

# History

of the

# U. S. Food and Drug Administration

Interviewee: Anthony C. Celeste

Interviewer: Robert A. Tucker

Date: October 5, 1994, and  
November 2, 1994

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.



CASSETTE NUMBER(S) 2

GENERAL TOPIC OF INTERVIEW: History of FDA

DATE: October 5, 1994, and  
November 2, 1994 PLACE: Rockville, MD LENGTH: 115 minutes

INTERVIEWEE

INTERVIEWER

NAME: Anthony C. Celeste NAME: Robert A. Tucker

ADDRESS: [REDACTED] ADDRESS: U.S. Food & Drug Administration  
[REDACTED] [REDACTED] Rockville, MD 20857

FDA SERVICE DATES: FROM: 1960 TO: 1985

TITLE: Deputy Director, Office of Regional Operations (FDA)  
(Last FDA position)

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RT: This is another in the series of interviews in the FDA oral history program. Today the interview is with Anthony (Tony) C. Celeste, former deputy director of the Office of Regional Operations in the Office of Regulatory Affairs of the Food & Drug Administration. The interview is being held in the Parklawn Building in Rockville, Maryland, and the date is October 5, 1994. Present, in addition to Mr. Celeste, is Robert Tucker. The transcript of this interview will be placed in the National Library of Medicine and will become a part of FDA's oral history program.

Tony, to start these interviews, we usually like a bit of autobiography. So would you please start with some of your early years, such as where were you raised, educated, and any work experiences that you had prior to coming to FDA?

AC: OK. I was born and raised in the Bronx, New York. I spent all of my educational years and employment years prior to joining Food & Drug in New York City. I was educated in the parochial school system and graduated from Fordham University in 1960 with a bachelor's degree in chemistry. Upon graduation, during my senior year, I should say, I was interviewed for a position with the Food & Drug Administration as an analytical chemist in the New York District Laboratory and was offered a position and accepted that position. Upon graduation I started on July 5, 1960, as an analytical chemist in New York. I spent all of my bench years, if you will, as an analytical chemist in New York and transferred in 1966 to the Kansas City District as a supervisory chemist.

RT: I might ask you, Tony, in New York you were serving as a working chemist?

AC: Right.

RT: Who was the district director and the laboratory director at that time in New York? Do you recall?

AC: The laboratory director at that time was Meno Voth. Meno Voth was the laboratory director that hired me in New York district. Now Meno apparently . . . I don't know, I mean, those were my early years, and it's difficult to remember all the details of some of the older folks. But Meno was a supervisor in Minneapolis, I believe, supervisory chemist, and then transferred to New York laboratory as the director. The district director was Charlie . . .

RT: Charlie Hermann?

AC: . . . Hermann. Thank you. (Laughter) You knew better than I. Meno was transferred after about two years, and then Ted Byers came in as laboratory director. Ted was there for about another two years and was replaced by George Schwartzman. Ted moved up into the deputy director role as Charlie's deputy. George came in, and I was with George for about two years after, and then we transferred out in 1966.

RT: During that initial period of your service in the laboratory were there any particular events or cases or situations that you recall working on that were particularly significant or notable?

AC: Mostly notable? Well, during that time in the laboratory, we were in a kind of a transition period in terms of at least pesticide residue analysis. Most of the analytical procedures at the time were paper chromatography and for the old chlorinated hydrocarbons. Gas chromatography was coming into vogue, and we were in New York district, probably one of the . . . I wouldn't say one of the first labs-- probably towards the tail end of the laboratories that were gearing up to do pesticide analysis using gas chromatography. So I was appointed as the point person, if you will, to learn the new techniques and to try to institute the new procedures. It was fun. They sent me to Barber Coleman (gas chromatography) school in Rockford,

Illinois, for a week. I learned how to use the gas chromatograph, and then returned to the district laboratory and set it up and got the pesticide program going.

RT: This Rockford, Illinois facility, was that a government-related facility or just an educational one?

AC: Well, it was actually the facility run by the Barber Coleman instrument people. They manufactured the gas chromatography units there and also held training courses for people that acquired the instrumentation and needed some education on how to use it.

RT: When you were in the lab there, were you also involved in some import analytical activities?

AC: Yes. As a matter of fact, the major portion of the pesticide program was for imported commodities, fresh fruits and vegetables, primarily from South America. Also fish and fish products from all over the world. One of the more notable, I guess, incidents that I was involved in involved the analysis of Spanish wines and liquors for methanol contamination. As a matter of fact, through the use of gas chromatography, we developed a procedure to detect methanol in ethanol concentrated alcoholic beverages. We were able to determine that some of the imported products did in fact contain methanol and were able to stop their importation into the United States. I guess that this incident stands out. In terms of having an impact, I think it would probably be this one.

RT: Of course, methanol would be a particular hazard to the optic nerve; it affects the optic nerve.

AC: It causes blindness at certain concentrations, that's right.

RT: I know that I asked you to dwell a bit on New York, and then you were about to speak of leaving New York and going to the next step in your career. Maybe you'd like to expand on that.

AC: Yes. Kansas City district laboratory. It was like moving from the big metropolitan area to the Midwest where the Indians and the buffalo roam. At least that was the impression my wife had of Kansas City. But once we got there, she was very pleased with the city and its surroundings. Really, I would guess if I had to pick out any one part of the country that we enjoyed the most, it was probably the Midwest. I think the people there were just super. And, of course, FDA people are super everywhere, not just in the Midwest. But your neighbors and the people that you need to deal with were pleasant as well.

Yes, that was a big change for us. I was in a laboratory that had sixteen analysts at the time and a raw supervisor. Don Healton was also a new laboratory director. He had just moved in taking Andy Allison's place in Kansas City.

RT: Of course, Don Healton and you later worked together in headquarters, which we'll perhaps touch on later.

AC: Well, and a few other places at the same time.

RT: When you went to Kansas City, you'd been promoted. Was it a promotion for you? And were you either a higher grade chemist or a supervisory chemist?

AC: Right. The move from Kansas City . . . I was a GS-11 chemist in New York, and that was considered a journeyman grade for chemists at the time. When I moved to Kansas City, I was promoted to a GS-12 supervisory chemist.

RT: Did we identify what year that was?

AC: That was in 1966. Right. Early '66. Actually it was January. I remember that well because we were delayed by a day or two in New York because of a snow storm.

RT: Well, you remember those things. And then how long were you at Kansas City, Tony?

AC: Well, unfortunately only for about eighteen months. Eighteen enjoyable months I might add, in spite of the fact that there were a lot of people to supervise and it was new for me as a chemist, making the transition from the bench to a management supervisory position. It was really enjoyable. We had a lot of good people in Kansas City. One of the activities, I guess, that sticks out in my mind in terms of what we were doing at that time was the controlled drug activity, what we called the BDAC (Bureau of Drug Abuse Control) support, analytical support activity.

RT: That was the Bureau of Drug Abuse Control (BDAC).

AC: Yes. That was a part of FDA at that time. We had one of the more experienced analytical chemists, an old time chemist by the name of Lloyd Yarnell, who used to handle all of the controlled drug analytical work. He was a crusty analytical chemist and didn't take kindly to supervision. He always concluded he knew more than anybody else, and from an analytical standpoint he probably did. But there was more to handling samples than the analytical portion of it. We had a good relationship though, and Lloyd was, I think, very kind to me, in spite of the fact that I was a new supervisor. He was very supportive and understood, you know, what the rules of the game were, so to speak, and did an excellent job as an analytical chemist in supporting the controlled drug work that we were doing at the time.

RT: And, let's see, the director of the district out there then would have been who?

AC: It started out being Al Barnard actually. Al was still there when I was officially transferred, but left shortly thereafter, and Charley Armstrong took over.

RT: I think that Al Barnard came in to be deputy of the BDAC organization under John Finlator.

AC: Yes. Right.

As I indicated earlier, it was a short tour of duty. I was only there for eighteen months. The reason I moved again was that I received a phone call from my former chief chemist, Ted Byers, who had transferred to Washington and was now the director of the Division of Regulatory Guidance in the Bureau of Regulatory Compliance, and Ted had indicated that he had a number of openings for Food & Drug officers, and was wondering whether I would be interested in one of the positions. Again, this was a promotion for me, from a GS-12 supervisor to a GS-13 Food & Drug officer position.

RT: So at that point in your career, you were really in a way converted from laboratory or science to regulatory management or administrative work.

AC: Right. Exactly. Ted had indicated that he had received the authorization to kind of beef up the guidelines section of the Division of Regulatory Guidance, and he was looking for some folks to help out in developing new guidelines. The group was going to be headed up by Taylor Quinn. Larry Stern was one of the members of the group. So we packed up and transferred into Washington. At that time, the offices were located in Crystal City, Virginia, and we moved to Alexandria. And, again, a fun job. We churned out--Larry Stern and I, together--we churned out a lot

of compliance policy, what are now compliance policy guides. At that time, they were administrative guidelines. A lot of the guidelines were based on data that was generated by the Foods folks at the time, in terms of studies that the food people had done in regard to insects and microbiological contamination of various food commodities. So we turned out quite a few of them based on foods research data. We established some E. coli levels and insect fragment levels and whatever. And now they've all been rescinded. (Laughter)

RT: They were kind of pioneering though.

AC: Yes, we were trying to give the field some guidance levels. I mean, some numbers that they could use as criteria for determining when a product should or should not be recommended for regulatory action. The field people you know, and even my experience in the field, as short as it was, really need some targets and some earmarks to help make a determination as to when the agency is prepared to do something in regard to taking action on certain commodities.

RT: Is that perhaps a decision that might have been an interest of the person then in the commissioner's post, or was it more a field management initiative?

AC: I think . . . I'm not sure the front office, the top, top front office, the commissioner's office, was really that interested in pursuing this; although at the time, the commissioner was Goddard, and Goddard's initiatives were clearly in the food area, particularly salmonellosis and microbiological contamination of foods and food products. But the director of the Bureau of Regulatory Compliance was Al Barnard, and the director of Division of Regulatory Guidance was Ted Byers, and all of these folks had considerable experience in the field area and were quite knowledgeable about what kinds of tools the field needed to assist them in making decisions. In addition, the associate commissioner for compliance was Ken Kirk, a

long-time compliance Food & Drugger, who had a great deal of compliance and regulatory experience, and I had a lot of respect for Mr. Kirk. He was a very, very sharp and bright individual.

RT: Yes, he was. Is it correct to recall that during Dr. Goddard's tenure as commissioner there was an initiative primarily prompted by him, as I recall, to give the field managers more discretion, rather than so much reference to headquarters on all the actions they took? Is that true?

AC: That's correct. That's absolutely correct.

RT: So this would have perhaps complemented that activity?

AC: You're absolutely right. It did cause some problems in terms of uniformity, which, you know, even exist today. I'm not sure those kinds of problems will ever be solved. Yes, I think Dr. Goddard was really probably the first . . . Well, he's the first politically-appointed commissioner who didn't have a career in FDA. At first they decided that the field needed to be autonomous in terms of its actions and activities.

RT: I think Winton Rankin was his deputy during that period, wasn't he?

AC: For a short period of time. It seems to me . . . Yes, I guess he . . . No, he was through the tenure. I guess Winton left after Goddard had left, and then there was this whole big change in organization.

RT: Well, of course, Mr. Rankin, like Mr. Kirk, was a career person in enforcement regulatory orientation. So he would have been very supportive of enforcement.

AC: Right. Well, of course, in those years, communications were not as good as they are today, and folks down at my level really didn't get a lot of a feel for what was going on at the top levels of the organization. And folks in the field, unless you were at the district director level, then the regional director level, they probably didn't know a whole lot of what was going on either.

RT: Yes. Well, what years were you in that role?

AC: That was from '66 to '68.

RT: So you were there about two years?

AC: Yes, a little less than two years, eighteen months.

RT: What was your next step in your career?

AC: Well, the next one was rather interesting. It was a move to Detroit as laboratory director. I say it was rather interesting because of the manner in which I was selected for the position.

RT: What was different about that?

AC: I received a phone call one day from the district director, Tom Brown. Tom said to me, "You've been in Washington now for a year and a half. Would you be interested in making a change?" I said, "Well, what did you have in mind?" He said, "I have a vacancy in Detroit, a laboratory director vacancy. Weems Clevenger and I would like to interview you for the job if you come down to meet us at the Ramada Inn bar after work." (Laughter)

RT: At that time, Weems Clevenger was the director of New York.

AC: New York, right. "You have to pass this test, you know, and then we'll see if we want you for the job."

RT: So a lot of decisions are made at conferences and informal meetings, and apparently this was one where you got a prescreen anyway at that point.

AC: Well, so I did, and we had a nice conversation about what he wanted to see in a laboratory director, and over a few beers and additional libation, I ended up going to Detroit. At that time, I didn't have enough time in grade for a promotion, and so I was a laboratory director in Detroit as a GS-13.

One of my most memorable experiences in Detroit was when I did get my promotion. There was a tradition in Detroit district. Detroit is located in the middle of a block, and right next to the district office is a bar called the Oasis. And one of the traditions in Detroit was for the recipient of a promotion to invite the whole district office to the bar for a drink on a Friday afternoon. So we all promptly started down to the bar after work. However, there were a bunch of folks who had started a little early, and contrary to tradition, everyone was buying me what they call rooster poops or rooster shooters or whatever, and this consisted of a beer and a shot of bourbon. I ended up having nine beers and nine shots of bourbon, which apparently was a record that lasted for a while until Ed Floyd beat it a couple of years later. I was feeling no pain. Tom Brown and Cliff Shane, who was chief inspector at the time, poured me into the back of Tom Brown's station wagon, and they drove me home, propped me up on the front door and rang the door bell and promptly left. (Laughter) And my wife opened the door, and I promptly fell into the hallway, and she put me to bed, and I was in no pain, no pain at all. But, again, Detroit district was a good experience. There were a lot of good people there.

RT: In Detroit, were there any unique operations or responsibilities in that laboratory? I believe at that time labs generally did about the same kinds of things at different locations. Later I think we'll want to talk a little bit about the specialization that occurred. But at that time, was it sort of routine analytical work?

AC: In the general lab, we had microbiological activities, as well as some food activities, and some highly specialized pesticide activities. One of the . . . I think again one of the memorable projects or activities in Detroit involved the contamination of Coho salmon with chlorinated pesticides and PCBs, and that was one of the major projects that I was involved in and the laboratory was involved in. And then from there we got into mercury in fish problems in the Great Lakes. And, again, that was a major initiative. As a matter of fact, Cliff Shane and I wrote an article for *FDA Consumer* on mercury in fish and our experiences in that regard.

RT: Now, I suppose that in each of these laboratories you had some dialogue and cooperative work with state laboratories. Were there any kinds of situations or problems encountered with people in state agency laboratories?

AC: Well, the Michigan folks were really very good and very cooperative. We had a lot of good cooperative programs with the Michigan folks. One that stands out, again, as a special kind of thing was help that Michigan requested. They needed some outside help for someone to come in and take a look at--and this is not even related to Food & Drug activities--but to take a look at their procedures for the control and analysis of samples associated with horse racing in the state.

RT: And there's some chemistry involved in that, isn't there?

AC: Yes, there is. And we spent a few days doing an overview of their analytical procedures and the handling--primarily the integrity handling--of samples. This was the focus, because there was some question about whether or not the samples could have been tampered with or not tampered with. We assisted them in that regard and provided them with a report. I mean, I did that personally, and I didn't see any particular problems in the way they were handling any of their samples. But aside from that, we were very active in AFDO (Association of Food & Drug Officials) and AFDO activities and had some good committees and a good working relationships with the state.

RT: Well, I seem to recall that the Central States' Association of Food & Drug Officials, with which the Detroit district would have been involved, did have a separate laboratory section. Many of the regional associations of AFDO now have such separate sections in their conferences, but I believe that was one of the early ones. And I'm sure you and your people were active in that.

AC: Yes, they were. In addition to the Detroit area, we had a very active science advisor, who worked for Wayne State University, who helped to establish an eastern analytical section of ACS (American Chemical Society).

So the laboratory was a very active lab. We had a lot of people that were interested in their profession and active, a lot that were going to school at night to try to get advanced degrees; and our science advisor, Dr. Boltz, was again, very actively involved in the district laboratory activities in trying to get folks interested in pursuing advanced degrees.

RT: And he was the science advisor?

AC: The science advisor. At that time, each laboratory had what we called science advisors, who were usually associated with academic institutions in the area. These

folks would be paid on an hourly basis to come into the district office and spend time with the analytical chemists and microbiologists, depending on their professional expertise, and assisting in problem solving, and to help with research and development projects, and to encourage these folks to better their education, put on in-house training programs on new analytical techniques and what have you. It was kind of a development project for the analytical people, for our chemists and microbiologists. It worked very well.

RT: Well, this is perhaps later in your career when you were in headquarters, but the science advisor I think came into headquarters to take up a position. Would that have been Dr. Boltz?

AC: No. Stevenson. That was Ken Stevenson. He was a microbiologist.

RT: Yes. I think that was at a point when--this is a little out of chronology--but when Hy Eiduson was retiring. Headquarters management was selecting a new headquarters laboratory director, so they called Sherwin Gardner, who I believe was acting commissioner then. Sherwin thought that a Ph.D. person should fill that position. And at that time, I think the science advisor from Detroit did come in and initially occupy it. But it was not Dr. Boltz that we were speaking of.

AC: No, it was Ken Stevenson. He was a science advisor, but there were two at the time--one for microbiologists and one for the analytical folks, the chemistry folks. Boltz was the chemistry side; Stevenson was on the microbiological side. He was from the University of Michigan.

RT: I see. I think it was a microbiologist that came in. But that, of course, is a little out of the chronology that we're speaking of.

AC: Well, your memory is better than mine.

RT: Well, I don't know about that. Now, let's see. You next moved to Boston, didn't you? After Detroit?

AC: Yes. That was an interesting move as well.

RT: That occurred at what time?

AC: Nineteen seventy (1970). So I was in Detroit for about two years, from '68 to '70. At the time, there was a major reorganization taking place in the Food & Drug Administration, particularly the field part of it, and a number of positions had been created and a number of folks had apparently retired, and there were a number of vacancies.

RT: Was that, Tony, at the time the EDRO had been established--the Executive Director of Regional Operations?

AC: Executive Director of Regional Operations, correct.

RT: And that would have been Paul Hile?

AC: Right.

RT: So it was really at that point that the field organization was being significantly reorganized?

(Interruption)

RT: This will be a continuation of the interview with Tony Celeste, which we started on the fifth of October and now continue on the second day of November here at the Parklawn Building. Tony, we were just beginning to speak of the reorganization under EDRO and Mr. Hile, particularly as it related to field activities. So let's now proceed with that, Tony. Thank you.

AC: The reorganization created a number of retirements and subsequently vacant positions, in addition to a number of headquarters organizational units that didn't exist prior to the reorganization. The regional director positions became available, and there were ten regional directors in addition to a number of district director positions that were established. Those districts where the regional office and the district office were in a sense not combined, but in the same location, the position of district director became known as the deputy regional Food & Drug director. Those positions were of a different grade than the district director position, where the regional director was not physically located.

RT: Tony, let me ask you, was this an initiative under Commissioner James Goddard, as well as Mr. Hile's management of the field?

AC: I think this initiative started . . . Well, I'm not really sure. I thought it started with Kennedy--not Kennedy. Excuse me. Not Kennedy, but Edwards. Actually, when Goddard took over, there were no regional director positions. There basically were district director positions, and those district directors had a lot of autonomy. It seems to me . . . My recollection was that that was in the mid-sixties, around the '65, '66 period. Then, of course, there was a small period of time where the CPEHS (Consumer Protection & Environmental Health Service) organization came into existence, and there was turmoil in the Food & Drug Administration in regard to, you know, where we fit in to this new organization.

RT: CPEHS, I guess, was the acronym, wasn't it?

AC: Yes, and I can't even remember what it stands for to be honest with you. Consumer Environmental Protection Health Administration or some such nonsense like that. But it was really confusing at the time. Of course, my position, a relatively low position in the field, you didn't have a lot of input or a lot of knowledge about what was going on at the management levels, so I wasn't really totally familiar with that organization. But it seems to me that the EDRO really came into its own during Dr. Edwards' tenure as commissioner in the early seventies.

RT: That puts it a little bit in perspective for those that would be interested in the top leadership at the time.

AC: Yes. I think the biggest change that came about during that reorganization was the creation of the headquarters' counterparts to the field part of the organization. The Division of Field Operations, the Division of Program Planning, the Division of Regulatory Guidance, and the compliance and policy activities where coordination was to take place. Each headquarters office had a counterpart field office. For instance, the Division of Field Science related to all of the laboratory directors, the Division of Field Investigations, all of the investigations branch directors, and Division of Regulatory Guidance was responsible for the compliance officers and their activities. The primary purpose was for coordination and for insuring that those folks had some representation at headquarters in dealing with the centers--at that time bureaus--and their compliance offices.

RT: You were discussing a moment ago, though, some of the developments in the field, and we've interrupted that. Perhaps you want to expand on what you were saying earlier.

AC: Well, the creation of the deputy regional Food & Drug director positions and the regional director positions and the subsequent retirement of a number of the older hands created a lot of vacancies in the field, and so in the early '69-'70 period, there was a lot of movement of people from one location to another. At that time, I was the laboratory director in Detroit, and Jim Beebe was the deputy director in Detroit. Jim was offered the position of regional director in Boston, and when Jim was provided that offer, he also had the opportunity to select his deputy, and he asked if I would be interested in moving with him to Boston, and I did--we did. That was a good experience for us.

RT: During your service at Boston, were there any particular kinds of experiences there that come to mind that might be of interest here?

AC: I think that probably two that stand out the most. One was our relationship with the New England state officials, and particularly one George Michaels, who headed up the Massachusetts Food & Drug program. Dr. Michaels, as he liked to be called, was a real character. I mean, he is one of the state officials that probably will remain infamous in Food & Drug annals for a long time to come.

I guess the question in regards to Dr. Michaels and his program was whether it was an honest Food & Drug program or whether it wasn't. No one was ever able to really--at least during my three years in Boston--to really conclude that it wasn't; although there were many indications of activities behind the scenes and people getting away with violations of the Food & Drug Act and activities. While we had a contract with the Massachusetts Food & Drug officials to carry out the inspection of certain programs, particularly food sanitation program area, we were constantly evaluating and reevaluating those activities and whether or not the contract should be renewed. It resulted in a number of meetings with Dr. Michaels and his staff, where we would present information that would lead us to conclude the program was

not working well, and he in turn would provide information to show us how well the program was working.

RT: I think one of the differences there with Dr. Michaels and the Food & Drug Administration related to the presence of mercury residues in swordfish. The state official in this case disavowed that there was any public hazard, and FDA and other public health folks differed in that opinion.

AC: That's right. Another area that really stands out--and then again it involved the states--was the problem with vibrio in shellfish and what we called then the Red Tide. This is an organism that contaminates shellfish at certain times of the year under certain conditions, and at certain concentrations, if consumed, is fatal and can result in paralysis and death. We had a lot of meetings and discussions with state officials in regard to the control of certain shellfish growing and harvesting areas in regard to Red Tide, and had a difficult time sometimes getting their full cooperation.

They had two objectives. Of course, one was to protect the public, but the second was to protect the industry. Sometimes there was a dichotomy there, because you can't protect the public and the industry at the same time in all instances. So they were trying to walk a fine line. And, of course, we were concerned. Our main concern was protecting the public; not too much worrying about the industry. So there were some interesting meetings and conferences and discussions with health officials and particularly Dr. Michaels and his Food & Drug staff.

RT: Well, I seem to recall that Dr. Michaels is perhaps the only state official that ever was successful in persuading the state legislature to appoint him as a lifetime official, like a supreme court justice. That, however, didn't in the end work out, as Dr. Michaels later was found in a very compromising gratuity situation and was removed from office. But that was an aspect of the Massachusetts Food & Drug program, which I think was corrected by successive leaders in the program.

AC: Right.

RT: But in addition to Massachusetts, were there any other states in New England that were noteworthy in their program in any way?

AC: Well, most of the New England states in terms of Food & Drug activities were basically involved in a lot of basic Food & Drug activities. You know, there was a lot of dairy industry and raw agricultural commodities and farming and things of that nature. The fish industry, of course, is very big along the coast, particularly Massachusetts, Rhode Island, and some in New Hampshire. I think, though, for the most part most of the state officials were very cooperative and willing to help and assist in the program. We had a lot of training activity and a lot of give and take with the state officials. Not too infrequently, some disagreements. But I think for the most part, except for Massachusetts, most of the other states were very cooperative and willing to work with us. I'm sure when Mr. Beebe retires he will have a lot of stories to tell about his relationships with the state officials, having been there since 1970.

RT: Then after you had been in Boston, I seem to recall that your next assignment was over at Cincinnati. When did that transfer occur and to what position did you move to in Cincinnati, Tony?

AC: In 1973, I moved to Cincinnati as the district director. At that time, the deputy regional Food & Drug directors that co-habitated, if you will, the same office with the regional food and drug director (RFDD) or were physically located in the same city, were GS-14s, and those that did not were GS-15s. So it provided me an opportunity to become a little independent and get a promotion at the same time, and so I took that opportunity and moved to Cincinnati district in 1973.

RT: Now as I recall, when you were at Cincinnati, there was some development of special laboratory capabilities there. What did that involve, Tony?

AC: During my tenure, I guess we really began to put together the expertise that currently exists in Cincinnati as a forensic laboratory, and it really started with the continuing education program that Fred Fricke got involved in at the University of Cincinnati in conjunction with our science advisor, Dr. Caruso. Fred was a very energetic and dynamic analytical chemist, and he put in a request to go back to school on a part-time basis to get his Ph.D. in analytical chemistry. We approved that request and supported his activities. In conjunction with his activities at the University, one of his research projects and programs was elemental analysis, and at that time, the inductive coupled plasma-atomic absorption analysis for elements was just coming into vogue. We were capable and had the opportunity to acquire one of the first instruments that was available for determining low levels of elements.

RT: The Bureau--or now the Center for Foods--also relied heavily on Cincinnati for laboratory research. Was that something different than you've just been speaking of?

AC: Yes. There was a foods research laboratory that was a part of the Center for Foods, or the Bureau of Foods at the time, that was physically located in Cincinnati. They were more or less an engineering group more than an analytical group. They did a lot of research with equipment and modification of equipment in the manufacture of food products, particularly ultra-high pasteurization, and you know, just basic sanitation kinds of things.

RT: So that facility really was . . .

AC: . . . was not a part of Cincinnati district, no.

RT: In Cincinnati, you were in the central states or mid-continental area. Were there different kinds of experiences with states or problems in your management at Cincinnati than you experienced at Detroit?

AC: Oh, not really. We were in a way I guess fortunate to some extent, because the only state we were responsible for was Ohio, so our relationship with the state was more or less on a one-to-one basis. We had a good working relationship with the State of Ohio. We started some initiatives to get them involved in a medicated feed program, if my memory serves me correctly, which was a different part of the state organization that had not previously been involved in Food & Drug activities. Of course, the state also had a contract to do basic sanitation-type inspections. We coordinated those with the state. We had a large resident post in Columbus, which facilitated communications with the state. My recollection is that our relationship was really for the most part uneventful in terms of any kind of crises or problems.

RT: Were there any kind of legal actions taken during your time at Cincinnati that might be noted here or was it pretty much routine?

AC: Well, we did have the mushroom industry in Cincinnati, and when I was first appointed as district director, we were in the middle of the botulism in canned mushroom crisis. At that time, Bill Clark was acting district director. He and I, we made the transition, and I had taken over the project. While it didn't result in any kind of legal action, it certainly did result in a significant impact on the mushroom industry in Ohio and getting them into compliance.

Other activities involved the illegal sale of Laetrile. More or less a health fraud type of investigation that we were involved in that resulted in prosecution of several individuals from the Ohio area.

RT: That was a cancer curer?

AC: A cancer cure, right.

RT: Allegedly so.

AC: Laetrile was being promoted as a cure for cancer. There were some interesting aspects to that particular activity involving search warrants and the marshals and that sort of thing.

RT: Then after your work at Cincinnati, is it correct to recall that you then moved to headquarters?

AC: Yes. At the request of Mr. Hile and Mr. Ottes and the retirement of Charley Armstrong, who was then the director of field operations, I was asked if I would be interested in moving to headquarters to take that position. And I did, and that occurred in 1976.

RT: You came in then in what capacity?

AC: As the director of the Division of Field Operations.

RT: With regard to Ron Ottes, was he in charge of the field operations?

AC: Ron was the deputy executive director for regional operations; Mr. Hile was the executive director for regional operations.

RT: Do you recall having worked again with the field in any particular situations such as the WEAC (Winchester Eastern Analytical Center) organization in Boston?

AC: Yes. The Northeast Region Radiological Health Laboratory, as I think it was called at the time.

RT: The WEAC acronym stands for what?

AC: The Winchester Eastern Analytical Center?

RT: I believe that's what it was.

AC: I think that's what it was. (Laughter) I don't know how we ever came up with that name, but that was right. But it was a radiological health laboratory. It was one being run by the Bureau of Radiological Health. Actually, Jerry Halpern and Mr. Hile and Mr. Villforth had apparently worked out an agreement whereby it would be transferred to the field or to EDRO, and we were charged with trying to come up with a proposal on, number one, how we would utilize the laboratory, and for what purposes, and what kind of staffing we would need, and how much it would cost to run WEAC, and then how we would smoothly transition the phase out of some of the things they were doing and pick up some of the things that they weren't doing.

RT: Did that have any relationship to the medical device amendments to the Federal Food & Drug Act?

AC: Oh, definitely. Yes. One of the objectives clearly was to try to come up with a field analytical laboratory that would have the capacity and the capability of doing some basic medical device testing. Associated with that medical device testing, of course, was radiological testing. The testing of microwave ovens for emissions and the testing of televisions, and that was just some of the basic things that were done. Some of the other things that needed to be done really involved a lot of R & D

(research and development) work, because there were no testing procedures for them. In addition, that laboratory was designated as the center for conducting radiological or radioactivity testing of food products in the Total Diet Program.

RT: Well, then they would have perhaps been involved in the Three Mile Island Nuclear Plant episode?

AC: Absolutely. Yes, they did an awful lot of testing up there at that time.

RT: Would they have tested foods such as milk for radionuclide problems?

AC: . . . contamination. Absolutely. Yes.

RT: I think in the time you were at headquarters in the position we're discussing now there were further reorganizations. This radiological health program was perhaps the principal one. But was there a reorganization of headquarters administrative offices as they related to the field. I think you mentioned something about that earlier. Did that all occur when Mr. Hile was the ACRA (Associate Commissioner for Regulatory Affairs) or did some of that occur when Donald Healton took over?

AC: Well, shortly after I came into headquarters, Sam Fine retired. Actually it really occurred before I even arrived on the scene. Sam Fine, the associate commissioner for compliance, retired, and Mr. Hile was appointed as the new associate commissioner for compliance. That consequently created a vacancy in the *executive director for regional operations* position. Donald Healton, who was the regional director in Chicago, was selected as the new EDRO (Executive Director for Regional Operations). When Don reported on the job shortly thereafter, there was a headquarters reorganization.

While the reorganization, I guess, to some extent wasn't all that significant in terms of what we did as an organization in providing support to the field activities and coordinating headquarters and field activities, from the headquarters standpoint, I guess, it did create a bit of a problem for some folks. I guess the biggest part of the reorganization was the combining under what was then the associate director for field support. Some of the planning and evaluation activities that were at one time independent as an independent division and the regulatory guidance and compliance activities that were also independent as separate divisions were combined under one office.

RT: Was that the Division of Field Operations then?

AC: Well, the Division of Field Operations, and the Division of Regulatory Guidance, and the Division of Planning and Evaluation all became a part of the associate director for field support, and they reported to that position as opposed to reporting directly to the EDRO (Executive Director of Regional Operations) position. So there was another layer established, and I think that certainly caused some people concern.

RT: So this latter organization would have been headed then by who?

AC: By me.

RT: By you. You were the head.

AC: Right. I was appointed as the head of that. At that time, there was also a rather interesting development that I guess to some extent . . . Oh, I don't know how to put it. It was a personnel-related thing and caused, I guess, some turmoil. Rich Cooper was appointed the general counsel under Dr. Kennedy, and I guess one of

the conditions under which Mr. Cooper took the position was that the then deputy counsel, Al Gottlieb, be reassigned to some other position within the agency. I guess Don Heulton was asked by Gerry Meyer, who was the associate commissioner for management & operations at the time, whether we could find a position for Mr. Gottlieb in our organization. Don and I got together, and we created a position as the deputy associate director for field support for Al, and he became my deputy in . . . Gee, I'm trying to think. It was about 1978.

RT: Now during the time that he was with you, there were quite a number of training courses for the field in enforcement and legal precisions. Did Mr. Gottlieb become involved in that as well?

AC: Well, Mr. Gottlieb had been involved in that prior to joining the EDRO organization, and so his involvement continued. But what he was no longer involved in were matters that were the purview of the general counsel's office. Legal matters and cases and things of that nature. Although I might say he did quite a bit in our organization in evaluating cases and determining whether or not cases that were turned down at various levels at headquarters should be appealed and he helped draft those appeals and coordinated with the field offices in working some of those cases.

RT: I think you were also involved in an initiative started by Mr. Heulton, and that was the establishment of research centers or Centers of Excellence. What was the nature of that initiative?

AC: Well, we felt that by concentrating, if you will, certain research activities in selected district offices that we might enhance the status of the analytical portion of the Food & Drug Administration's activities, particularly the field activities. By doing that, we would create, you know, a number of things. There would be a center where

one could go for all research and development activities and certain problem commodity or analytical related areas. That would hopefully result in an increase in a number of papers and publications and research projects that would be produced by the field organization. That in turn would result in some recognition by the scientific community that the Food & Drug Administration was not only a regulatory agency, but also a research agency that could focus on problems related to the regulatory aspects, but, you know, more . . .

(Interruption)

AC: OK. . . . more to problem solving and science as opposed to strictly the development of mundane analytical procedures. Then ultimately, what we hoped was, as a result of these activities, we would be able to upgrade the grade level of some of these researchers. That's one of the problems the agency always faces is the promotion of technical people into management positions. The reason, of course, is because there doesn't seem to be a good avenue for providing people with the *grade levels and the monetary rewards of doing a good job at the technical level*. So we were constantly looking for ways by which we could accomplish increasing the grade levels of some of these technical people to keep them in their area of interest and expertise, while at the same time providing them with proper rewards.

RT: The mid-level and senior executive development programs were then a reachable goal for some of these folks through elevated grades. Is that correct?

AC: Well, the mid-level and executive development programs again always seemed to be focused to getting into the administrative and the management line of succession in positions. What we were trying to establish by establishing the research centers was more or less through example and through the publication and the recognition that the centers would achieve and to, you know, be able to justify and

support promoting some people that would continue to work as analytical people in the research and development area and maintain their technical expertise without having to go into management positions and give up that hands-on work, if you will.

RT: I see. Very good. Now, during your tenure, I believe you were also responsible for compliance program reviews and evaluation from the field management perspective. Can you speak to that a moment?

AC: Sure. Yes, one of the responsibilities of our office clearly, because we had comparable organizations within headquarters, was to assure that compliance programs that were developed by the centers for implementation by the field were proper in terms of their instructions, their format, the policy, the procedures, the amount of work that they were requesting in terms of manpower, the laboratories which were assigned the various types of analyses to make sure that they had the expertise. Our good offices were responsible for reviewing all of these compliance programs, the laboratory portion of a program would go to the Division of Field Science, the investigations portion to the Division of Field Investigations, and the compliance or regulatory portion to the Division of Regulatory Guidance, and the manpower allocation, of course, to the Division of Program Evaluation.

We would critique these programs and provide to the centers our comments with the hope that eventually these would be revised and would reflect what we felt was proper guidance. In addition, we were quite active and quite heavily involved in field/center committees. The food committee, the drugs committee, advisory committees that were established to coordinate with the center, the annual planning, the annual preparation of compliance programs and activities, and we participated in those activities on a regular basis.

RT: You mentioned some of the field management committees. There were periodic planning and discussion conferences for the regional Food & Drug directors

and also for the district directors in some cases, both levels of top field management were involved. Did you have some special responsibilities with regard to those conferences at headquarters?

AC: It would depend on what the particular agendas were for those conferences. But not too infrequently our staff was requested to make presentations and to provide some input in regard to the agenda and to identify problem areas that should be discussed during the course of the meetings. What we tried to do, of course, was to heavily involve all the headquarters offices, in addition to our own, like the centers, the associate commissioners, the general counsel's office, and certainly the commissioner, to provide them with time on the program to address the group. But the real working level subject matter that was discussed at these meetings was, I guess for the most part, my responsibility, particularly in the processing of regulatory actions and the planning and analysis aspects.

RT: Tony, you had played a key leadership role in those conferences, as I recall, particularly with the district director group as well as the combined RFDD and DD meetings.

AC: That's right. The district directors were the most vocal of the group. They were the most difficult to deal with.

RT: Well, that's probably why they let you handle them.

AC: Yes, they were fun.

RT: You had been one of them recently, and maybe you understood their views.

AC: Yes, but once you're gone, you're gone. It doesn't last very long.

RT: Now, Mr. Heaton, of course, at one point in time, and I don't recall the year exactly, took an assignment as a regional Food & Drug director in the southwest region, Dallas. When he returned to the field, what changes occurred with regard to yourself and Mr. Ottes in the field headquarters?

AC: Yes, that was the second reorganization that occurred. What basically happened was that the executive director for regional operations became a part of the associate commissioner for regulatory affairs. Mr. Hile, who was the associate commissioner for compliance, his title was changed to associate commissioner for regulatory affairs; and the executive director for regional operations reported to him as opposed to reporting to the commissioner, and that was Mr. Ottes, and I became Mr. Ottes' deputy. Then all of the ADFS organization (the Associate Director for Field Support) became a part of the Office of Regional Operations.

Well, in addition though, I might add that there was also a split that occurred of some of the responsibilities of that office. The Division of Federal-State Relations then became a part of the Office of Regional Operations. The Division of Regulatory Guidance became a part of the Office of Enforcement, which included regulations and case processing, as well as compliance policy and guidance, and the planning and evaluation and computerization management information systems were split off and became a part of the Administrative Office under the Office of Program Management I believe it was. So there were three separate offices established at that time. The Office of Enforcement, the Office of Regional Operations, and the Office of Program Management.

RT: Now, who were the heads of each of those respective organizations?

AC: OK. Merv Shumate was the director of the Office of Enforcement, and Mr. Ottes was the director of the Office of Regional Operations, and I know Ronald Chesemore was appointed as the Office of Program Management. But it seemed to

me there was a time lag there prior to Ron's appointment. I don't remember. I guess someone was acting. There were actors in those positions. I think Ron was the first permanent appointee to that office.

RT: Of course, Ron Chesemore later in the course of events became Director of the Office of Regional Operations.

AC: Well, he was the director of the Office of Regional Operations on Mr. Ottes' retirement, and then appointed the associate commissioner for regulatory affairs when Mr. Hile retired and currently is in that position.

RT: Well, as you worked here in headquarters, who were some of the folks at the upper levels of management that were of particular assistance to you or particularly helpful in your responsibilities?

AC: Actually, in thinking about this, I think that one of the people that I don't think at the time commanded an awful lot of respect by a lot of agency people, who I had a lot of respect for and that I thought really was very supportive of the field organization is Dick Crout, who was the director of the Bureau of Drugs. No matter when you asked Dr. Crout for anything in terms of wanting to get some input from him in terms of field programs, field activities, or problems associated with processing legal actions, he was always very responsive. He always showed up and supported the field meetings, whether it be district directors, regional directors, or branch directors. I mean, if you invited Dick Crout to either be on the program or to attend a social function just to meet with the guys and talk about problems, he'd show up. He'd be there, and he would bring his people along to be responsive to questions and problems.

So I seriously think that of all of the center directors that I had contact with, Dick was probably, in my experience, the most supportive of the field programs and

field activities, contrary to what some other folks might think. He didn't always have the . . . I mean, I think he tried to understand more than any other center director what the field's problems were, what the field programs were, and he would try to have some impact on assisting on getting problems resolved.

The other parts of the agency that I think were very supportive of field programs, field activities, and some of, you know, my own personal kinds of things were certainly OMO (Office of Management and Operations). Gerry Meyer, Sharon Holston, and Don Sauer were always very supportive and helpful in terms of getting things resolved and providing the field with whatever resources were available that they could muster up. Jake Barkdoll's group in addition I think. Jake's activities were to some extent supportive of the field programs.

RT: And Jake was the . . . ?

AC: Jake was the associate commissioner for planning and evaluation, and Jake's staff would do a number of evaluations of the programs and activities and provide input in that regard. I think some people to an extent sold some of those things rather short. You know, gave them short shrift and were real short-sighted in terms of what impact some of those studies could have on agency programs and directions. So I think Jake was helpful. He was also helpful in identifying problems between the centers or the bureaus and the field offices.

RT: Now, of course, you also worked with field management at the regional director and district director level and perhaps even with directors of inspectional and analytical units in the field. Were there any field personnel that were noteworthy in a positive or negative way?

AC: Well, I really hadn't thought about that much. You know, I think for the most part the support by the field organization was somewhat mixed. There are always

leaders in every group, and there are always those that will sit back and do not really participate all that much and yet quietly go about doing their business and doing it in a very effective and efficient way. No one in particular really stands out.

RT: Well, you've served as most younger persons in the agency--younger in the terms of the agency's history--under a number of commissioners. During the several commissioners that have served during your FDA career, are there any comments that come to mind about any of those leaders in terms of their impact on the agency as it affected regulatory work in the field?

AC: Well, actually, you know, I think that Don Kennedy--in my view anyway, in my personal view, in my personal relationships with commissioners--was probably one of the most dynamic and supportive commissioners of the field activities and field programs that I've had any dealings with. I have a lot of respect for Dr. Kennedy and enjoyed, I guess, more or less the personal contact with him. I probably had more with him than with some of the others. Of course, with the reorganization some of that kind of dwindled away since there was another layer between myself and the ORO organization and the commissioner, and that was the ACRA. So the relationship was somewhat changed.

RT: Well, you've had a rather long and varied career in the Food & Drug Administration, and, of course, you left to enter food and drug related activities in the private sector. Do you have any comment regarding your decision or your perspective now as a person on the outside about the agency and its direction and so on?

AC: Well, one of the things that shocked me immediately on leaving FDA was how much I really didn't know about FDA in terms of what I was doing in my little world versus, you know, the rest of FDA.

RT: Now, Tony, when did you leave and where did you go into your current activities?

AC: Well, I left FDA in 1985. I was provided an opportunity to join a consulting company as a consultant with the proviso that if I liked the work and I liked the company that we could work out an arrangement whereby I would eventually take over the company. I was provided with a two-year window to exercise an option to take over the company. I exercised the option after a year and took over the company in 1986. It's a food and drug consulting company in Washington, D.C., which had traditionally hired ex-FDAers to provide professional and information services to the Food & Drug regulated industry, and we currently have twenty full-time employees in the Washington office, with another six that work for us from time to time on special projects. There are approximately eight people that are support people, the rest being full-time consultants.

RT: Do you care to mention the name of that consultant?

AC: The consultant . . . Oh, who owned the company prior to my taking over? Yes. It was Arthur A. Checchi.

RT: And the firm continues under that name?

AC: No, the firm had to . . . As part of the leverage buy-out, I was required to change the name of the company after four years, so the name has been changed to AAC Consulting Group, Inc., and that was done in 1991. But we still operate under the same traditional roles that we operated under Arthur A. Checchi, and that is providing both information and professional consulting services to the clients on Food & Drug related regulations and policy, procedures, enforcement, and it has been an interesting nine years.

**RT:** Now you mentioned that after you left, you discovered how many things the agency is involved with that you weren't really intimately familiar with as a retired or former FDAer. Do you see the agency itself in a different light than you did when you were a part of it?

**AC:** Well, not really. I think there were certain parts of the agency, and a lot of it is personality related, that caused me some anguish and concern. There are certain parts of the agency that move very slowly, and it's difficult to get information that is critical to the industry and that will help the industry to achieve and maintain compliance with the agency's expectations. One of the things we try to do is to keep up with what's going on at FDA and to provide that kind of information to our clients to assist them in knowing what are the agency's expectations. And it's not always easy to get that information from FDA, because of certain personalities or people in the agency. They are really reluctant to talk about what the requirements are. I don't know whether that's because they really don't know or are afraid to go on record saying this is what we're looking for, this is what we want. And that's difficult. It's difficult to explain to the industry, particularly when you try to defend the agency.

There are other problems. And, you know, a problem that I think I recognized when I was here that continues to be a problem is the uniformity of FDA policy, particularly relating to inspections. The caliber of the investigator, how does one try to achieve uniformity in terms of investigators, both their knowledge, their experience, their ability to conduct good inspections and to provide the company with some good feedback.

**RT:** There was a time in earlier history of the agency, of course, when there was a very structured headquarters control of most policy and most decisions about field operations. Then as I recall under Dr. James Goddard, when he became commissioner, he gave the field management team more latitude and looked to them for

taking more responsibility independent of calling headquarters. Do you see, with regard to uniformity, any kinship with one style of management versus another? Has the current style created greater problems with uniformity in your view?

AC: Yes. I think that there needs to be at the headquarters level a good quality assurance program to provide to upper management, whether it be the commissioner or the associate commissioner for regulatory affairs, a comfortable feeling that at least from these QA (quality assurance) activities, the field is carrying out their programs in a comparable manner from district to district. At the present time, it seems to me that a lot of authority and responsibility is being delegated to the field without comparable oversight to assure that they're carrying that out in a uniform and proper way.

Now, I know that there's an awful lot of activity going on in regard to trying to certify investigators in certain inspectional areas to assure that at least there's a process by which investigators are trained, provided with some experience, and evaluated to determine that they can in fact conduct certain kinds of inspectional activities the right way; and that's an admirable and I think the proper direction to be going. Whether or not that can be achieved to the extent that we would like to see it achieved is another question.

RT: Well, in some programs of the agency, and those that come to mind are the milk sanitation program, perhaps the shellfish program, and the food service or food safety program as it relates to food service establishment inspection, there are processes for the standardization of field personnel. Of course, we don't have that for the inspection force in general, and perhaps it's not even amenable to that, because these are very parochial programs. In those activities, perhaps a large measure of the uniformity has been achieved in that way.

AC: I think that's probably to some extent a good thing to be doing. At least the expectations are identified and recognized. Of course, in the drug programs and the devices programs, there's such a variety of processes, and firms, and products that have to be inspected which are manufactured under different conditions and principles that it really does become difficult. But there needs to be a greater effort to assure that's happening. I mean . . .

One of the really discouraging things, as a former FDAer, is if you go in and you look at the operation of a particular manufacturing establishment and you come up with a whole list of things that you think are problem areas, deviations from GMPs and observations of things that should be fixed, and you discuss these with management, and they come back and say, "Well, six months ago I was inspected by FDA, and they didn't point out any of these things to me. What are you trying to . . . ? I mean, you know, are you guys trying to tell me I'm not complying, whereas FDA has just been in here and said everything's okay?" Well, that hurts our credibility and it hurts FDA's credibility as well, because the next time they get inspected by FDA, it might be a more experienced investigator, who in fact will find not only the things that we've found but maybe some others that might be even of greater significance, and before you know it, the firm's in deep trouble.

There seems to be a sense of complacency on the part of the industry, particularly when they've been repeatedly inspected by FDA, and there are no problems pointed out. Then all of a sudden, a more experienced investigator comes along or one that has an expertise in a certain area and the facility is a disaster. Well, I recognize that it's not FDA's responsibility to point all of these things out to management; however, it is their responsibility to find problems if they exist, and when they don't, it creates, you know, the wrong impression.

RT: Well, the agency I think has moved from a time a number of years ago when only the mandatory information was given to a firm, and then a remedy was sought

through a legal action. I think we have perhaps moved more to an educational mode combined with compliance.

AC: At least a more open mode.

RT: Exactly.

AC: To be able to at least identify to management what the problems are as you conduct an inspection and then at the conclusion of an inspection. The agency has the right to expect that those things are going to be dealt with, and when they're not, then they should be taking regulatory action.

RT: Well, Tony, we've covered quite a large area. Before we conclude, is there any wrap-up comments that you wish to make?

AC: Well, I think that the agency has a very important mission in terms of consumer protection and enforcement of the Food, Drug & Cosmetic Act and regulations. I guess I'll always consider myself an FDAer, and I still have a problem with saying "we" and "they," and some of my clients don't appreciate it all the time. I think by continuing to do the work that we do on the outside, I hope that at least we're helping to educate the industry and in our own little way, if you will, achieve compliance that makes it easier for FDA.

I think in terms of my own personal career and decisions, the biggest thing I miss by being outside of FDA is my relationship with the people inside FDA. That, *of course, has changed, and I do miss the activities with my former colleagues, the field offices, the district offices, the regional offices, and the headquarters offices. You can't get that back, unfortunately.*

**RT:** Well, we miss you, and I, as a retiree, miss that association, too. Well, thanks very much, Tony.

**AC:** Well, my pleasure. Thank you, Robert.