

History

of the

U. S. Food and Drug Administration

Interviewee: Edward Steele
Interviewer: Ronald Ottes
and
Robert Tucker
Date: May 23, 2001
Place: Rockville, MD

INTRODUCTION

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

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

DEED OF GIFT

Agreement Pertaining to the Oral History Interview of

Edward Steele

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Date: September 29, 2001 Signed: Edward Steele

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RO: This is another in a series of FDA oral history recordings. Today, May 23rd, 2001, we are interviewing Mr. Edward Steele in the Parklawn Building in Rockville, Maryland. Mr. Steele retired from the Food and Drug Administration as Director of the Division of Special Programs in the Center for Food Safety and Applied Nutrition.

The transcript of this interview, together with the tapes, will be placed in the National Library of Medicine, and become a part of the FDA oral history recordings. Interviewing Mr. Steele is Mr. Robert Tucker and Ronald Ottes.

Ed, we'd like to start this interview this morning with a little biographical sketch of where you were born, raised, educated, and any relevant work experience prior to coming to FDA.

ES: Thank you, Ron. I was born in Brooklyn, New York, in 1942. My family moved from Brooklyn out to Long Island early in my life, so I spent my youth and early years in Syosset, Long Island, New York. I attended a military school in Huntington, Long Island, Eastern Military Academy, for my high school years, and then attended Roanoke College in Roanoke, Virginia, for my undergraduate degree. I received a B.S. degree in chemistry at Roanoke. It was after I started with FDA that I went on to get my master's degree in business administration at Adelphi University on Long Island, in New York.

As far as work experience, I didn't have relevant work experience prior to FDA, I just had summer jobs. FDA was my first professional job. I started right after college. During my summers while in high school, I did work in country clubs. I worked as a waiter and shoeshine boy in the locker room, and those kind of things. Then I did have a job during college, in the summer, as a ramp serviceman or a baggage man for Air Canada at JFK Airport. So FDA was, in fact, my first real job.

RO: You came in as what?

ES: I came in as a GS-5 chemist making a hefty sum of \$5,280 at the time.

RT: Where did you report for duty?

ES: The New York District Office at the time was located on Varick Street in New York City. The District Office was in the process of moving to their new facilities in Brooklyn, so we were only at that Varick Street location for probably the first year of my FDA career.

RT: That was over at Bush Terminal in Brooklyn?

ES: The location they moved to was in Bush Terminal in Brooklyn, yes.

RO: Who was the chief chemist, I guess they were called that, when you came in?

ES: George Schwartzman was the chief chemist when I first started with FDA and was kind of my first introduction into the agency.

RO: And the district director then?

ES: Charlie Herrman was the District Director when I first started, but he was soon replaced by Weems Clevenger. Weems was, in fact, the district director for most of the entire time that I was at the district office.

RO: Did you receive any special training as a chemist then?

ES: Yes, they had a very extensive on-the-job training as part of your entry into the agency. I don't recall exactly how long that was. I think it was an extended time. I don't know if it was three months or six months. It was an extended time. We had several of us start the agency at the same time, and went through the program as a group. Al Ratay was the supervisor of the training program at the time.

In addition, within the first year or so I was sent to Georgetown University for the advanced analytical instrumentation course that the agency sponsored. This was an intensive three-month, graduate-level program.

RO: Do you remember some of the things that you did during the District's training program? It seemed to me at that time that you had to go through certain types of analysis before you could even be considered for a promotion to a GS-7.

ES: I don't remember all of the particular procedures that we went through. I know we did filth samples. We did sugars and those kinds of analyses. It was, as I say, an extensive program.

RO: Had you received a promotion before you went to Georgetown?

ES: I don't believe so. Well, that kind of fades my memory of that time. I don't know. If I had, it was just GS-7, but I think I went down either a five or a seven.

RO: Who ran that Georgetown program?

ES: From the agency or from--

RO: From the agency, yes.

ES: That I don't recall.

RT: Did you get into some import chemical analyses work in New York?

ES: Yes, one of the import commodities that we did in New York was spices. We conducted many micro-analytical tests for spices and those kinds of things. I can recall a particular incident after I returned from Georgetown, after being immersed in heavy chemistry and advanced instrumentation techniques. The first sample they gave me when I returned back to the district was another sample of black pepper for rat excrement. One of my colleagues, who had been through the Georgetown program, was grousing at me for lowering myself to do such a rudimentary thing. Of course, my whole philosophy in the agency was to do whatever was assigned to me the best way I knew how.

RO: Your supervisor let you know that you were back in the Food and Drug Administration."

ES: Back in Food and Drug Administration, yes. Of course, my thing was to do as many samples as I could the best way I could, as fast as I could, and he was very upset about that. Of course, when I found that I was promoted to a GS-14, and he was still back at the district office as a GS-11, I thought maybe that was the right thing to have done at the time.

RO: How long did you serve in the New York District? Was that quite a long service?

ES: Well, no. I was in the district office from 1964, when I started, to late 1969. I stayed in the laboratory for all but a year of that. In 1969 I got my master's degree and realized that I was not destined to be a chemist for a career. I considered myself a cookbook chemist, not a real chemist,

if you will, compared to some others who really knew their chemistry.

The last year of my field career was spent as a management analyst position at the district director's office. I left the New York District office in late 1969.

RT: Let's see, looking back. You got your advanced degree, was that at Georgetown or at Adelphi?

ES: No, that was at Adelphi University.

RO: I have to ask you why, from New York you went to Roanoke?

ES: I often get asked that question. Having graduated from a very small high school, I wanted to attend a small college. My mother happened to have come in contact with somebody that had graduated from Roanoke College, and he suggested that I consider Roanoke as an option. When I went around to look at schools, I included Roanoke as one of those that I would consider, and went down to Virginia, which was at that time a pretty long way from Long Island, and fell in love with it. That's kind of what happened.

RO: The management analysis position, did you stay in New York then or did you transfer to another district, or come directly into headquarters?

ES: No, I came directly into headquarters. The story behind why I came to the headquarters may be of some interest. I became good personal friends with Ben Perillo, another chemist in the New York laboratory, and he had taken a position in Washington with the Bureau of Narcotics and Dangerous Drugs. When Ben took that position in Washington, I decided to seek a position in Washington as well. So I looked for positions that were vacant, and I applied for and was

selected for a management analyst position here in Washington.

RO: So you didn't go into the laboratory?

ES: No.

RO: I guess you had decided you weren't a chemist?

ES: I wasn't a chemist. One of the problems I saw with FDA laboratories is they had a combination of chemists and technicians, and, ironically, both were getting the same pay. Both, if you're there long enough, would rise to the top of the chemists pay scale. Some were truly outstanding chemists and others that were not. My strength was more in the management and management-type activities. I was interested in business-type activities, so clearly I saw my opportunity in other areas.

RO: Was this management analyst's position in foods?

ES: The name of that division was the Division of Management Systems in the Office of Commissioner, and we were first located in Crystal City, when I first moved here to the Washington area.

RO: So that wasn't with the Bureau of Foods?

ES: It was not, no. That management analyst position was a position that I just found off of the vacancy announcements. The function of that particular unit was to do management surveys and organizational design for units throughout the agency. I enjoyed that work, but at that same time,

Mary Dolan, who had been the Deputy District Director for Weems Clevenger in New York, had come down to Washington and she was the head of the agency's compliance program functions. Soon after I got to Crystal City, Mary was asking me if I was interested in doing compliance program work.

RT: So there were others than yourself in that unit. Wasn't there a fellow by the name of Frank Thompson on that staff at one time?

ES: Yes, Frank Thompson. I guess, Bob, you're jumping a little ahead, because in the management analyst's position, Frank was not in that unit. When I did move over to the compliance program functions, which Mary Dolan managed, Frank was in that unit, yes.

RO: Have you spent all of your career at New York and headquarters? Were you ever in other districts in the field?

ES: No, there's only two locations I've had in my thirty years; those five or so years in New York, and the rest of it has been here in Washington.

RO: So in the section under Mary Dolan, you started working on compliance programs that the field would implement?

ES: Yes. At the time that I started to work for Mary, which is about a year after coming down from New York, she was responsible for the compliance program functions for the entire agency. Soon after I started to work for Mary, I was assigned to work as part of the team that was involved in recommending organizational changes for the reorganization of the entire Agency. This resulted in formation of the Bureau for Foods, and Bureau for Drugs, etc. That

reorganization was back in the early seventies.

RT: Under what commissioner was that? Was that under Dr. Edwards?

ES: I'm going to guess, Bob, that that is probably correct. I am not 100 percent sure. Edwards was the Commissioner when I was in New York. Whether he was still at that time, I don't recall. But anyway, Charlie Coffindoffer was the division director that I worked for. When the agency reorganized, Mary's group was divided among the various bureaus, Bureau of Foods and so forth.

Mary, herself, then became the Division Director in the Bureau of Foods For Compliance Programs. Frank Thompson became the Branch Chief, and I was a Program Analyst doing compliance programs at the time for Frank.

RO: How long were you in that particular operation?

ES: Well, the answer to that, Ron, is that in various capacities I had ultimately worked my way up to be the division director, but through various different organizational changes. I'm just trying to think. That was 1974, I guess it was, I became the chief of the compliance program branch. So that means that Frank Thompson had retired and I took his position. I moved in 1978, so four years after that, I assumed the position of the division director's position, which is when Mary Dolan, in fact, passed away during that period of time.

RO: Of course, in your involvement in the reorganization, were there any other significant changes or issues that you dealt with in this period of your career?

ES: Oh, yes. There are a couple of things that kind of stand out in my memory. First of all, one of the very first assignments that I was assigned was to develop a compliance program on lead

and cadmium in ceramic ware. It was kind of an insidious problem, because the lead and the cadmium are in the glazing on ceramic products. If the dinnerware is not properly fired to a high enough temperature, the lead and cadmium can extract into the food that people put on their plates and consume. Because the toxicity of lead and cadmium was of great concern, it became an agency issue.

Over time, I evolved into the agency's expert on the issue. One of the factors that became part of my career was my involvement with the international organizations in setting international standards throughout the world. So during the same time period that you're referring to, Bob, I traveled to ISO [International Safety Organization] and WHO [World Health Organization] meetings throughout the world in order to establish internationally accepted standards. This called for international visits once or twice a year, and I did that for many, many years, starting back in the early seventies.

RO: Was that primarily an import problem, or were there some domestic manufacturers that were involved, too?

ES: It was both an import and domestic problem, but the bigger problems came from the foreign countries.

RT: Was Mexico one of the primary sources of imports?

ES: Yes. Mexico was a big problem, and the other one that turned into rather significant activity for me was that of China. China was ultimately put on an automatic detention list, so all shipments of dinnerware from China was precluded from coming to the United States.

The Chinese sent a delegation to the U.S., and subsequent to that I led a U.S. delegation to China and worked out an arrangement where they would test all shipments that they export to

the United States, using our criteria and certifying that it was in compliance. That was an activity that has opened up trade for the Chinese and provided a safe product to the U.S.

RO: Did you ever check their laboratories to see whether or not they were reputable as far as the analytical capability?

ES: Yes, we did. To our surprise, they had controls in the laboratories that even exceeded what we would normally expect. For example, one of the requirements for the test is to let the 4 percent acetic acid sit in the dinnerware for a twenty-four-hour period at room temperature. Room temperature was defined in the standard. But in China, because they don't heat their buildings, they recognized that room temp would be outside the limits of room temperature. So they built special chambers to analyze these samples. The net result was that the testing program was quite effective.

The problem--and I imagine that problem still remains today--is that in traditional Chinese ware, the kind of ware that you see in Chinatowns here in the United States, those particular products are not tested. They get them into the country by calling them something other than dinnerware. They call them decorative ware, and all kinds of ways in which to get it in. But the normal dinnerware made for the U.S. consumer coming from China, I think are quite good.

RO: So they certified each manufacturer in China?

ES: Each lot.

RT: Now, these products from both Mexico and China, were those high-priced items or more low cost in the range?

ES: They're generally lower cost, but not entirely. But the bulk of them would be low-cost items. As I say, that did turn into a significant activity. In fact, even when I was in the Office of Seafood at the end of my career, I was still getting involved in ceramic ware. Of course, it was well beyond my responsibility at that point.

RO: In writing these compliance programs, a lot of those were for implementation in the field offices, and obviously you had to work with someone involved in the field organization. Who was primarily your contact here?

ES: Let's see. You're right, all the programs that we drafted in the Bureau of Foods (and later in Center For Food Safety) were reviewed internally, and then they were reviewed by ORA [Office of Regulatory Affairs] before sending them out to the field offices for implementation.

One of the key people that we'll talk about later in my life history is Tony Celeste. Tony was in ORA and it was his office that was responsible for the review of those programs. Of course, I knew Tony because he was a supervisor chemist in the New York office when I first started with the agency.

RO: What were some of the other significant areas you were involved in, besides the ceramic work?

ES: Bob mentioned to me sometime back about my involvement in the Intergovernmental Exchange Program. That was an opportunity for federal folks to go out and work at the state level and state people to come into the agency and work at the federal level.

The position that I was assigned to was that of looking into duplication of effort in the Commonwealth of Pennsylvania. I was assigned to the governor's office in Harrisburg. The assignment was to look into the inspectional work that was done by the Department of

Agriculture and the Department of Health with respect to their inspections of food facilities, restaurants and bakeries. We were looking into the fact that both state agencies would send inspectors into the same establishments and they were looking into the feasibility of having one inspector in those operations to avoid that duplication.

RO: You mean that was the state duplication, not duplication with the federal government?

ES: That's correct.

RT: As I recall, the Department of Agriculture in Pennsylvania requires on food labels and maybe other products, but certainly that foods be registered with the Pennsylvania Department of Agriculture. Was that program one that actually involved state inspections, or was it more a kind of paper registration?

ES: Bob, I don't know too much about it, but I believe that was more of a paper exercise, if I'm not mistaken. The particular activity that I was involved in was actually the on-site inspection thing. I remember there was a restaurant in York, Pennsylvania, that was a very well-known local Italian restaurant that all the locals frequented. It was a very nice outside, the eating section was very, very nice, and very pleasant.

I went into the kitchen area, and it was one of the most deplorable sanitation situations I'd ever seen in my life. You had to literally step over boxes and stuff to get back to where they did their baking. The bakery was inspected by the other agency at the state level. They had a separate built-in room where they did their baking, and that was very, very clean and sanitary. It was obviously a reflection on the requirements of one of the agencies and not the other. The irony is that the one inspector would have had to go past those unsanitary conditions in the kitchen to get to that clean bakery.

RT: Was part of your work there to bring together a common interest in these inspections?

ES: That's right. That was the focus of it. I don't recall what the ultimate outcome was. It would be interesting now to go back after these many years to see whether it's changed or it's the same.

RT: What year did you spend up there?

ES: Oh, my gosh, I'm not 100 percent sure, Bob. That would have to be in early, mid-seventies is my guess.

RT: Did the state of Pennsylvania in this case exchange someone to come to the Food and Drug Administration?

ES: I don't believe so. It wasn't a one-for-one exchange at that time.

RT: Were there other FDA personnel that you're aware who went on a similar type of state assignment?

ES: I'm sure they did. I don't recall who they might be at the time. There were some more, yes, but I don't recall.

RT: Can one assume that because of your management analytic expertise, you were selected for this particular assignment?

ES: I would hope to think so.

RT: I'm curious why you were interested in that.

ES: I guess I'm interested in anything that will broaden my perspective and be helpful to my career.

[Begin Tape 1, Side B]

RO: We were in the middle of a question when we broke at the tape side. Go ahead.

RT: I was going to ask Ed what position he came back to from the Intergovernmental Affairs assignment.

ES: I don't really recall where I was in my career, but it was back to whatever I was assigned to, and I assume that was back in the compliance program at the time.

RT: When you were up at the state, you were still an FDA salaried person, or were you under the state personnel system?

ES: No, no, I retained my salary.

RT: Was the state obligated to pay for any of the expenses relevant to your assignment?

ES: I don't believe so. I don't believe so. I don't recall that detail, but I don't think there was any exchange of funds.

We were talking earlier about my career in compliance programs. One thing I failed to mention is that somewhere along the line, I want to say about 1984, another reorganization changed the organizational location of the compliance program function. My position as the division director had reported to the Office of Compliance in the Center for Food Safety. Taylor Quinn was one of the major individuals in that position for a good number of years during my stay there.

After the reorganization I reported to Brad Rosenthal in the Office of Management. During the time I was in the Office of Compliance I not only was responsible for the compliance program function, which was planning and evaluation programs, but the industry activities staff and the international staff also reported to me.

When I went from the Office of Compliance to the Office of Management, I retained the compliance program function, and I also picked up the planning functions for the center activities as well. So there was a shift in responsibilities, but still at the core of that was the compliance program function. I believe that was done from 1984 to 1988.

During that period, I had another very interesting outside assignment that was along the lines of the ceramic ware. It was with the U.S.-Saudi Arabian Joint Economic Commission for work in Saudi Arabia to set up a food-control system for the Saudi government. I, along with Dick Ronk, who at that time was the deputy director for the Center for Food Safety and Applied Nutrition, managed that program by putting current and former FDA staff in Saudi Arabia. This required that I travel to Saudi Arabia on short-term assignments. That went on for about four years and it turned out to be a very interesting project, to say the least.

RT: Who were some of the other FDA folks over there at the same time you were, or who followed you?

ES: One of the people that comes to mind that we sent over there was Cliff Shane. Cliff was

over there on an assignment. We generally sent people over for one- or two-year assignments.

RT: Was Clifford on active service in FDA?

ES: No, he had retired from the agency. He was a regional director with the agency when he retired.

Cliff was a little much for Saudis to handle sometimes, because Cliff was pretty dogmatic in what he felt was the right thing to do. Of course, the Saudis have a similar personality, so there was a little bit of a conflict there.

RO: How successful was that program?

ES: In my honest opinion, Ron, it was not successful at all, and I owe it not to anything that the U.S. side had done. It's just the Saudis are not in a situation where they wanted to be taught the right things to do and to carry on and do a transfer of the knowledge. What they were more interested in having done is to hire people to do the work for them. That was not the intent of the U.S. Government to work for the Saudis; it was to share with them the knowledge we had so they could carry on on their own.

There were outside contractors at the time that were more than willing to do the work because they were getting paid big dollars to do it. But from a federal government standpoint, it was a no-win situation, because you go over there, share the knowledge, and ask them to pick up the ball and carry it themselves, and they just were not interested in doing that.

RO: Where did these contract people come from, outside of Saudi Arabia?

ES: Yes, the contract people, the Saudis would hire workers from Pakistan, but they would hire

U.S. technical people to work on contract work. They had a group from the University of Rhode Island that was in there doing long-term work on analytical work. We were pretty critical of them, because it was not an issue of transferring the technology, it was an issue of them doing the samples. Of course, that was not our vision of what the whole project was about.

RO: Did you have any problems getting equipment in their laboratories?

ES: Oh, yes. There was a big problem getting virtually anything into Saudi Arabia, and equipment was one of those. So a lot of the projects were held up trying to get equipment into the laboratories.

RO: I wouldn't have thought money would have been a problem.

ES: Their procedures over there are so cumbersome, that oftentimes got in the way of the simple things.

RO: That program is terminated now, as far as you know?

ES: It was administered out of the Treasury Department. I don't know if that activity may be still going on, but my involvement, and I think the center's involvement ended back in 1980 to 1990. We just pulled out of it.

RT: You have mentioned assistance or involvement of FDA personnel in China and in Saudi Arabia. Were there any other countries where such initiatives emanated from the center or bureau?

ES: Yes, but those were the majors ones that I personally was involved with.

RT: The Chinese apparently were more cooperative, but then they had an economic incentive themselves to be so.

ES: Yes. I've been over to China on a couple of occasions. The ceramic ware issue resulted in a joint memorandum of understanding between the Chinese government and the U.S. The commissioner ultimately signed that memorandum of understanding between the two countries. Because of my rather intense involvement with the Chinese, I got to know the Chinese equivalent to the FDA quite well on a personal basis, and still today I have activity in the consulting work that I do after I retired with the Chinese, and it is still an interesting culture to observe, because when there's an incentive in there, they will tend to react, otherwise they will tend not to react. It's kind of human nature in its best of worst form.

RO: Your work has been primarily in the area of foods, and, of course, the Chinese are great exporters of herbal and other kinds of medicinals and so on. From your perspective, does the Chinese food and drug program have any teeth, if you will, or real requirements that at all parallel that of other countries?

ES: Funny you should ask about the herbal stuff, because that's an area that I'm particularly involved in right now with the Chinese. The answer to that is, in general, no. The manufacturing conditions in some of the Chinese facilities are far below what we would find to be acceptable here in the United States, and yet they have very extensive government control programs. So when you say have the teeth, obviously it doesn't have the teeth enough to do it the right way yet.

On the other hand, we're finding that there are some technical people that are very knowledgeable, far more so than you would ever have expected. So you have a situation where

the beginning is there, but it's going to be a long time before, I think, things will really take hold.

We are actively working with the Chinese government right now on the herbal situation, and we see a tremendous opportunity, if they can get their house in order, for them to do a tremendous amount of business in the U.S. because of the nature of the product and the demand here in the United States for supplements.

RO: This is jumping ahead a little bit, but you say "we." In your position as a retiree, you're now in the consulting business?

ES: Yes, that's correct. The firm that I'm with does consulting to the industries that are regulated by FDA, so that would include products such as herbal products coming into the U.S.

RO: In your consulting capacity you work with them so they try at least to meet what FDA requirements might have?

ES: That's correct.

RO: Let's get back to your FDA career. We'll get back to this other one later.

ES: Okay.

RO: You didn't stay in that particular position forever.

ES: No. Let me just try to give you a time frame. I guess it must have been 1988, that was probably the time frame that would be when the center director at the time, Fred Shank, came into his position. He was interested in setting up a staff that supports his office, which is known as the

executive operations staff. I set up that office and I served as its first director for a period of time. The function of that was to do science policy analysis and the support work for Fred's immediate office.

He had some very strong feelings about the kind of people that he wanted in that office, and they were people that he had general confidence in, that reported to me. It caused a little bit of a stir within the organization because it was superimposed on top of a program management system, and we had program managers and we had line managers and then we had Fred's immediate staff.

RO: So this was really a staff position, not a line?

ES: That's right. It was a staff position to the center director.

RT: Was it, by comparison, something like an old CPEHS [Consumer Protection and Environmental Health Service] over the Food and Drug Administration?

ES: Yes. It was a little bit of that, for sure.

RT: Did Dr. Shank reorganize foods?

ES: I would imagine every center director has a little bit of reorganization. I don't recall the extent of it at that time, but certainly did establish this executive operation staff, which I headed up.

RO: Who was Fred's deputy?

ES: That was Doug Archer. Dr. Archer came to that position from the position of Director of the Division of Microbiology. He was commissioned corps. I guess he attained the commissioned corps rank of admiral. Very knowledgeable in science and microbiology issues.

RO: Was it about this time when the seafood operation was established?

ES: Yes. That's how my career took another turn. The agency was under severe criticism about the regulation of seafood. Seafood was just another food commodity that was regulated like any other commodity up until then. Fred decided that we needed to establish an Office of Seafood. He asked me to set up that office, and it was my task to organize, recruit, and establish that organizational entity. We were working out of a one-room office on the third floor of FOB [Federal Office Building] 8 in Washington for the beginning of that.

As we started to bring people on, we had a room with about four or five desks around it, with phones ringing and people coming in. We finally used a conference room down in the first floor of FOB 8 as our temporary quarters. At that time we brought in Tom Billy as the first permanent director. I acted as the director of that office up until the time we were able to get Tom to come from the National Marine and Fishery Service to join that office.

RO: That office was known as what?

ES: The Office of Seafood.

RO: Office of Seafood Safety, or it's just Office of Seafood?

ES: No, it's just Office of Seafood. Because they did not have space for us in FOB 8 any longer, we secured a rental space in an office building on Vermont Avenue, where the office still resides

today, and that office was staffed with some thirty-five people or so to get that program off the ground. It was there that we developed the seafood HACCP [Hazard Analysis and Critical Control Points] regulations, which has served as a model for the way that seafood in general are controlled today.

I retired in the end of September of 1994 to take the position of Director of Food, Dietary Supplement, and Cosmetic Consulting with the AAC Consulting Group. When I retired, Tom Billy left his position the same day I did, and he went to the Food Safety and Inspection Service at USDA, and there he subsequently developed the mandatory HACCP regulations for meat and poultry.

RO: Of course, you know, Ed, that HACCP program was not new to FDA.

ES: Yes!

RO: You remember a man by the name of Dr. [Robert] Angelotti.

ES: Yes. Bob Angelotti. That's exactly right.

RT: He started that.

ES: I worked for Bob Angelotti. He was the director of what was the Office of Compliance, before Taylor Quinn. Bob had some very progressive ideas, probably a man with ideas before his time. You're right, the HACCP regulations were built into the low acid canned food regulations in the early seventies. They didn't call it HACCP at the time, but that's what it was. Of course, the original HACCP came out of Pillsbury Corporation for the space program back in the sixties. So HACCP has been around, but it really became a regulatory tool known as HACCP starting

with that seafood HACCP regulation that we developed.

Seafood HACCP was mandated by regulation. Meat and poultry HACCP is required, and now they're extending to juice products and other high-risk commodities. In my experience as a consultant, I notice that all the major food processors in the country are using the principles of HACCP, whether they're required or not.

RT: After Tom Billy left, who succeeded him in charge of this seafood program? Is that Richard Dees?

ES: No, Dick Dees was a division director. There were three divisions within the Office of Seafood. I was director of the Division of Special Programs that handled the National Shellfish Sanitation Program, and also a joint program with the National Marine Fishery Service on HACCP. Dick had the other programmatic division, which was in the field enforcement-type activities. There was a third division for the laboratory and scientific issues that Dr. George Hoskins headed.

When Tom left FDA and went to USDA, his deputy was Phil Spiller. He assumed the position as the office director and still remains in that position today. Dick has subsequently retired from the position I just mentioned, and is, in fact, working for us at AAC Consulting Group.

RO: You worked for a number of bureau or center directors while you were in foods. I'll use that generically. Would you care to comment on some of them, their different philosophy on how the bureau or the center should be operated? Who was the first director that you worked under there?

ES: In the food area. I think the progression was Virgil Wodicka. Dr. Wodicka was the first

center director Let me see if I can get the chronology right. Howie Roberts was in there as an acting center director for a period of time. I always comment that Howie never got the position on a permanent basis because he wasn't heavy enough. All the center directors seemed to have a bit of a weight problem, which is kind of an irony.

RO: Howie was a mathematician

ES: Yes. That's right, he was a mathematician. He has since gone on to the Soft Drink Association after he retired from FDA

Then let's see. Sandy Miller was the center director. I guess Dick Ronk was acting for a period of time between Sandy and Fred Shank. Of course, now Joe Levitt is the center director.

RT: I'm trying to recall the name, I can't. Kind of a gray-haired man and he went to industry out on the West Coast. I thought maybe he was director. The name eludes me.

ES: You may have better recollection than I have.

RT: Well, it doesn't matter.

RO: There was a Summerson.

ES: There was a Lipscomb with the agency, but not in that position. You may be right, but I don't recall who that might be.

I guess the common element in all these people is that they're dedicated to their jobs and they are dedicated to consumer protection.

RT: Some of them came either from academia or industry, did they not?

ES: Yes. Virgil came from industry. He was with Hunt-Wesson. So he was an industry man. Sandy Miller came from MIT [Massachusetts Institute of Technology], so he was an academic. The route of Fred, I don't know exactly where his original background came from. I know he got his Ph.D. while he was working at FDA. He was with the Center for Foods or Bureau of Foods and got his Ph.D. while he was working with the agency. Of course, Joe Levitt's background is the legal profession, so he's really breaking the mold from that standpoint.

I characterize Virgil as a real gentleman and a person that just commanded respect because of his knowledge, and one that was very well respected for his background.

Sandy Miller, his style was a combination of a team approach with Dick Ronk as his deputy. I guess Sandy recognized that he didn't have the regulatory background coming from MIT. Dick was with the agency for years. Dick, for those who know and love Dick, is a character, to say the least. A very intelligent person, has a tremendous intellect about him, but a style that is unique to Dick Ronk, I guess is the way to say it. Very personable, funny person. He's the kind of guy that can get up and make an hour-and-a-half speech and everybody laugh hysterically at the end of the whole thing, and say, "What the hell did he say?"

RO: But could be abrasive at times.

ES: Dick could be abrasive at times. The two of them were like a tag team.

Sandy was very concerned about what he called "chemophobia," or the public overreacting to pesticides and other chemicals in the food supply. I think time has borne that out. We have shifted from when the agency put a lot of its attention on perceived problems, such as filth and pesticide issues, to those issues that actually cause illness and injury.

While I think we might be neglecting some of the other food-safety issues right now,

because food safety today has become synonymous with microbiological issues. However, pesticides was a major initiative of the agency, and I guess many years back it was a real problem. But as time went on, the levels of pesticides found in finished products were few and far between and not very significant at that. Yet that's what people were concerned about. Today I don't think the same emphasis is on those kind of issues.

Fred Shank, again, was dedicated to his job. His management style was one of trying to control things from behind the scenes. I would marvel at the way Fred would get a bunch of us in a room and really try to engineer the outcome of the meeting before the meeting took place. Then the meeting would take place and Fred would not say anything, but everybody else was supposed to say the right thing. Of course, if they didn't say the "right thing," he would get very upset.

[Begin Tape 2, Side A]

RO: I was just asking Ed about the transition from Fred Shank to Joe Levitt.

ES: I was saying that that transition took place after I retired. I was mentioning a second ago that I knew Joe from my activities when he was in the commissioner's office. So I knew him as a person, and now I've seen the results of his introduction into the center, so I do have some reactions to what has happened here.

He went into the center and he admitted that he was not a professional scientist, a food scientist in particular, and I think that was a wise thing for him to do, because the industry did not have that to jump on. Essentially his platform was to listen to what they had to say and to make some rational decisions. I think he's been very successful in doing that.

One of the other things that he has done to win over the staff support is to identify that the center can no longer do everything that it's mandated to do. He has set up a series of priorities

and he has made it his task to complete those things as they identify as an A-priority list, those things that are on their A-list, and therefore, make it known that the other things that are the responsibility of the center may not get done in a timely fashion.

That immediately got a lot of support from the staff at CFSAN [Center for Food Safety and Applied Nutrition]. So at the same time that he was winning over support from the industry by not coming in and acting as if he knew all the answers, he was prioritizing the work and not insisting that the staff do the impossible. However, once they're identified as a priority, he is making it his task to get those things done. So unlike before when everybody was trying to do everything and nothing was getting done, or very little was getting done, now you can see progress and commitment to those things that are of highest priority.

It has also served as a very useful purpose to identify the things that we should be doing that we can't do, and therefore he's been very successful in getting funds to support that. So his management style, and I think the difference is he's a professional manager, as opposed to a scientific type, I think is serving the center in a very positive way. So I'm very pleased with the changes that he brings to the table.

There's been a tremendous drain in talent from the agency because of retirements. There have been a lot of people that do not have the institutional knowledge, and yet I see an influx of new talent into the agency, and with his method of management I think things are going much better than I would have expected at this point.

RO: Since this relatively recent change in management style has occurred, have there been any indications of congressional oversight interest in that kind of prioritized agenda?

ES: I haven't followed it that closely, but I think what is happening is when the Congress identifies things that they want done, by Levitt's prioritization system you either fall into it or he is prepared to go up and say that we don't have the resources. I've been involved in too many

congressional hearings when the manager has spoken for the agency, "Yes, sir, we'll do the best we can," and try to do more with less, and it has gotten to the point that you just can't do it all. So I think his style with the Congress is working. For sure there will still be congressional oversight and criticism and those kind of things, but I think it's working.

The one area that I'm actively involved in right now is that of food additive approvals. The agency has moved into a different system. Rather than approvals, they've gone to notification systems. CFSAN has made commitments to review notices within a certain time frame, and it's getting done.

I mean, all of a sudden, rather than to wait four, five, six, seven, eight, ten years for an additive to be approved, 120 days later after a cursory FDA review are being permitted to be marketed. So I think from an industry standpoint, without sacrificing consumer protection, that's all a very positive thing.

RO: What's the difference between the approval and notification?

ES: The manufacturer would submit all the information to support the safety of an additive. It would go into the agency and be reviewed by the various offices. If they had a problem with something, FDA would then go back and ask for additional information, and this went on and on and at the end, if there was an end, the additive would be approved. A notice would appear in the *Federal Register* and it would be updated in the Code of Federal Regulations. So it would be codified in the CFR, and there would be a record that this particular additive was approved and what its limitations and uses are approved for.

The notification requires the same level of detail. However, oftentimes, depending upon what kind of approval it is, there's a time frame, usually 120 days, for the agency to react to it, and by the prioritization issue that I mentioned, all these resources have gone to the review of the data within this 120 days, because after 120 days, if the agency does not object, the manufacturer

can legally market that product, assuming it to be safe.

So it's not an approval and it does not result in a codification in the CFR, but it does result in FDA's review, and then at the end of the 120 days the agency will write a letter to the submitter saying that they have no reason to object. That then becomes something they put on the FDA website. So it becomes a matter of public record, but does not appear in the CFR.

RO: But it doesn't really have the tacit approval of the agency?

ES: It does have a tacit approval, just not a formal approval.

RO: Does it ever get approved?

ES: No, it never gets formal approval.

RO: The agency, of course, has the option, should they experience adverse reactions, to come back to that problem.

ES: Sure, but that's the same situation if it was regulated through a formal approval process.

RO: Where do they stand on reviewing the GRAS [Generally Recognized as Safe] list?

ES: They went through the initial GRAS review. I don't know if they're continuing to do anymore on that. But GRAS is now part of the notification process. To determine something to be GRAS today, you no longer have to submit a petition. You submit a GRAS notification. So it's the same process I just described. Manufacturers always had the option of doing their own self-GRAS determinations, but by going through this process it brings it out into the open. We're

finding that less people are doing their own and not submitting to the agency. So, in effect, more information is becoming public and it can be done in a more timely fashion. So it's a system that's working, and again, it's working because of Levitt's process of prioritizing, making commitments and doing them, and then getting the funds to support the amount of work that needs to be done.

RT: Periodically the Congress and others have talked about the Food and Drug Administration and Department of Agriculture, and maybe there should be one agency, or a separate agency, not under either department. What's your reaction to that?

ES: That's a tough question. From the outside, it looks like the logical thing to do. Whether it can be done is another thing. The first problem stems from the control of the committees within the Congress itself. There's battles at all levels that would have to be worked out.

I, personally, think it would be a good idea, if it could be done. I see a tremendous misappropriation of resources to the traditional way that USDA inspections have been done in the past, compared to the limited amount of resources the FDA has for products that may present a similar or even more significant health hazard. Certainly, if you combined the two agencies, I think all those things could be addressed. But it's very difficult. There is right now in Congress another push to have that happen. I would imagine some day it will happen, but I don't know if it's going to be in our lifetime.

RT: Do you think it would be a separate and independent agency, like CPSC, or would it go into another department, like Commerce or something?

ES: I couldn't tell you. I don't know. It's whatever politics would prevail at the time.

RO: Popular at the time.

ES: Yes.

RO: Do you have any feeling at all on why Dick Ronk, who was the deputy when Fred Shank came in, didn't get the job?

ES: No, I don't.

RO: Sandy had left and Dick was deputy and acting.

ES: Yes. As I say, Dick, with all of his positive qualities, I think he probably worked best under the tag team of Sandy and Dick. He certainly didn't present the typical image of a person heading a major agency component. Of course, I don't know to what extent his lack of Ph.D. degree played in his not being selected, but obviously Joe Levitt has broken that mold. I have a lot of personal respect for Dick, but Dick needs a front man.

Part of my job when I worked in that office was to try to keep Dick from doing himself in. He had a way of doing something that was humorous on one level, but not entirely appreciated on the other. He would come to the office with a new pinstripe suit, and white basketball socks with blue and yellow stripes on them. He often wore wing-tipped shoes that had holes in them that were grass-stained. We had the kind of relationship that I felt comfortable saying things like, "You're acting center director now, you have to at least look the part." I have a lot of admiration for him, but he...

RT: Let me interject, we were talking about leadership in the foods operations. The name I was trying to reach and couldn't is Lindsay. Was there a Lindsay, Dr. Harold Lindsay?

ES: There was a Dr. Lindsay, but not as a senator.

RO: He was in science.

ES: Dr. Lindsay. Was he not the commissioner's scientific director?

RO: Yes, perhaps he was.

RO: Are there other areas that you'd like to cover?

ES: I don't know if you want to talk about what I'm doing today.

RO: Post-FDA?

ES: Well, only because it seems to be like an extension of FDA. The people I work with now are all from FDA. It is an interesting perspective to look back at the agency from an outsider's perspective. We work with the FDA on a continuing basis, and it is interesting career to have concluded, also interesting to maintain the relationships we do with the agency. More importantly, I guess, we feel that we are continuing to carry out the mission of the agency as consultants to the FDA regulated industries.

RO: It's interesting that some of the regulated industry would seek a consultant to do some of the things that they could probably get from FDA.

ES: Yes. First of all, I don't know if you know the background of the company, but Arthur A. Checchi was the original owner and founder of AAC Consulting. Checchi was an Associate

Commissioner with the agency back in the fifties. He was responsible, to some extent, for the food additive amendments to the Food and Drug Cosmetic Act. When he retired from the agency, he started a small consulting firm. I assume he just started by himself initially, ended up having a few FDAers working for him. He did a lot of work for the major food manufacturers, particularly food-additive work, and was responsible for helping them submit food-additive petitions for FDA approval.

As his career went on, he hired more and more FDA people to work for him, and it wasn't until about fifteen or so years ago that Tony Celeste left FDA to join Mr. Checchi. He literally left FDA because he did not have the age or the time for retirement. He served as a consultant for Checchi for about a year, and then ultimately purchased the business from Checchi.

Tony retained Checchi's initials, AAC. The company is now known as the AAC Consulting Group. Tony expanded the functions of that initial business to include all the industries that are regulated by FDA. So that today AAC provides consulting advice and assistance to all the industries FDA regulates, including the pharmaceuticals, medical devices, foods, cosmetics, and dietary supplements.

Today, we have upwards of fifty-five salaried employees. In addition, we employ more of that number as part-time outside consultants, most all of which are former FDA employees. There's well over a hundred people that are now working for AAC.

RO: When you said that FDA, you mean ex or retired FDA? There are no active persons in there?

ES: Yes, they're all retired from FDA. We do have a validation staff that does process validation and computer validation. They do not have an FDA background. All the rest of our consultants came to us from FDA.

You're right, Ron, people come to us when they could get the same information from the

agency. The reason for that is severalfold. First, they oftentimes don't want to be identified as having asked the question. Of course, since we have confidentiality agreements with all our clients, we don't disclose to anybody who we are working for. That preserves their anonymity.

Also, it's not easy to get information from the agency. I don't think it was ever easy, but in particular I think it's getting harder and harder to pick up the phone and get to the right person to get an answer today. We sometimes have our own little problems ourselves, but in general we can get to the people we need to in a much more timely fashion than they can. And we're finding that most of our clients are very knowledgeable, they have developed regulatory affairs people, they come to us not with the easy answer to the questions, but they come to us with the tough ones.

Of course, we now enjoy the luxury of some very senior people from FDA, oftentimes the ones that were involved with setting up those regulations, and we have the ability to give them some thinking behind what went into the thought process of the agency, which is what our clients are really looking for.

RT: Is there any impact at all on this requirement that for a certain period of time after leaving the agency one doesn't represent--

ES: Right.

RT: It's a different type of service than you're performing.

ES: Yes, we preserve all the requirements in terms of any kind of conflict of interest. We will not get involved with issues that we personally were involved in. We won't represent a client to the agency within a certain period of time. But generally that's not a problem for us.

RT: You really don't get involved in any litigation, do you, that the regulated industries might have?

ES: We do occasionally. It's not a big part of our business, but we do serve as expert witnesses for firms that get into disputes with whoever. So we do to that extent, but, of course, those people would not be involved with that kind of work if they were involved with that same work with the agency. So we preserve that.

The other big function that we have gotten into, and it's becoming a major part of our function, is third-party inspections and audits. We have hired (either on a full-time basis or on an outside contractor basis) a large number of former FDA investigators. A good percentage of our work now is going into actually doing the certification audits or third-party inspections or pre-FDA inspections, or those kinds of activities that require actual going to the plants and looking at their operations.

RO: Does your consultation include any foreign governments or other governmental, or is it primarily restricted to the regulated industry?

ES: It's primarily to the regulated industry. However, it would not preclude us working for a foreign government.

We do occasionally do contract work for FDA. For example, Carl Reynolds, the former Director of the Office of Field Programs at the Center for Food Safety, was involved in setting up a control program for the raspberries coming out of Guatemala while he was with FDA. FDA is now trying to see if that program is being carried out by the Guatemalan government as it was designed when Carl was with the agency, and has contracted with AAC to have Carl go back to Guatemala to review the control program. He's doing that within the next couple of weeks.

RO: Does your firm do any training seminars for clients?

ES: Yes, we have for years, I guess way back from when Mr. Checchi had the operation, the firm always provided training to the industry. Back then, it usually took the form of in-house training for the client. It was probably four or five years ago when we started putting on public seminars, announcing them, and allowing whoever wanted to register for the programs to attend. They have been very, very well received. We now do training in the pharmaceutical, validation, medical device, food, and dietary supplement areas.

I head up the food, dietary supplement and cosmetic consulting for the company. We put on a series of Dietary Supplement Labeling and GMP Seminars. In addition we offer a Food Labeling Seminar and a Good Agricultural Practices (GAP) Seminar. Yes, we do a lot of training, and it's been very well received.

RO: That pretty much covers the areas that we wanted to cover. We'll close, and thank you for participating in the FDA Oral History Program.

ES: Thank you very much to both of you. I enjoyed having a chance to relive my past and to share some of the favorable experiences I had while employed by FDA. It is a great agency with an important mission.

RT: You'll get a copy of this transcript to review and edit.

ES: Good.

RO: Thank you, Ed.