you took a Civil Service Entry Exam -- and was thrilled to be interviewed and very proud to be able to say that I was an FDA employee.

RT: What year did you graduate?

SMN: Nineteen seventy-one.

JS: When you came into the agency, was that part of Project Hire, or was this after Project Hire?

SMN: I was part of one of the groups that was hired under Project Hire, which was an enormous hiring initiative by FDA. In New York District, we came in three waves, and I was part of the second wave, along with many other folks that I worked throughout my career with. I was fortunate enough thereafter to be able to assist the agency in recruiting under other hiring initiatives. But, yes, I came into FDA under Project Hire along with a lot of other folks.

RT: Were you recruited as a Consumer Safety Officer?

SMN: I began my career as a GS-5 Consumer Safety Officer in New York District, Brooklyn, New York, and learned the ropes from the bottom up, and was trained for a number of years before I'd be able to go out and do inspections on my own.

JS: Was this typical training at the time for an inspector, investigator, in the agency?

RMN: Yes. Unlike recent times where there's greater pressure on the agency to get folks

out as quickly as possible, there was a fairly rigorous training course for Consumer Safety Officers upon their entry. I mean, it went on for quite some time.

For the longest time -- and I can't recall exactly -- you weren't allowed out by yourself at all. You were always accompanying and witnessing experienced investigators doing what you would consider at some point to be the most routine jobs later on. But they were a challenge, and it was always chain-of-custody and the importance of documentation and the importance of everything that you did that laid a good foundation and groundwork for how you built cases and how you regulated the industries.

RT: Were you recruited in New York District or out in the college?

SMN: No. I was recruited in New York District. I had been back home by then.

I had some other jobs, fairly menial jobs, between the time I graduated and started with FDA, and this was really my first real job after college, and I chose to stick with it throughout my career.

JS: So you went through the good old food-and-drug-law course and the evidence-development course and lots and lots of on-the-job training. I assume this was for a general purpose. You didn't develop an expertise in one particular product area at this time. Right?

RMN: No. At that point, you wanted to learn it all. And as most investigators started back then, the goal was to be a generalist. You didn't have a really active device

program back then. We were first getting into biologics, first getting into blood banks and areas like that. Basically, you were either a drug inspector or food inspector. Most people cut their teeth on the food area because it is a little bit, not necessarily simpler, but it's a little easier to do. And certainly in New York, having the wealth of warehouses all over the place, it was very easy to develop an expertise in that area.

And then, as time went on, based upon your performance, aptitude, and desires, folks were targeted to get drug training. We didn't have formal device training back then; I guess I did go to device school right before I left New York District. And each of us developed new areas of expertise that we began to nurture.

RT: Who was the Director or Chief of Investigations in New York District?

SMN: It was Joe Faline at the time, and George Gerstenberg was the Regional Director.

In fact, my first supervisor was Jerry Woyshner, who ultimately became the District Director in FDA's New York District. When he retired, he had stayed at New York all of his career. I ran into him several times. I was fortunate to have a good dialogue with him.

RT: When you came in, were you initiated in a ceremony by the District Director?

SMN: We were sworn in, absolutely. We were sworn in, as we currently do. In the ACRA's [Associate Commissioner for Regulatory Affairs] office we'd swear folks in, at least when they started their careers in headquarters.

JS: Even historians get sworn in.

SMN: Right. So when you start your career here, you get sworn in. If you're part of ORA [Office of Regulatory Affairs], you get sworn in up at the ACRA's [Associate Commissioner for Regulatory Affairs] office.

We were sworn in, absolutely, and it was a moving exercise, and being a young kid at the time, it was sort of exciting.

RT: The reason I asked is that we interviewed someone else who started in New York, and that individual thought Mr. Gerstenberg was rather abrupt in his initiation of new hires.

SMN: Well, that's a personality thing. You know, I learned to get along very well with George. After he left New York District and went out to the West Coast and headed up the West Coast area in Los Angeles, and, of course, I was much more seasoned and mature, as I was running more programs. I would travel out there to do training and assist with speeches, etc. We developed an excellent rapport and I realized that he's a human being like everybody else, and I'm sure he had a lot of frustration and a lot of pressures on him in New York District as well, and I really have nothing bad to say about George.

RT: That's good.



JS: Are there some inspections that stand out in your mind, I mean, at this point?

RMN: In the early years?

JS: Yes, in the early years, things that really had an impact on . . .

RMN: There were a few that were really interesting.

There was one, a huge, huge food warehouse off the East River that had rats that were so enormous that Joe Faline used to comment, "Let's just saddle them up and get around the warehouse that way." We found horribly rodent-defiled products throughout the warehouse which I think ultimately wound up in a mass-seizure at the facility.

But there were a lot of unique inspections, like one facility -- I'm sure it's no longer there -- on Fishers Island, New York, that manufactured topical creams, drugs. Fishers Island, New York, is only accessible through Groton, Connecticut, and you used to have to take a ferry over to this desolate island, this isolated island of homes and golf courses, and it was more like a summer retreat. There was this little company operating out of a garage, and you'd literally have to drive up to Groton in order to make the ferry, and if you missed it for the day, you blew it. You'd go over and spend some time doing this inspection, which was not a lot of time, and then you'd have to wait all day for the ferry to come back to Groton to be able to drive back down to New York. And the reason New York had it was Fishers Island has a New York address. And so that was sort of interesting.

I remember doing undercover buys in Montauk Point and Riverhead for swordfish that, at that time, was contaminated with mercury. I tried to make undercover buys from truckers to see if we can get our hands on some swordfish.

JS: Did you have a certain attire you had to wear?

RMN: Not business attire.

JS: No coat and tie?!

RMN: No, no. And you'd go out and you'd hang around the truckers and you'd hang at the truck stops and you'd do this and that, trying to see if you can make some buys because at that time basically, no swordfish was to be found. There wasn't a ban, but it was, because of the concerns about mercury and the pollution, nothing should be sold, it shouldn't be available. And, quite frankly, that's what we found. I don't think we were able to ever make a buy. But I used to go out, drive out to Montauk every day and see what that was like, and I didn't mind that duty too much either, roaming around.

But we had a lot of fun assignments. We had a lot of good things to do.

And of course, we had at that time some large pharmaceutical firms in New York.

After about three years in Brooklyn, I moved up to the White Plains Resident Post. Even while I was in Brooklyn, Pfizer's main headquarters was in Brooklyn at the time, and that kept FDA busy, for sure.

JS: Was Squibb in your jurisdiction, or was that in our New Jersey District office then?

RMN: New Jersey I believe took care of that, yes.

When I got up to White Plains, Lederle was a big player, USV Pharmaceutical was a big player. That's where, once I got up to White Plains, we really began to cut our teeth more on the pharmaceutical side. And handling Lederle and Ciba-Geigy and USV, I mean, and all the government contracts that were going or were being let at the time resulted in my spending an awful lot of time in these different pharmaceutical firms.

I also learned how to do blood bank inspections and methadone clinics. We'd have to inspect methadone clinics to determine whether methadone was being distributed properly. I remember going to methadone clinics in Harlem, where you weren't sure when you came out whether you'd have a car; you weren't sure when you came out or went in whether you needed protection, you know, not in the ripest neighborhood and with the right clientele.

JS: This involved primarily records inspection?

SMN: Yes, accountability, right; accountability, storage, etc., distribution.

So we did that kind of stuff as well.

And then there were a couple of firms I remember up in the White Plains area that made what I guess is frequently referred to as patent medicines or quack medicine, and we'd go in and inspect those facilities, and that was always neat.

We had Carvel, which at that time was headquartered up in Yonkers, on the river. I remember there being -- I don't recall if it was a hurricane or not, but there was flooding and there was widespread damage to all the facilities along the river as a result of this huge storm. And I remember being assigned to go into Carvel shortly after that to find out what the disposition of their products were, how much was ruined, whether they were still distributing, and etc., etc. And I remember walking in there and Tom Carvel says, "I'm Tom Carvel. Who the hell are you?"

And I said, "Hi. I'm Steve Neidelman, and I'm with the FDA. And what are you doing about this stuff?"

So, I mean, that was kind of neat.

JS: What sort of things did they market?

SMN: Well, they supplied all the local Carvel stands. At that time you had local Carvel stands. I think we had them here in Maryland, small, self-standing stores or stands. That's all they sold, was soft-serve ice cream and cakes and stuff. Now they sell them in the supermarkets, but they provided all the supplies for these franchise stands that were located all over. So it was kind of neat.

But we had lots of great opportunities.

Down in New York, when I was in Brooklyn, inspecting wonton-skin manufacturers in the middle of the night, in the middle of Chinatown, located in

basements that you wouldn't think to go down there in a million years. They operate from three o'clock in the morning until eleven, so you'd have to be there in the middle of the night. And these guys supply wonton skins to all the Chinese restaurants all over the country, where they wrap their own egg rolls or they wrap their own wontons.

So there's a wide diversity of stuff we did. And, of course, being located in New York, you're exposed to a tremendous variety of product on all angles, on all aspects of it, you know, food, drugs, cosmetics, too. We did a lot of cosmetic firms.

We had a lot of the big cosmetic companies in White Plains -- we had Revlon, Avon, and we had Estee Lauder out on the Island. We had another one I can't recall off the top of my head, but there were a number of large cosmetics firms.

JS: I don't want to get ahead of ourselves here, but I'm curious to learn what you have to say about, at what point do investigators start getting trained in a more specialized way? Because this didn't remain the case for very long, did it, that investigators came out and just started doing all kinds of products?

SMN: When you started to show an aptitude. There'd be one drug school a year. Each district will have two or three slots. And if they felt you had the aptitude, if you expressed an interest, if you were able to demonstrate some level of adeptness in an area, and you'd be lucky enough to be selected, you'd go to a drug school. Drug school, for example, used to be a month up at the University of Rhode Island, at the School of Pharmacy, and it was during the summer months, when the University of Rhode Island didn't have regular summer school. There would be two sessions during the summer.

And I assume it was costly for the agency. Wow, if you got selected for drug school -- that was like the cat's meow; that was really the top . . .

JS: Pretty competitive, I gather.

SMN: Yes. It was extremely competitive, and, you know, I was fortunate. I got to go after my third year, fourth year with the agency. And once you got that school, you became a drug investigator. You sort of got labeled -- well, he's been trained, so he can "do it." And we followed some experienced investigators for a while, but you sort of learned pretty quickly on your own.

RT: You probably had achieved a promotion or two at that point, though.

SMN: Yes, it was typical that you would be promoted at a steady pace initially. I mean, most of us started -- not all of us started as GS-5's, went to 7's, 9's. It was much more competitive to become an 11, and even that much more competitive to be 12's. And back then, it was, "Well, how many enforcement actions did you take?" That was really the criteria. What substantive work did you do? And substantive was based upon, not just complexity, but what actions did the agency get? How many -- at that time you had regulatory letters, not warning letters. You had, how many regulatory letters were issued, or any seizures or injunctions or prosecutions at the time, because we were taking misdemeanor prosecutions back then. And that sort of weighed heavily on -- you had to really prepare a heavy-duty package to be able to be considered for an 11 and even a 12.

RT: Some of those grades, as it went along, I guess, qualified you to become a resident, or you had to achieve those levels before you could take a residency. Is that correct?

SMN: To morph into a resident post?

RT: Yes.

SMN: No. Actually, in New York, they took some younger people into the resident posts.

You know, New York is sort of a unique situation because both resident posts at the time was Hicksville, Long Island and White Plains. You know, with no traffic, it was within a half-hour of Brooklyn, 40 minutes of Brooklyn. It was a matter of just getting the people spread around where the industry was. They weren't like many of the resident posts we have today that are really isolated. You really have to demonstrate your knowledge, you really need to be able to be self-motivated and a self-starter. In New York, we had supervisors, we had other things at these resident posts.

They were set up basically, quite frankly, for the convenience of the agency just based upon traffic in New York. To have people out on the Island, people up in Westchester County, it will just save the agency a lot of time than having them commute back to Brooklyn every evening or leave every morning. It would leave very short an inspectional time in the field.

So these were really set up, not like I think some of the resident posts that have been set up now or even, as a result of the bioterrorism act, in really remote areas where you really had to display and demonstrate a proficiency. There were people who were 5's and 7's in the resident posts back then. They had supervisory oversight. And they grew just like the other folks in the district. So that wasn't as much an issue in New York.

And it's probably safe to say the same thing in Newark at the time, because they were heavily populated areas. It was more for the sake of convenience and needs of the Agency that those resident posts I think were set up.

RT: So when you became a resident at White Plains, you had to relocate to your residence then, I assume.

SMN: Yes, we did. My wife and I, at the time -- we had since gotten married, and my wife, who's a teacher, was teaching for the New York City school system at the time. She was teaching in the Bronx anyhow, so we relocated up to Westchester County, which was fairly close to the office. The office was in White Plains and we lived in Scarsdale. It was very nice up there. We really enjoyed it.

In fact, what happened was, before attending drug school, I had begun to do a lot more device work. FDA began to get more into devices, as there was prospect of a device law that was coming along. There were a couple of fits and starts with those. They expected legislation to be passed earlier than later. And, again, I was fortunate



enough to be selected for medical device school before the amendments were even passed.

So I came down here to the Parklawn Building for the very first time back in '95, and attended device school.

JS: Bck in what year?

SMN: Nineteen seventy-five.

JS: Right on the eve of the act.

SMN: Yes, prior to the act. And Alexander Schmidt, I remember, came to talk to us, and it was great. I mean, it was an interesting course in that you really got specialized training in a particular area. And the way they broke it out, on the downside, everybody missed two-thirds of the course because you were put into one of three buckets, one of three categories. So I got training in cardiovascular devices, but then there was also diagnostic devices, and then there was another; I think it may have been orthopedic or plastics or something. But it was a wonderful course, and it sort of really exposed me to medical devices and I really enjoyed it.

JS: Obviously, we had devices under our control since 1938.

SMN: Yes.

JS: No doubt about that. But there were elements in the 1976 Medical Device Amendments -- did we really know what was going to be in that law?

SMN: No, no. But I think the premise was, we needed to start getting people introduced to devices, getting them greater exposure. I think they really did expect the act to pass a year earlier; I think it was anticipated that it would pass earlier.

RT: Did they have any organizational unit set up for devices at that juncture?

SMN: I think at that time, the Bureau of Medical Devices was in its infancy. I think it existed, but it didn't have a lot of authority. I think it was just ramping up and staffing up because there were folks that certainly were part of the Bureau of Medical Devices that assisted in the training. This was a completely FDA-sponsored course. It was down here in one of the conference rooms on the third floor of the Parklawn Building, and it was great. I mean, they took us to Walter Reed. We observed surgeries, we did this, we did that.

RT: Would David Link have been heading that in the beginning?

RMN: David was not at the course, but David certainly headed the Bureau of Medical Devices, because when I went to the Bureau of Medical Devices, he was the Center Director. Larry Pilot headed up the Office of Compliance at the time. And there was a

fellow -- his name was Stretch. But Stretch Kennedy was the Deputy Center Director, and he was about 6'5" or 6'6" back then -- his real name was Robert Kennedy.

So what happened was, I went to drug school and met a woman who knew I had interest in devices. She worked for the Center for Vet Medicine, and her husband was a supervisor in the Bureau of Medical Devices and she tossed my name to him. And he kept encouraging me to apply to come to Washington because he wanted to fill the positions for CSO [Consumer Safety Officer] with folks that had device field experience.

So I did come down here in 1977, a year after the amendments. I applied and was selected to work in what was then the Regulatory Guidance Branch of the Bureau of Medical Devices, providing guidance to industry, helping with advisory opinions and a variety of other things. Since it was a new law, it was really fertile ground. It provided me an outstanding opportunity to really help shape that program. I was the first person to ever use an administrative detention. I was the first person who was involved with and the first and one of the only device bannings -- I think there's only two products that have been banned, but for years it was only one.

JS: Tell us what that was.

SMN: Well, actually, the administrative detention and the banning actions are both associated with the same issue, and Larry Pilot and I sort of devised the program. At that time, there was widespread promotion of synthetic hair fibers, wig fibers, for baldness that they were literally implanting in the scalp and, obviously, causing infection and resulting in, for so many men, having to be scalped to get these fibers out. Because

they'd be inserted into the scalp and knotted, they'd become a wick for infection right into the scalp. There were people that were being injured left and right, and there were a growing number of firms all over the country that were setting up because it was an easy target for money and was widely promoted as a big thing. Franchises were established due to its popularity.

I did, personally, a number of investigations of these sites. In fact, one was also under investigation by the FBI [Federal Bureau of Investigation], and I remember meeting in a hotel room to discuss our mutual findings about one of these sites, and he had advised us, "Just be careful, this guy carries a gun, just in case you see a black bag," so it was kind of neat.

And then we decided, as an Agency, that we needed to test the waters. Nothing would be a better case to test for administrative detention." So we located a facility. We froze the product on-site. We held the first administrative detention hearing as a result. It became a marathon hearing. There was an attorney who I had a lot of respect for on the outside -- his name was Joe Radzius -- at the time, which, he used to be a principal in a firm called Burdett, Bowls, and Radzius. He was a partner with George Burdett.

JS: Burdett?

SMN: George Burdett, right.

And Joe Radzius took their side, and we learned after the very first hearing experience that these administrative detentions could be extremely resource-intensive for the agency. The hearings became witness battles. There are evidentiary hearings. If we

have six witnesses, they'll have seven; if we have seven, they'll have eight. If our top guy is from Harvard, their top guy will be from Yale, you know. And, of course, the government was unable to pay what is required for such witnesses.

But this marathon hearing went on for like 18 hours, and, of course, FDA won. We were upheld and the product ultimately was seized.

Then we decided to pursue the first use of our banning authority, and, again, testing the waters, nothing would be a better candidate. And in that instance, the agency has to make the case to support the ban. It's not just a frivolous declaration. And it took quite a while, but we got the ban through. There was a proposed regulation that was the expedited route. I can't even imagine what the unexpedited route would be. The expedited route was taken because of the imminency of the danger, we were able to proclaim it banned and then offer our action for comment. But it took quite a period of time, a lot of work, and a lot of research, a lot of article search, a lot of library work, contacting affected patients, etc., etc.

So that was a very exciting time back then.

And then, around the same time, we were developing the first GMP [Good Manufacturing Practices] for medical devices, and I was fortunate enough to go out and do the first pilot inspections, because I was still fresh out of the field. And so I went out and did the first couple of pilot inspections for the new GMP back then. They had developed this checklist to go out and do inspections which I absolutely hated, and that was my opinion of it because you didn't get people to think. They just needed to know to check yes, no, and not applicable, and they weren't able to think on their own and apply some of the stuff. But, nonetheless, my vote back then as a GS-11 or -12, whatever it

was, was taken lightly. But that was the initial GMP work, and the GMP ultimately got passed back in '77 or '78. So I got to work on that as well.

Back then, there was a whole different mindset. We would take cases back then that today wouldn't even pass the laugh test. We took seizure actions against cassette tapes that were being promoted for weight loss and for smoking cessation. We took cases against stuff that today we wouldn't have the resources to even consider or think about taking cases -- tons of electrical muscle stimulator cases or TENS [Transcutaneous Electrical Nerve Stimulation] cases. You know, we seized Diapulse devices, and we ultimately wound up working with Diapulse to try to get them on the market for the soft-tissue healing. But stuff that was going on back then, there was a different sense of urgency, quite frankly.

We would have a seizure, if somebody in the District developed a seizure, in particular Steve Kendall, for example, in Buffalo, who had his own pilot's license, he'd literally be at my door by the time I arrived in the morning. That case would be cleared by me, hand-carried over here to the Office of Enforcement [OE], which at the time was in Parklawn and then cleared through General Counsel, and he'd fly home that night with a signed document ready to deliver to an Assistant U.S. Attorney the next day. That doesn't happen anymore.

JS: No.

SMN: That does not happen anymore. But there were a number of seizures that we used

to get through in 24 hours, and the product would be seized by the next day. And when I think about the workloads that we used to have . . .

I went from the Regulatory Guidance Branch and then was recruited to the Case Management Branch under Dan Beardsley. When he had a vacancy, he asked me to come over, and that was where we did the case development, case processing, and get recommendations from the field.

And, again, I assisted with congressional inquiries and stuff like that, and I worked there for a number of years.

And I remember, I applied -- when Dan left -- for the supervisory position. I had acted for a while, and I applied for that supervisory position. I remember being very rejected when I didn't get it. But the reason I didn't get it was I was offered the Deputy Division Director instead, which was even above that. So I worked under Bill Damaska as the Deputy Director of the Division of Compliance Operations. And we handled all compliance and enforcement issues involving devices. At that time, there was a Recall Branch and two Regulatory Guidance Branches, one for devices and one for diagnostic products. We managed a number of branches in the Division. So I got to play in a lot of those areas, which was nice. It was a good opportunity to learn for us.

And then ultimately, because the workload had grown so large, we got split into two divisions, and I wound with one division and Bill kept part of the original division.

JS: What were some of the biggest challenges in the early days, after the Medical Device Amendments? Was it just in educating industry or going out and enforcing the law?

SMN: Well, it was both.

JS: Not that the two are dissimilar.

SMN: A, you have an industry that's basically a mom-and-pop industry, it's very entrepreneurial, it's very innovative. Some folks, that's all their dream is, is to work in their garage, come up with some new idea and develop it. Whether they intend to market it or not -- they don't necessarily look at it for the financial gain, although today probably it's not as much the case.

Here's an industry that basically was unregulated for pre-approval purposes. They didn't have to get pre-clearance prior to the '76 amendment, although there were things that were established as "transitional" devices back then, products that, once they determined there could be potential risk at the time -- intraocular lenses were relatively new that weren't as routinely used as they are today, pacemakers, and things like that, but they were life-sustaining, life-supporting, or implantable, or more significant products to be concerned about -- they were initially transitional products regulated as drugs. And so we used the drug authorities to get these products cleared, and it was a challenge, but we did it.

And so we sort of had to educate. We needed to work hand-in-hand with the industry. As the agency has historically operated, every so often, when industry doesn't get it, you regulate by example, and you take that one or two cases and you make them



the poster child for where the agency wants to be, and for what actions the agency has taken, you hope that the industry comes in line.

I think for the industry, the resource issue was significant. I think a lot of the regs that we developed and a lot of the policies and procedures, you know, the agency historically regulated an environment which is typically large firms, diversified, and all of a sudden you're walking into a firm that had two or three employees, and you're hitting them with these regulations that are all over the place.

#### TAPE 1, SIDE B

SMN: We had a Division of Small Manufacturers Assistance that the statute required be set up. To some people within FDA, that was heresy: How could you provide assistance to the industry? We're regulators; we heavy-duty law enforcement. But you know what? They provide a valuable service to the industry, they really do. They're not supposed to be the sharpest consultants, but they do provide guidance and set them up in the right direction and minimize spinning of the wheels on both sides. The agency has been successful over the years; there's no question about that.

Some of the challenges were certainly resources, being with a new Center, a new Bureau at the time. You're the orphan and you don't necessarily get the resources that you need to really get the job done effectively. So, in many instances, it was long hours, and a lot of people wearing a lot of different hats to try to get the job done.

But working with industry, we definitely needed to work with industry.

And then, when the Bureau of Radiological Health was combined with the Bureau of Medical Devices, it was like the mouse swallowing the elephant. The Bureau of Rad Health was a much smaller organization, and by that time the Bureau of Medical Devices had grown. And John Vilforth and Jim Benson became the Center Director and Deputy.

JS: They were from the Bureau of Radiological Health.

SMN: They had previously been the managers of the Bureau of Radiological Health, which was a very, “un-FDA-like” bureau in that law enforcement wasn’t an issue. They worked hand-in-glove with industry, Mr. Friendly, no bad news or enforcement; there is no reason for enforcement. You just do whatever is necessary to work with industry to comply. And to a certain degree, I think they convinced people that there’s no reason to be heavy-handed unnecessarily, and I think they got their point across.

And then over the years, since then, I mean, you had a lot of significant issues -- the Shiley heart valve -- which identified many flaws in the Act as it existed based on the ’76 Amendments, the fact that you had a product that was continuing to fail, that was resulting in deaths, because it had disks that were escaping and causing blockages. The firm would submit new PMAs [Pre-Market Approvals?]. When they submitted a new PMA Supplement, the Agency didn’t fill their previous PMA, since there was no way to truly evaluate that data. The firm would be recalling product without telling us. This situation identified a lot of regulatory loopholes, which ultimately wound up being closed in the Safe Medical Device Act of 1990 that sort of closed some of those loops, and this was strictly the result of Shiley.

The Shiley situation was very frustrating for a lot of folks, and there were a number of people that had been in the Center for Devices who were very trusting of Shiley, very believing of Shiley, and there were many people that were very suspicious that we weren't getting the full story. And it turned out, after a number of years, that when they were pushed, we found that we weren't getting the full story. And as a result, I mean, they had a lot riding on that valve, the least of which were the liabilities of claims, you know, count the suits against them. But we worked through that, and like I said, this resulted in a lot of significant changes to the Act, in the Safe Medical Device Act of 1990.

JS: You were there, I believe, when the whole issue associated with breast implants came around.

SMN: Breast implants were subsequent to that, subsequent to Shiley.

Dr. Kessler -- David Kessler was Commissioner at the time -- had the belief that certain breast implants were of significant concern, the silicone-filled at least, and working with then Margaret Porter, who headed our Office of Chief Counsel, we sort of went after the industry heavy-handedly, did a significant amount of document review, retained, obtained God knows how many documents, and basically determined after extensive review that these need to come off the market, maybe even stop being sold.

I did very little personally on the breast-implant issue. I sort of stayed away from that and had my own thing to do. There was a special group, a special cadre that were assembled to focus on breast implants, and I was not part of it. Fortunately or

unfortunately, I was not part of it, so I only got hearsay about what was going on with the breast-implant situation. There were certainly opposing views as to how significant some of these findings were.

JS: Within the Center?

SMN: Within the Center, yes, within the Center. There were folks that thought maybe overkill; there were other folks who said no, we're really dead serious. There were concerns about the lupus issue, the autoimmune issue, and that there's something there, and that FDA needed to address. So that got on; that sort of steamrolled along.

I was also part of the Center when Kessler came to me and asked me to help, me and two other people to help develop a strategy to regulate cigarettes as devices, and to figure out a way that they wouldn't be regulated as a drug so that we can get a handle on them and try to do that as best as we could. But the first go-around was killed by Congress, and now I think that's on a track of its own again.

JS: It is. When that happened, when you were in the group that he came to with that challenge, what were you thinking?

SMN: Well, quite frankly, I was sort of intrigued. There were folks who came to the agency and wanted to regulate smokeless tobacco filters -- they wanted to sell certain filters for cigarettes and wanted them regulated as devices, and we literally went through and said, "We don't regulate tobacco. We don't regulate cigarettes. We don't regulate

any smoking product.” In fact, I remember being down at one of the courthouses in D.C., where it sort of got tossed because they failed to exhaust all administrative remedies by requesting an advisory opinion, or file a citizens’ petition, or whatever. I don’t remember the reason. But basically the agency’s position is we don’t regulate these products; they don’t fall within our jurisdiction.

And now all of a sudden, we were trying to regulate these products, recognizing that that may impact what we said in the past, and you don’t want to look arbitrary either. But, you know, what innovative way could we say that the filter of the cigarette was a device that reduced the risk to health, recognizing that the downside, the tobacco side, the nicotine side, is a drug and that, you know, this literally unsafe product. How can we allow it to stay on the market, then, if it was regulated as a drug? So what was the hook that we could come up with that said that the filter had to have pre-market clearance or the pre-market approval or something along those lines?

We came up with something that he bit on, and subsequently created this group of folks under Mitch Zeller, and Natanbluth. In fact, Ann Kirshner, who worked for me in the ACRA’s office, was part of what they created, and they went off and did their own thing.

So we saw a whole variety of different things at the Center for Devices. It was really, the experience was quite good. I know I certainly enjoyed it.

JS: I want to just go back to one thing that you mentioned and see if you might recall. You make a point of saying -- and those of us in FDA know this is not unusual -- that you try to educate people, and when you can’t, sometimes you educate by identifying some

key cases that you want to go with. Do you recall, do any of those stand out in the sort of early years of the Medical Devices Act?

SMN: Yes. I'll tell you a perfect example. We developed -- I was part of a small team, just Ron Johnson and I at the time, and the first action was taken in my group when I was a Division Director at the Center for Devices. We started to think, as the device industry grew and became multinational, and they had several sites and they had different things going on, and they were starting to import a lot of products, some were third-party-provided products, subcontractor supplier-control type stuff. We began to look at these firms in a larger context and would start looking for common findings and loose threads. You know, we looked at a firm's site in Maine and we looked at another site in California and another one in Florida. Were there common problems? What were the findings? Were there any commonalities? Was the Florida site clean and everybody else was out of whack, or whatever?

And what we started to look at was, for example, there was a firm called National Medical Care, which manufactures dialysis equipment and supplies it to its own dialysis clinics, because it sells supplier equipment, dialysis equipment, dialyzers, blood tubing sets, etc. What we found was a lot of the product that was manufactured, the blood tubing, especially, was being manufactured at a plant in Mexico at a lower cost than the United States, and they had huge problems. What we found was, at the different sites, a lot of common problems with all their sites. Rather than attacking them as separate entities, we decided, let's try a corporate-wide approach. Let's hold National Medical Care headquarters responsible for all their facilities. It goes along with the quality-

system notion of a system-wide problem. And it was the first time ever we had a corporate-wide injunction. We basically shut down all their facilities with one filing, and we filed a request with the courts for consolidation. It was all done. And it took months, more than a year, actually.

This is the first time I ever met John Taylor, Jr. He was the GC attorney who was representing us in that case.

In a period of about six to nine months, we took about between five and seven corporate-wide injunction actions against the device industry, to the point where the device industry came in to plea at the time, actually to Joe Levitt, who was then the Deputy Center Director, and begged to be given six months to get the industry cleaned up because they couldn't weather another corporate-wide injunction. Joe approached us in the Office of Compliance. We said, "Okay, no problem, we'll give you six months." We'll see how well they do, but if they don't, we're still going to continue this practice.

So we were the first ones who started that whole notion of corporate-wide injunctions, corporate-wide warning letters. Again, I wrote the first corporate-wide warning letter. It was against a firm which, interestingly, still has problems, another dialysis firm; and, again, multiple facilities having similar findings. And now we just recently, a year and a half, two years ago, Boston Scientific, one was used as well. It's been a very effective deterrent for them. They're not allowed to get any new PMA products approved; they can't ship to certain foreign countries, and it's really had a chilling effect on their ability to remain technologically competitive.

So, in the interest of saving scarce resources, to become more risk-based and to maximize the scarce resources in the agency developing these corporate-wide actions, we

learned to evaluate the intelligence that the agency has and get the biggest bang for the buck where it's appropriate. Can you target a firm? You can look at and evaluate a firm that has a huge number of MDR [Medical Device Reporting] reports and many recent recalls, that is, look at what their inspections look like. You can build a profile and see whether or not you want to pursue an action against a firm. Those are the ones that probably are not taking care of themselves as well as they should be.

The same thing enforcing mandatory recalls. Again, it involved a dialysis product. The first 518(e) actions where we demanded a recall of product. The need for mandatory recall authority for all of FDA's regulated products is now being discussed at President Bush's level. We had it for devices as of the Safe Medical Device Act of 1990.

JS: Are there other products that are subject to that under the FDA's jurisdiction?

SMN: I think there are infant-formula requirements; there are some under infant formula as well. I don't think they've ever used it.

JS: But other ones?

SMN: No; 99.999 percent of all recalls are voluntary actions. The agency may need to coerce a firm into recalling a bit, but with devices they can demand that recall.

JS: I think we can identify a hazard to health under . . .



SMN: 502(j) and . . .

JS: Yes. But, otherwise, medical devices and infant . . .

SMN: That's it. Those are the only ones where you have that authority.

In fact, when the Bioterrorism Act was being passed, I had suggested it for foods, and the thought process within the agency was, well, devices has it, they've only used it five or six times since 1990. Do we really need it? And there's something to be said for that. And some of those recalls, quite frankly, we were very fortunate in the device area in that five of those six recalls -- there may be seven now -- five of those six recalls, one of the premises of this mandatory recall is you have to offer an opportunity for a hearing, one of these regulatory hearings, Part 16 hearings, which are as cumbersome as an administrative detention. And we were fortunate in the first five. They never requested a hearing, so we prevailed.

The sixth one requested a hearing, and, again, a very lengthy, cumbersome, difficult, challenging hearing, and it involved a neonatal jet ventilator, where it was a close call.

JS: What happens to the product in the meantime?

SMN: It's frozen, it's frozen.

But this little ventilator was, this ventilator was being used on neonates, and it was sort of blowing holes in lungs. Despite the information we had from our own experts within the Center that there was alternative care available, because we didn't want to shut off everything, we learned that, while the alternative care was available, it hadn't been used in many years, nobody even knew how to use them. So we were sort of put between a rock and a hard place: were we doing more harm than good, or not? But we prevailed again in that hearing and, actually, the firm ultimately threw in the towel because there had been so much precedent involved.

And after that hearing, everybody thought twice about using that authority again, although we did use it a few years ago in a case down in the Atlanta area, where ob-gyn devices were being distributed without ever being sterilized but were labeled as sterile. But, again, just like another authority that's seldom used as administrative detention, etc. They sound great, but with all that comes with it, people really have to think twice about whether you want to expend the resources or whether there are more expedient ways to get it done.

JS: Did you want to go over anything else on devices before we move on to ORA?

RT: Not that I recall right now.

JS: Okay, okay.

Well, it's around 2001, I believe, that you come over to ORA, to the Office of Enforcement. Can you walk through how that came about?

SMN: Yes. Actually, it was sort of interesting.

I had been at the Center for Devices for about 24 years, throughout the Office of Compliance, and I was actually serving as their Acting Director of the Office of Compliance at the time. I was sitting in for Lillian Gill, who had been asked to come up to the Center Director's office.

There was this announcement for a detail as Deputy Director of the Office of Enforcement under John Taylor, who had just become the Director two or three months prior. And all of a sudden I got e-mails all over the place: Why don't you consider applying? Why don't you consider this? I had not gone on -- I think I was on one detail in my entire career, also to the Office of Enforcement, way back when, when John's father was the ACRA, and the very same position that I was taking this detail for. I applied for the detail figuring it was a waste of time.

And, interestingly enough, I got it. I got selected for the detail. They were 30-day details, and I was the third in a string of three. I even said to my assistant at the time, "They'll probably never even get to me. By then they'll have selected the permanent Deputy," because they announced who was selected for the details, they announced the position was open.

So it turns out that they had some difficulty due to SES changes. I applied for the position, and, again, my arm was sort of twisted by some people. At that time, it was announced as an SES position. It was an opportunity, and I certainly had the breadth of the experience in the office from my experience in Compliance. So I was encouraged to apply, and I did, and I remember spending one Christmas vacation, the entire vacation, 10

hours a day, writing my application. And I made the panel. And I learned I made the panel once I was on my detail. The detail did come to fruition. And after the first 30 days came and went, John said, “Will you extend?” I said, “We can extend, it’s no problem.” I was able to extend from 30, 60, to 90 days.

And in the meantime, I was interviewed for the job. Then President Bush came into power, and all of a sudden these SES positions got lost in the shuffle and they decided they didn’t know how they were going to fill them. At the time HHS didn’t have a Secretary, so they didn’t want to give SES authorities to the agency. It was a political haranguing.

Nonetheless, John ultimately offered me the job, which I took, and I was very pleased. It was something different for a change, after 24 years in one Center. I felt I could learn a lot, increase my breadth of experience by learning what other Centers are doing because I told them, unless I went to an agency-wide meeting, I only knew what was going on in CDRH [Center for Devices and Radiological Health].

It was really refreshing during the detail to know about mad-cow disease, BSE. I didn’t know anything about it other than we had done some work at Devices with some dura matter that was contaminated which resulted in a couple of deaths. I had no idea about the expanse of the problem or the veterinary implications of it.

While I was at the Office of Enforcement, unfortunately, September 11<sup>th</sup> occurred, and the Bioterrorism Act ensued, which I spent a lot of time on, from that point forward, in helping CFSSAN [Center for Food Safety and Applied Nutrition] develop administrative-detention requirements with foods, which paralleled those that were already in place for devices.

I also did a lot of negotiating and a lot of talks on the Bioterrorism Act for the agency with other foreign governments, with Mexico, with Canada, with others, to provide some level of assurance at the border when their products approached there and on the Hill.

We had the great glory of developing warning-letter procedures. Probably John Taylor and I were the two most hated people in the agency. When Dan Troy and the Deputy Secretary said, "Warning letters are out of control. You really need to set up procedures so that they don't become paper tigers," and I think if they could have, we would have been hung by most of our colleagues.

JS: What was your personal thought about that directive?

SMN: I think nobody likes to have all procedures in place, but the reality was, warning letters were out of control. Warning letters were so easily written, they didn't need to meet a statutory requirement: "Well, you know, let's just send them a warning letter." But in that warning letter, you threaten that if they fail to comply, you will take action. And whether or not you met that statutory threshold to reach that action, you were threatening it. Not only that, we were sending warning letters on warning letters because we'd never follow it up. So we'd send a firm two or three warning letters, and they'd never comply. "I'll promise FDA correction." We never went out to verify promised correction or anything. So it sort of caused the agency to refocus and make them more meaningful. Sure, nobody likes them; nobody likes the requirements that come with it. We really did set time frames. We set up systems to assure where warning letters were.

Before that, nobody even was able to account for the letters that were issued. There was no repository of warning letters anywhere in the agency. It was really difficult to trace or find out what had happened -- you couldn't tell what the history of warning letters was.

So we set up all these processes and procedures, and I know, when I was at least here, they were very tightly controlled and we made sure, for example, that any inspection at a firm, nothing more than four months from the date of the inspection, preferably three, but absolutely, if it went beyond four months, no, you're not sending a warning letter. If it's so important to us, we needed to get that out sooner. They needed to become meaningful.

The firm is supposed to respond in 15 days. Well, depending upon the extent of the problem, obviously, some things can't be corrected in six months, but they work towards it. And you can go out and follow up: where do they stand? Then, if they didn't comply or they didn't correct, then you take the next or start the next step.

I think what's happened as a result of personnel changes and things, not to disparage him, but Dan Troy was the lightning rod for this, and Dan left, and I'm not sure Sheldon had the same gumption for it; the attorneys may or may not have the same gumption for it. John left, I left, and so things sort of have a tendency to slide a little bit.

I think the procedure is still being followed since all warning letters get OCC [Office of the Chief Counsel] review, they get OGC [Office of the General Counsel] review, but I'm not sure the follow-up phase of it is as stringent as it had been. I know certainly from the outside, I see firms getting warning letters that are six and nine months after the inspection has been completed, which aren't very timely.

In the Office of Enforcement, we had the pleasure of doing that. We had the ability to hire a lot of people and restructure the office, get people back on track. It was an office that, you know, criticism was one that was lacking over a period of years and one that I think we made significant progress in refocusing and getting them more involved and engaged in agency issues and decisions, and, once again, were brought back to the table when policy issues and other things were going on and that made a valuable contribution. We served as the advocate for the field, and OE helped support their interests by their increased involvement.

RT: Somewhere along the line, the Office of Criminal Investigation was established. How did that tie in with your tenure at the Office of Enforcement?

SMN: You know, the Office of Criminal Investigations was created in '94, I mean '84; '87?

JS: This was right after the generic-drug issue, and Congress mandated its creation.

SMN: Yes, so that was in 1991 -- because I remember doing a lot of training on that.

JS: It was around '91.

SMN: Yes, but they weren't active. They were created, but they didn't get set up and moving till 1994. By the time -- they were authorized to do that, but by the time they

hired the people, set up the infrastructure, got the office going, I think it may have been '94.

When I was with CDRH, we used to work with the Office of Criminal Investigations. They'd identify a case, asked us if we had any interest, etc. In fact, right before I left the agency, I testified for them as a rebuttal witness on a case that developed while I was still at the Center for Devices, and I was the Division Director at the time. So we worked with them, but not terribly closely.

In the Office of Enforcement, they were more of a player. They were more involved and engaged, got to work with them a little bit more closely, especially the headquarters folks, and they were engaged on issues involving counterfeiting because counterfeiting started to grow as an issue for the agency; Internet fraud, Internet issues, as the Internet has become a bane of everyone's existence and has become much more of an issue for the agency. So we developed rapports and relationships with these folks in the Office of Enforcement and learned a lot from them, and I think both ways, and we developed a good relationship with them.

Do they still do their own thing? Yes. Did we encourage them to work as a team? I think we have made progress in having them better engage with the local District Office when cases are being developed. In fact, I continue to hear that, even from the outside, "Oh, yes, we have a great rapport with those guys. We work with them. We know about all their cases, they know about ours," etc., so I think that's good.

I didn't really get to work with the Office of Criminal Investigations till I came up to the ACRA's office, and, in fact, they reported to me. Then I really got to know and value their contribution to the agency.



RT: They are able to carry firearms, which was something our staff never had the authority for, and some of our people used to get into rather dangerous situations. Has the establishment of OCI really given us a forward motion in terms of the safety of investigations?

SMN: I think we've used them from time to time to accompany our investigators on certain cases. I think they don't want to be known as folks that brandish their arms and show them. In fact, I spoke at a conference a year or so, two years ago, I think, where one of the attorneys referenced OCI as, "Oh, somebody comes in and brandishes their weapon," and this and that, waves their gun. And I remember Terry Vermillion going absolutely bonkers over that statement and how -- and it was stated. I think it was unnecessary. I don't think they like that kind of image.

We have used them from time to time, though, on the civil side when we need, if we need some folks to accompany an investigator in a potentially serious situation. Or OCI will arrange for -- and they have done this too -- arrange for local police to accompany our investigators into a particular site. They have a wonderful rapport with the law enforcement community, not just at the federal level, but the state and the local level as well.

RT: Those field personnel are called agents rather than investigators.

SMN: Yes, they are special agents; that's correct. They are called special agents. They have a whole different nomenclature.

JS: Different badge too.

SMN: That's correct; they have a different lifestyle and, you know . . .

JS: Just for the sake of the record, I want to ask another issue about OE.

We did have a cadre of criminal investigators in FDA, in what is now ORA, in the field under the Drug Abuse Control Amendments. We did have criminal investigative powers. They were certainly trained in criminal investigation techniques by the FBI and others. Of course, that's the function that eventually transferred to what's now the DEA.

SMN: Many years ago, when I first came on board way back in the '70s, my former Director of Investigations, Joe Faline, we at one time worked with that group and did undercover buys, buying uppers and downers and truck stops and . . .

JS: Well, I have to ask, though, Steve, did that come in handy with the swordfish undercover work?

SMN: No, didn't help in any way.

JS: I wanted to ask about OE, your experience in the Office of Enforcement in ORA, because we do want to move on to your tenure in the ACRA's office. You touched on this in a couple cases where you talked about the Office of the General Counsel. Obviously, in the Office of Enforcement, you worked fairly closely with OGC, and Dan Troy was there at one point. I don't know if there were others there during your tenure in OE. But I wonder if you could kind of characterize what their enforcement philosophy was like. You must have had your ideas about enforcement philosophy too. And what's your take on that?

SMN: There was no question that Dan had his own philosophy on enforcement, and probably is perceived as very pro-industry, one who would do whatever was necessary to preclude any kind of an action. I know it caused frustration within his own attorneys, within his own group. It caused frustration among the Center folks. I know Center directors at the time, Dave Feigel, for example, from the Center for Devices, would tell me, "I'm not going to ask any questions. I'd rather sit and not make a decision than go before Troy, get a decision that we'll have to live with forever." So, people learned to work around him to a certain degree. But Dan was definitely perceived as very pro-industry and somewhat frustrating.

One example is I wound up serving as the arbiter for the Abbott injunction. There were so many factions within the agency when Abbott was enjoined. You had the Center of Devices and Center for Biologics, you had the General Counsel, and you had the field, not necessarily on the same page. As we progressed and Abbott was enjoined and . . .

JS: What was this about?

SMN: It was quality system injunction, and as a result, they decided there needed to be an arbiter to serve as a voice for FDA with Abbott, and . . .

#### TAPE 2, SIDE A

SMN: So I sort of served as the arbiter among the different parties, recognizing that there had to be a determination made as to whether or not this firm is operating in substantial compliance. They had been paying huge fines for each day they were noncompliant. And there definitely was a sense among the people involved that they were not in compliance. We had a lot of problems within our own agency convincing our Office of Chief Counsel that they were not in compliance, and it was somewhat frustrating to think that there are our experts telling our chief counsel, “No, they continue to have a problem.”

So we ultimately prevailed, but there was a lot of hand-wringing and a lot of frustration.

Dan is very pro-industry, you know: “Well, can’t we work with them?” It gets to a point where we worked with Abbott for years before they were enjoined, many, many, many years. We had partnership agreements, we had everything else. They were given God knows how many bites of the apple. And so we ultimately prevailed.

Dan Troy, for the purpose of those who do not know him, was the Chief Counsel appointed -- actually, he was a presidential appointment that came to the agency.

So Dan was sort of a lightning rod, and as a result, Dan had his own thoughts, and he was very influential on the Office of the Commissioner, probably a little less so once Mark McClellan came on board, but he was certainly influential prior to that.

And it was a challenge to work with him; it was a challenge in many . . . I mean, he was very nice with me, I had a very good relationship with him, I had a lot of respect for him and I think vice-versa. But you knew there were certain topics you wanted to pick on and there were certain topics you decided, "You know what? Let's just let sleeping dogs lie."

JS: Did that influence in the Office of the Commissioner, and the fact that we basically did not have many permanent commissioners confirmed during a lot of that tenure, do you think that had anything to do with it?

SMN: Well, I think he had, I think when he first came in, I guess he came in before Les Crawford came on board as the Acting Commissioner. Was he here when Bern Schwetz was still acting?

JS: I think so.

SMN: So he was the presidential appointee, and he was permanent. And that is typically the case. The Office of the Commissioner, especially the Commissioner, very much

depends upon the Chief Counsel to provide guidance, and they are present at meetings where policy is discussed and issues are discussed. So Dan had the opportunity to shape, rightfully so based upon his position, shape policy and decisions, he being the permanent one and the others not. So I think it was only natural that he had that opportunity to lead.

JS: Right.

Well, John Taylor, the Director in OE, moves on to become the Associate Commissioner for Regulatory Affairs.

SMN: Right.

JS: In or around 2001?

SMN: September, yeah.

JS: Okay, 2001. So . . .

SMN: Actually, 2002.

JS: Two thousand two.

SMN: Two thousand two.

JS: Two thousand two, okay.

And you're Acting Director in OE for a time, I think.

SMN: Yes, three or four months.

JS: And then you joined the ACRA's office as the Deputy ACRA.

SMN: John, shortly after he left to go to the ACRA's office, John and I, we had a wonderful relationship and were very supportive of each other, complemented each other in many ways. John brought a lot of pharma expertise, I brought the device expertise, we worked together very, very well and had a wonderful relationship. When John got to the ACRA office, he realized he needed more assistance than what he had there, and it wasn't long before he realized that he needed to have -- his assistant was Amy Holden at the time, joined him to give the level of assistance that he was accustomed to, and early, early on said, "I've got to find a way to get you up here. I need you here. I need to have somebody I can depend on and get things going."

It took a little bit of time, recognizing that the Office of Enforcement really had nobody behind it, and I didn't have a deputy. I tried to recruit for a deputy, an acting deputy, and some folks, most folks didn't want it. They didn't want any part of that stuff. So I recruited at the time, I remember asking Gene Ledger, who was an institution in the Office of Enforcement, to just help me, and he did.

As the Director, I think I was working 14, 16 hours a day, seven days a week just to stay abreast of what was going on.

And then the opportunity finally came for me to come up to the ACRA's office, and because, again, the political climate being what it is and what comes around goes around, deputies were not a term to be used. Deputy was a no-no, so they had to come up with new terminology, new this, new that. So when I was ultimately invited to join, I was the Assistant Commissioner for Regulatory Affairs, and assistant commissioners were okay, deputies were no good. Deputy, you know, it was just not a term that was in vogue. It was sort of good to a certain degree because John Marzelli was the deputy, and he held that title.

John Taylor and I continued to work very closely, and we ran pretty much day-to-day activities, being present at almost every agency meeting there was that involved anything involved in the field or policy issues. And, again, with the premise being that John was asked to replace Dennis Baker, it was an opportunity to rebuild the confidence in ORA -- nothing against Dennis, but obviously there was a reason that they asked him to step down, for whatever reason. And so we felt we had an obligation to ORA to again show what we can bring to the table, what benefit we can, what's our value-added, what can we do, and so both of us were very committed to work hard and to continue to do what we had started at Office of Enforcement. And, again, we worked 12-, 14-hour days, whatever it took to get the job done. And so we sort of split the work a little bit and, with no fine lines of demarcation. It would be, "Okay, you're going to take that, I'll take this." It wasn't -- he positioned it for the sake of I shadowed him. We worked autonomously. He handled certain topics, I handled others.



We would speak to each other 10, 12 times a day. “Hey, what’s going on with this, what’s going on with that? Why didn’t you take this? Why did you take that? This is what’s happening over here. Why don’t you go to that meeting,” etc., and it was really very ad hoc. You never knew, despite what you thought were your best-laid plans for the next day, you never knew what you were going to be doing. You never knew what was going to be coming up. You never knew what was the new issue du jour.

And despite spatial separation -- I was, at the time they didn’t have any room in the ACRA suite, so I was on the 13<sup>th</sup> floor and John was on the 14<sup>th</sup> floor. That meant nothing. I mean, it was as if we lived in each other’s . . . And then, all evening long, the e-mails would continue between the two of us to set up for the next day, till 11, 12 o’clock.

And so we, it was clearly one of the bright spots of my career, was working with John, and we had, and to this day have a wonderful relationship.

Then John decided to leave FDA and join private industry a little bit earlier than I thought.

JS: Well, I wanted -- but go ahead.

SMN: John decided it was time to leave, and to a certain degree, there is a tremendous amount of pressure taking on this job in the ACRA’s office. There’s a thousand and one things constantly thrown at you, and it’s a difficult challenge. And despite the support of the ORA staff and others, it’s still, it’s a grueling pace. The Hill is getting, the Hill interactions alone were significant. John testified at I can’t tell you how many countless

hearings on drug imports and other issues, where no matter what we would say anyhow, we'd get beat up. Whether we told them what they wanted to hear or they didn't want to hear, it didn't matter. And it depended upon which congressman you were going -- we'd wind up going to one congressman in the morning, telling our story and get beat up, and tell the same story in the afternoon to another congressman who was a supporter of what we were doing, so . . .

John made the decision that the time had come. His dad had passed away and he needed to take the time. It was his time in his career, as a fairly young man, to make the move to go to private industry, and so he did decide to leave and was replaced with Maggie Glavin, who at the time was part of, was head of the Bioterrorism Office. Maggie had been brought in by Les Crawford in that capacity.

JS: And she had been where?

SMN: Prior to that, she was at a think tank, and prior to that at USDA. That's where Les had known her. He had worked with her at USDA.

But, you know, during those years that I got to work with John, it was really super. We worked together, we handled a lot of complex issues, most of which, a lot of time spent on bioterrorism, the Bioterrorism Act. The whole import issue had grown, with the volume of imports, the concern about how much oversight were we providing on imports, especially in light of the Bioterrorism Act. I remember making a presentation to OMB [Office of Management and Budget] raising concerns about that very issue.

We had getting the Bioterrorism Act passed and getting all the regulations implemented and getting the field up to speed. We continued to support, for example, presidential conventions, the Olympics, and, again, with the added heightened concern about these are opportunities for bioterrorism, so we spent a lot of time on bioterrorism. We spent a lot of time on Internet. We spent a lot of time on drugs of foreign origin that were being promoted through the Internet and sale with the pharmaceuticals, a tremendous amount of time on that, again sometimes feeling that you were banging your head against the wall because other people didn't share the same interests -- not within the agency but external, public health concern about safety, buyer-beware situation.

JS: Well, there was a great deal of concern, certainly on the Hill, about the ability of Americans to get their drugs cheaper in Canada.

SMN: Right, but many of them were not coming from Canada. They thought they were from Canada. Those websites existed all over the world under names of Pharmaceuticals of Canada or whatever showing on the website. Just because they have a Canadian flag on their website does not make them Canadian.

JS: When we went on the Hill, or when you went on the Hill and John went on the Hill and others went on the Hill to give them the evidence that these people are ordering their drugs from the Internet and they might get their drug or they might get something completely different, I mean, were they buying this?

SMN: No. It was interesting because we did a lot of on-site visits with members of the Hill at JFK mail facility and other mail facilities where . . . You know, products come into the United States one of two ways. They either come through the United States mail or they come through one of the courier services, Fedex, UPS, etc. If they come through one of the courier services such as Fedex, UPS, DHL, Airborne or whatever, they have to file a manifest and you sort of declare what's coming through and you have a sense, unless they lied on that manifest, what is coming in, and we can pre-clear it, we can review it.

When it comes through a U.S. mail facility, it's unknown. We only know, based upon working through Customs, based upon a return address or an x-ray of the package, what's contained in it. There is no manifest when you go to ship something from the U.S. post office. You don't have to declare what it is other than do you need insurance or not, does it contain anything hazardous. So the mail facilities became the primary mode of product coming in because they knew we didn't have the staff to look at these. And so product was coming in in huge quantities. And we took many of the staffers to, on many occasions we took them to the JFK mail facility, for example, where we worked hand-in-glove with customers to identify pharmaceuticals that were coming in.

Part of the difficulty for us was our statute in that it's a very cumbersome statute, and that is, if you detain a product for import, you need to offer an opportunity to present evidence as to why it shouldn't be detained. It comes with time limits, etc., etc. And what happened was we had this wall that was at least 16, 17 feet high by 30 to 40 feet long with steel shelving, with U.S. postal bins, boxes filled with samples of product

waiting for responses. I mean, the load was so overbearing, we couldn't even get the stuff out once we ever got a response.

But they saw what was coming in. They certainly witnessed what was coming in. They certainly heard what was coming in. They saw product coming in in teddy bears; we saw product coming in packaged with salted fish in the same package. They saw product that was coming in to try to circumvent, looking like a package in a flat envelope where the pills were literally taped to masking tape very neatly, and in stripes based upon the different drugs, so it was pretty. When you'd go in to go take that masking tape off, you took off the coating and everything else from the drug. So they saw all of this.

But, again, it depends what point of view they wanted. We would literally go down to the Hill, certain congressman, certain on the Senate side, or even on the Hill: "You're not doing enough to stop these drugs from coming in. You're not doing enough. You should be spending all your resources. They should totally stop."

"Well, if they totally stop, what don't you want us to do? Do you want us to put all our resources, all our -- at that time 1,200, 1,300 investigators on this? Do you want not to get new products approved? Do you want us not to do pre-market approval inspections? Do you not want us to look at bioterrorism issues other than pharmaceuticals being imported? What don't you want us to do? Because the reality is that, with such a monstrous problem, it's difficult."

And similarly, on the other side, why are you stopping any? This is, these are fine, etc. And the bottom line that always came down on these hearings was, FDA, what bodies do you have to show these are unsafe? What evidence do you have to show these products are not the same, that they're unsafe, that people have died, that people have

gotten ill, that people haven't been treated? And, really, there's not a plethora of information like that. And, you know, this whole story, unless you have a body, you have a tough time convincing these people. That was always the question that was difficult to answer.

JS: Sometimes, even with bodies, you have a hard time convincing people.

SMN: That's true; that is true.

So, I mean, that's the one issue today.

I was able to work with Customs Service. Several years ago, we worked out a deal where, because the, because they were starting to get beat up as much as we were for what was apparently our inaction because so much product was being kept somewhere, they agreed to use the requirements in their Act to handle these pharmaceuticals. And FDA's authority would only be used when there was an appeal, otherwise Customs Service would automatically detain a product. They instructed the importer that the product is going to be destroyed within 30 days unless you file an appeal with FDA, and that CBP considers this to be detained. It's an illegal product, etc., etc., etc.

It really did help our agency significantly. It got product processed a lot quicker. They were able to process in about three -- they were able to process a package every three minutes. We were spending two to three hours a package.

JS: How could they do that?

SMN: Because they had such an automated process. They didn't care what was in it. If it was a pharmaceutical, it's illegal. They didn't have to go to the extent of evidentiary documentation that we did. Our law tied our hands. We had to identify where it came from, what does it look like, how does it look. We had to take a photograph, we had to do this, we had to do that, and then pack it back up, and then put it on a shelf and send out a letter, providing an opportunity to provide evidence why it shouldn't be detained. These guys, two to three minutes a package.

In fact, when I heard two or three minutes a package, I called my buddy in Customs and said, "This must be an error."

He said, "Yes, it is, it's really between one and two minutes a package."

JS: Is that so?

SMN: And it was very effective. Then all of a sudden, about a year ago, after I left, Customs started to get beat up by Congress so bad, they finally said, "You know, we're going to abandon this. Why should we take FDA's heat?"

JS: Do you know about when they started this new approach?

SMN: November 20-something of 2005, because I remember approaching the Commissioner to notify him. We had some concerns about it. We had a bunch of philosophical concerns. Would the Hill look at us as if we're abdicating our

responsibility? We were concerned that, you know, there will be consumer campaigns to protest everything, and FDA will just get buried because the number of appeals would increase, leaving us in worse shape. There was concern Customs was able to handle that many more packages than we were, that even if they had a 10 percent appeal rate, we'd wind up with more work than what we had initially. You know, the response was from the Commissioner at the time, and Pat Ronin, who was here, Christmas came early.

What could be better than this?

I said, "Well, we'd better alert the White House, we'd better alert the folks, because we're going to be out of this established practice."

So we decided to put forth a revised strategy.

Then last year after some hearings, Customs said, "We're tired of getting beat up for you guys. We're walking away."

I don't know what the most current practice is. I don't know that Internet pharmacies are as big an issue right now as some of the other things that are going on. We have many import issues at our ports, especially in light of the food, the pet food, etc., etc.

JS: It's almost like take your pick when it comes to an import issue nowadays.

SMN: But it all basically boils down to the same issue, and that's resources and being able to get your hands around what's become a huge, huge, huge percentage of product that the American public is depending upon.



JS: So imports were a huge concern when you were in the ACRA's office.

SMN: Yes. John and I were working very strongly to develop an office of imports. We'd developed an imports strategic plan. Actually, Dennis initiated that; Dennis Baker initiated that. And we continued to develop the imports strategic plan. As of when I left, I know the imports strategic plan was coming close to finalization, but I don't know that it was ever finalized.

RT: Well, the New York District had pioneered the concept of a Resident Post at JFK.

SMN: At JFK. They had a whole bunch of people.

Other districts also picked that up, sort of, because they realized this had become a huge problem.

Invariably, there were always issues that came up with the ports. All of a sudden, a staffer from the Hill would surprise-visit somebody in Miami or surprise-visit somebody in Chicago and find that they weren't doing exactly what we said they were doing, and it would create all sorts of problems and we'd have to run around and chase our tails all week, got everybody back on track.

JS: An unannounced visit.

SMN: Yes. So we've been aware for a while, quite frankly, that imports are an

important issue and recognized we badly needed the MARCS [Mission Accomplishment and Regulatory Compliance Services] system. We needed different databases. The OASIS system is sort of antiquated, it's cumbersome, it's difficult to use, which is the import IT system. Most of these systems take a long time to develop, as we all know. Unfortunately, especially in government, by the time they come to fruition, they're antiquated.

What happens is, you know, like MARCS is moving along great until the Bioterrorism Act came, and all of a sudden they required FDA to develop a prior notice system under the Bioterrorism Act for all foods being imported into the country. It was an unfunded mandate. Well, you had to pull the money from somewhere, so MARCS was a target for funds -- which delayed its implementation. They are not intentional. They're not done with a blind eye. They're conscious decisions you must make that force you to rob Peter to pay Paul somewhere.

But imports are growing in importance.

RT: In staffing investigators or inspectors, whatever, hasn't there been different criteria applied in the grading of people that did just imports as compared to those with broader field experience and training?

SMN: Well, yes. That's one of the factors. There's a number of factors that play into that. Despite our efforts to try to get parity for the import group where it is looked upon, for whatever reason, as a secondhand group in the field, there were efforts underway, I know at least when I was there, to get new PDs [position descriptions] for those folks to

get them the same parity as the domestic folks, because in my opinion, over time, the industry is going to be overseas. We're going to have more foreign sites to worry about than you are domestic, and we'd better get ourselves tuned up towards that.

Just look at the volume of products coming in. Just look at the potential headaches coming in. Not having the ability to send somebody out to wherever in the United States, you know, from one of our offices, to send them overseas to do something, it's a costly investment that is not as readily available as the domestic side. We need to do something to sort of establish groups and get us ready for what looked like an inevitability that the overseas industries are growing so immensely. The volume of imports has been growing between 25 and 50 percent a year. The increases were enormous. We couldn't keep up with the old, so every year we just got further behind just percentage-wise.

JS: All this seems like a logarithmic increase.

SMN: We did some sting operations. We did do some pharmaceutical sting operations. We did, for example, target four countries in one week. All packages that we believed contained pharmaceuticals coming from Israel, Costa Rica, Vanuatu, and I forgot the last country -- it may have been India -- that were coming through the mail facilities, all packages that had return addresses from those locations. And different districts had different sites. New York had Israel and India. Los Angeles had Vanuatu, and I had never heard of Vanuatu till the very first "Survivor" TV program. I never knew Vanuatu existed. But, apparently, it's a huge distribution point for pharmaceuticals, in case you're

interested. And Miami I think handled Costa Rica. They literally opened up every single package that week, and we tracked them and traced them, and I forgot how many thousands of packages came in. And I think among those thousands of packages, we came across 30-some-odd counterfeits, and we came across a variety of different things.

Actually, that one week's work was able to be used to show, hey, you have no idea what you're getting; you have no idea where they're coming from. You think you're getting a product from something in Canada. The return address or the bill or the invoice had a company that was something Pharmacy of Canada, but the product was shipped from India or the product . . . So there's no comfort factor in saying you're getting the same pharmaceuticals as the Canadians. It really showed a lot. We developed that sting operation fairly quick, and the outcome was used for a long time. I don't know whether they're still using it. But we had press on it; we used it in front of the Hill. It was well done.

RT: That's what I was going to ask you. At that particular time, were these pharmaceuticals or devices really being brought strongly out in congressional testimony?

SMN: Yes. In fact, we even issued press releases. We even brought it up to AP [Associated Press], and we brought it to Reuters. In fact, I did press interviews.

I think the timing of it was less than fortunate. I think we wound up doing it around Christmastime. For a variety of political reasons, we held off doing it sooner. I think they wanted to get other press announcements out first. So we didn't get a lot of play on it.

But we did get some play on the Hill. In fact, I had to do -- there was a congressman from Michigan who was very anti drug import.

RT: Hagel?

SMN: No, no, no, no. I'd never worked with this guy before. But he asked me to do a TV show with him. He does a monthly TV show for his -- it's a cable show for his constituents. They asked me to join him for a half-hour to talk about drug imports, and I talked to him about the outcome of this operation and everything else. He was absolutely fascinated. I figured anytime we can get somebody in our corner for some of this stuff, it wouldn't hurt. So he was very supportive.

You know, some of these folks, you know, when we'd go before certain congressmen and they'd say, "Why aren't you stopping these drugs from coming in? How are you allowing these to come in?" and these were congressmen from the very states that had import programs that were state authorized.

When we'd push back and say, "Well, if we did stop them, how would you respond to your constituents who are being allowed to bring the stuff in, the pharmaceuticals in, based upon your own state's program? How would you respond to them when you're saying we should be stopping it?" and they'd sort of pause for a while and realize, hmm.

"Well, that's really not the issue. The issue is you should be stopping them."

"Well, but, you know, you've got to think about that."

There were a number of states, especially in the Midwest, that had state-endorsed programs, which most of them, I think, have been underutilized. In Wisconsin, Illinois, and Michigan -- there were a number of programs that had state-sponsored programs that they developed in relationship with Canadian pharmacies. When you buy from those pharmacies, you'll get it cheaper, you'll get this, you'll get that.

And I said, "You want us to stop all of it?"

"Absolutely!"

"Well, how are you going to handle your constituents when they can't bring stuff in under the state program?"

JS: It seems like a logical . . .

SMN: Yes, but they didn't think of that. They didn't think that broadly.

So that was interesting, and we've had tons of issues like that.

JS: What I want to ask about -- and I know by the time you left, things were still in formation more or less. But there was a concern in the ACRA's office with the infrastructure in the field. For example, we had laboratory space, maybe it was unused, and it was the whole issue of sort of bringing things up to the 2000s in terms of how we deal with the products we regulate. And there was a program that started, I believe . . .

SMN: The TLT.

JS: The ORA transformation.

SMN: Transformational leadership.

JS: Right. That was -- was that before you left?

SMN: Yes, absolutely. It started before I left. It was still underway by the time I left. I was not managing it. Diana Kolaitis took that role.

The premise behind it was basically no different than now. Resources were an issue. The number of investigators in the field had a high point, close to 9/11, of about 2,000 investigators, 1,800, 1,900 investigators, something like that. We were able to hire 650 investigators as a result of funding that was provided the agency based upon the September 11<sup>th</sup> episode, mostly to support the borders and enhance our presence.

As you're well aware, human resources comprise a tremendous portion of our budget throughout the agency. We're not an agency that has huge grants; we're not an agency where we can look at other places to save money.

When the agency got this money for the huge hiring effort, what they failed to budget for were these people who were on a career ladder, so every year there are, besides cost-of-living increases, some of which were only partially funded by the congressional increase for our budget, you also had salary step increases or promotions. People who start as a 5 aren't going to want to stay as a 5 or a 7. People want the 9's and 11's and 12's, and those cost a lot more money, and there were no subsequent funding

increases that were associated with the initial funding. So what it did was ultimately eat away the number of employees that you can afford to retain. As older employees started to leave, we did not have the fiscal ability to be able to replace them. Consequently, in short order, relatively short order, we lost those 650 investigators. We lost that additional capacity. We didn't lose them physically, but we weren't able to replace those that were attritic.

Consequently, as the industries grow, as imports grow, as things grow, and we aren't able to stay abreast, we have to look at other ways where we can come up with the resources, recognizing that it was not likely, we weren't going to bank on or anticipate that there were going to be huge influxes of increases to FDA, so where could we save money? We knew we needed IT infrastructure; we knew it was important to get MARCS off the ground because that was sort of tying our hands. We knew we were losing ground.

## TAPE 2, SIDE B

SMN: We knew we were losing investigators. We knew we had to look at different ways to become more efficient. Where could we save some money? Where could we better utilize our money to create a risk-based environment that perhaps can help us in different ways?

So a transformation leadership team was created. The intent wasn't to abolish jobs or anything. It was to make the organization more efficient, the premise being, laboratory samples, for example, are on the wane. We had a lot of labs, we had a lot of



lab space, we had a lot of lab inventory or equipment, etc., that's being underutilized, or not utilized at all. Can't we better consolidate to make that same capability available for other uses?

You know, when I was an investigator early on, you used to collect samples almost every time you went to do an inspection. It was a routine thing. You collected samples upon samples upon samples. Now, they don't collect as many samples. And certainly as you get to more high-tech products and you have to offer to pay for these things, they are much fewer and further between. You can't afford to do many of the market-basket surveys that we used to do routinely when I was an investigator because of the cost. It becomes a monetary thing.

So one of the thoughts was, maybe what we want to do is consolidate some lab space, maintain the expertise, use those people, many of which were qualified as CSOs, as investigators, and expand your field force to be able to go out and do more inspections and assist in that regard.

Leases, monetary costs associated with space, etc., another factor that comes out of your budget.

I think they were trying to take really a holistic approach and a holistic look at -- and that plan came out after I left -- a holistic plan as to how can we perform more efficiently, have our folks available, and build on what we already have, actually expand the inspectional force with the savings that we may see in other areas. And, obviously, most recently that plan met opposition. And again, like I said, the final plan was created after I left. But that was the mindset and that's where they were moving towards when I was here.

In fact, one of my staff members had done an inventory of lab capacity and lab capability and what they was currently doing. It was strictly an inventory. It wasn't with any recommendations, any suggestions, or anything.

So, I mean, it's a matter of continuing to do what we are doing, knowing you're not meeting your mark and finding ways to possibly improve that; or do you do what's necessary to try to improve, with the anticipation that there wouldn't be any significant increases.

Increases over the years have seemed to go everywhere but ORA. ORA's not a user-fee-funded Center, which creates the "haves" and the "have-nots." We are "have-nots" at ORA. At the other Centers, you've got to meet those trigger points to receive user fees, so you make sure you meet those trigger points, and it may come at the expense of someone else.

JS: The Center for Foods, I believe, has had some budget issues, too.

SMN: Huge.

JS: In part because they haven't been able to have access to user fees, for the most part.

SMN: Keep that in mind that post-9/11, they were the best-funded Center, and when I left, there were buyouts that year, two or three buyouts that year to reduce staff. So, I mean, you want to act with some level of fiduciary responsibility, so you make sure your

staff expenses do not exceed your budget. You could always not take that approach, I guess, if you didn't want to be fiscally responsible, and you could always beg for forgiveness after the fact and come up with the money. You want to work within your fiduciary responsibility since there's very little latitude as far as choices are concerned -- it's not like, well, we just won't make that grant. We won't renew that grant this year and we'll have \$100,000 or whatever. Money's tight; money is very tight, especially in a non-user-fee Center.

JS: Over your career, you've been recognized in many ways -- you received the Award of Merit, Commendable Service Award, and there's another award we wanted to ask you about. You were the recipient of the first Ronald H. Brown Award from the U.S. Department of Commerce. I wonder if you could tell us a little bit about that and a little bit about who Ron Brown was.

SMN: Ron Brown was the Secretary of the Department of Commerce under President Clinton, I believe. I was really fortunate throughout my career. I had the opportunity to work sometimes through the Department of Commerce, other times through FDA, but I had the opportunity to assist other countries in developing regulations compatible with FDA's, in the area of medical devices especially. I had the fortune of working in Moscow shortly after it became a democracy. I had the fortune of visiting China and providing them training, GMP training to the device industry. And I believe I was in Israel three or four times to do on-site training where there's a huge incubator device industry as a result of Russian immigrants that fled to Israel once Russia became a

democracy. Israel was very pro medical device, very pro high-tech, and developed these incubator industries to help nurture some of these young fellows and women who had ideas, some of which were able to sneak out prototypes, or just in their minds, or had drawings from what they had been working on in Russia.

Back in 1994, I was lucky when I was asked to head a cadre of trainers. There were six or seven of us. I was fortunate to be asked to head a cadre of trainers to Israel to do training, not just for the government, but for industry as well. We started with an industry course followed immediately by a subsequent course in another location, actually on a kibbutz, for the government, our car industry counterparts.

That training took place almost immediately after President Clinton and, back then, I guess his name was Menachem Begin signed this U.S.-Israeli Science Technology agreement where we would offer to share science and technology information with the Israelis and vice versa, if it was needed from the U.S. side.

What was interesting was part of this agreement and part of this course that we offered, especially the government side, was the first time that Palestinians, Jordanians, we invited Palestinians, Jordanians, and Israelis, and it was the first time all three were training, were attending the course together.

Three days or so before we arrived, there was, of course, a skirmish on the Gaza somewhere, where people weren't allowed to cross, and somehow or other they, because of this course, they were able to get people over to attend the course. We had to learn all sorts of cultural differences between the different parties. We needed to be careful as to who sat with who. We needed to be careful as to how they interacted. We needed to be very sensitive to the fact that this was the first time, probably, the three parties who had

similar interests would be in the same room attending the same training during the same time. And it was really fascinating. It really was an event.

Initially, of course, everybody stayed very much within their own groups, and by the third day or so, there was some interaction. By the end of the week, they were buddy-buddy, they were terrific.

One day at lunch, some fellow walks up to me. He had on a jean jacket, a pair of jeans, and with a beautiful woman. Because we were on a kibbutz, we ate in the dining room. The kibbutz is self-sufficient, so we ate their food.

He came up to me, he introduces himself and he says, "I'd like you to come back to my country and talk to my people."

"Who are you?"

He was the Secretary of Health for Jordan dressed like I would go on a Saturday to Home Depot. The Secretary of Health.

He says, "I have my people here. They're telling me how wonderful this is. I'd love for you to come and talk with . . ."

And I figure I'd better be real careful here. "Oh, I have a really tight schedule. I'd love to come back. I'm sorry, I can't do it right now."

But they were so grateful. And, again, this was at the time very heavily touted in the press, not just our efforts, but the whole Clinton-Begin agreement, sharing information, etc., etc.

So Ron Brown was killed in a plane crash, unfortunately, and so they came up with a Ron Brown Award for the Department of Commerce, and they gave it to us for taking the first steps on this U.S.-Israeli mission. And that's really the background for

the award.

RT: When you presented this course, I assume you had a number of interpreters. Or how did that work?

SMN: No. Actually, it was all in English.

RT: Is that right?

SMN: It was all in English. They, every one of them understood English. Most of the folks -- Israelis all understand English. The folks from, the Palestinians and Jordanians, it was interesting when you got to speak to them because we made overtures to make sure we were very friendly to them and got to know them. Almost all of them were trained in the United States. Almost all of them had went to either U.S. pharmaceutical schools or went to some U.S. university. They all spoke English fluently. There wasn't any problem with that at all.

They even said, "You know, among us, there's no problems. It's the folks that don't understand, the lower-class folks, the people who are desperate and the people who are in poverty," and etc.

When I asked several, I asked the Palestinians and I asked the Jordanians how they thought the course was, they said they were fascinated by it. They didn't see their people being ready for high-tech work but could see themselves as providing support to Israel in that they needed somebody to learn how to do a subassembly, they needed

somebody to learn how to put two pieces together or three pieces together. They could do that and then help the Israelis.

The Israelis had ideas back then that you heard about, and you said, “Oh, yeah, right, this will never happen,” for example, the pill with the camera that you swallow for a colonoscopy.

I remember two young guys, and I said, “You really think you can?”

“Oh, yes, absolutely.”

And, sure enough, it’s come to fruition.

Each time I visited the folks, for example, in Israel, on three different occasions, four different occasions, it was interesting to see the same folks, how they matured and how they developed and how their products were getting along. And they’d come up and say, “Hey, I got the CE mark in Europe, so at least I have some money coming in. We’re still waiting. Without the United States market, we’re dead. We need to make sure we conform to GMP, we need to make sure we conform,” you know, “we need the U.S. market.” And some of the ideas and some of the thoughts that they had were just absolutely remarkable, and many of them have certainly come to fruition. So they’re a pretty bright group of people.

Conversely, when I went to China to do training, we had to have our overheads and our Powerpoints to them quite a bit in advance because we had to translate them to Chinese. And they had an interpreter. We taught for eight hours a day. They had the same interpreter for all eight hours. And we had no idea what she was telling them. We had no idea whether she was even relaying the message. Almost nobody spoke English, almost nobody spoke English.

So, yes, when you work through an interpreter, it's certainly slower and it's much more difficult, and it's more convoluted.

JS: So, when were you doing this international training?

SMN: Most of the time when I was at the Center for Devices. Israel was '94, China was '99.

JS: So the '90s.

SMN: Yes. Moscow was '97, '96. That was very depressing.

Back to Israel a number of times. In fact, one time I went to Israel, I literally flew in on a Sunday evening to give a talk Monday night and was back on a plane Monday to come back. And my clothes didn't make it, and I had to give a speech, I had to give my presentation in a sweatshirt and a pair of jeans.

JS: Well, someone probably thought you were the Secretary of Health from Jordan.

SMN: The worst case was I was wearing a sweatshirt and it said "U.S. Embassy, Moscow, Russia." And, sure enough, I picked up my bag when I went to the airport that evening to fly home, and there were stewardesses who said, "Nobody's ever come back with us. We're not even allowed to fly all the way back. We have to get off in Ireland



because we're not allowed to have that many hours in the air in such a short period of time. It is what it is.

I had tons of things going on here, you have a lot of juggling to do trying to get back.

JS: That's pretty rough.

SMN: Yes.

Those were great international experiences, working with those folks.

And the one in Moscow, we were really there to promote trade to help our industry; the device industry was finding it difficult getting their product into Russia at that time. Every time they'd make a shipment, the Russians wanted a different kind of test performed. They didn't want to accept anything without some level of testing at a huge fee.

So we went over to try to arrange an agreement with them that, if it's an FDA-approved product, you have some level of confidence. You don't need to do this extensive testing at a huge cost. And, in turn for doing that, we'll provide you training in U.S. requirements, U.S. GMP.

"We understand you have medical shortages over here." They would never admit that. "We understand you have shortages of medical products."

"No, we don't. We're absolutely fine."

"Well, why are you importing so much?"

It really became a little testy at a point where, “Well, stuff from the United States is crap. It’s not good, it’s not good.”

After about the third or fourth day, I finally had to ask and say, “Well, I don’t understand it. If everything from the United States is crap, why do you have a complete fleet of brand new Ford Crown Victoria police cars?”

“Those are humanitarian products.”

“What is that?”

“They’re free. They’re gifts.”

So I said, “Oh.”

But, anyhow, we worked this out, and the premise behind it was, 10 days later, the following week actually, there was going to be an agreement signed by their Prime Minister Cherna Meerden and Al Gore, at the time Vice President, here in Washington. We got them to kindly sign off on that agreement by Friday. It ultimately never got passed. They killed it once they returned to Russia. So it worked on the pharmaceutical side; it did not work on the device side.

JS: So that never really was . . .

SMN: It never materialized, no.

But it was a wonderful experience, very interesting. It was fascinating seeing Moscow. It was certainly at a time of transition, a lot of dark. A lot of folks there were very desperate at the time. We wondered if the transition to democracy was really

happening a little too quick. We saw a lot of poverty, a lot of huge poverty, people laying corregated on the sidewalk with their underwear to sell to get money for food.

RT: Since you've retired from FDA and look back in, are there any observations that you would care to make about where we are and where we maybe should go as an agency?

SMN: Well, first of all, every day I look back and think I had an absolutely wonderful, marvelous career, one that probably, while I went through some of those experiences, I thought it was the most daunting stuff, asking myself why am I doing this, and looking back and in hindsight, I was exposed to tremendous experiences, tremendous opportunities. I did things that most Americans would never dream of doing, spent a tremendous amount of time on the Hill. Sure, it seemed miserable at the time, but thinking back on it, it was pretty good exposure.

I was at a briefing to the Vice President on the Bioterrorism Act. I got to speak with the Secretary on a number of issues. I got exposed to bio- and counterterrorism issues, operating in SKIFs, self-contained, sealed rooms where everything was held confidential. We had clearances up the ying-yang, things that John Q. Public wouldn't have had the opportunity to do. I was exposed to new and novel technologies involving industry. I was hopefully of some help to them.

I saw the agency grow and mature. I've also seen its high points and its downside, low points. I think it's at the point now where you're going to see FDA get the attention it needs to grow.

I think, based upon the most recent hearings, and even the support of the President, who is generally anti regulation, is saying, “You guys need more power if you guys need this.” He wants to set up foreign offices, something that’s been discussed in the past, foreign sites, foreign offices. I think it’s easier said than done. But he wants you to have mandatory recall authority, he realizes there are resource issues. So, hopefully, everything will be on the upswing.

I think FDA should be very proud of its accomplishments. I think it has a wonderful mission that the American public depends on day in and day out. I think it gets a bum rap many times because people don’t understand all the issues FDA handles. They don’t understand all that FDA has to do. Anytime I give a speech, I remind people that FDA regulates 25 cents of every dollar, and they’re amazed by that. I said, “And look what the budget is. It’s peanuts compared to what some of these other agencies are.”

I just think it’s time for FDA to be on an upswing, and I hope, certainly, for its continued future and success.

RT: Is there anything else we want to cover?

JS: No. I think that’s been terrific, just a marvelous look back at the agency and your experience in the agency. I think there’s a lot here for scholars to digest.

SMN: I hope so. I certainly enjoyed it.

RT: We really appreciate your taking time out from your current work to give us this interview.

SMN: My pleasure.

JS: Really appreciate this.

SMN: My pleasure. Thank you.

END OF INTERVIEW