History

of the

U. S. Food and Drug Administration

Interviewee: Adam J. Trujillo

Interviewer: Robert A. Tucker

Date: March 16, 1995 & August 3, 1995

Place: Sterling, VA

DEED OF GIFT

Agreement Pertaining to the Oral History Interview of

Adam J. Trujillo

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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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

CASSETTE NUMBER(S) 3

GENERAL TOPIC OF INTERVIEW: History of the FDA

DATE: March 16, 1995 & August 3, 1995 PLACE: Sterling, VA LENGTH: 120 minutes

INTERVIEWEE	INTERVIEWER
NAME: Adam J. Trujillo	NAME: Robert A. Tucker
ADDRESS: [redacted]	ADDRESS: U. S. Food & Drug Administration
[redacted]	Rockville, MD 20857

FDA SERVICE DATES: FROM: June 20, 1960 TO: April 3, 1993

TITLE: Deputy Director of Regional Operations
(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 Adam J. Trujillo, former deputy director, Office of Regional Operations in the Food and Drug Administration. The interview is being held at the Phoenix Regulatory Associates, Ltd. office in Sterling, Virginia. The date is March 16, 1995. Present, in addition to Mr. Trujillo, 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.

Adam, to start these interviews, we like to begin with a brief autobiography. Therefore, would you start with some of your early years, where you were born, raised, educated, and include any work experiences you had prior to coming to FDA.

AT: OK, Bob. I'm from Las Vegas, New Mexico. I was born there in 1938, and I went to school at New Mexico Highlands University, and I graduated from there in 1960.

In terms of what kind of work I had done before coming to FDA, it basically was part-time work, taking care of yards. I particularly remember this medical doctor in Las Vegas had a lot of stature in the community, and I was basically a tutor to his son, as well as taking care of things around the house. Worked for a time as a bookkeeper for this doctor, as well as for a homebuilder's supply company. But these things were on kind of a part-time basis as I was going to college.

I was going to be a teacher in New Mexico. My mother had taught school in small communities around northern New Mexico for many years. In fact, she overall taught for forty-four years, and I think it had a lot to do with how I developed myself.

So I was getting ready to be a high school teacher when I decided to take something called the Federal Service Entrance Examination. In those years to get into certain federal positions, you had to take a written examination and pass it. As I remember, many people failed to pass it, so I was a little surprised when I got notified that I had indeed passed.

This was in the spring of 1960 when someone showed up outside the biology lab in my senior year of college, and it was Paul Hile saying that he would like to interview me. So that evening we met at his motel room, and I remember him showing me this little FDA's inspector badge. It was about maybe, oh, maybe a little more than inch and a half in diameter--maybe not quite that much. And he proceeded to tell me about the Food and Drug Administration. At that time, he was a GS-9 inspector in the FDA.

RT: Where was he located at this time?

AT: He was out of Denver. In those days, the Denver District included New Mexico, and he was on a special recruiting trip. I knew nothing about the Food and Drug Administration, and at that time, the little community where I lived was fairly isolated. I hadn't traveled very much outside of the community. I was involved in athletics in the high school and college level. I think the farthest I had been was Alamosa, Colorado, and Enid, Oklahoma, to play baseball. So I didn't know anything about Denver or the Food and Drug Administration--other than, as I recall, as a biology major, I recall having read about the aminotriazole in cranberry incident which was in 1959.

But in that small community, which was I would say 80 percent Hispanic, you didn't get a lot of information about the rest of the country, particularly in terms of professional opportunities. So I had no knowledge about what the FDA was all about. My goal was to become a teacher and maybe go into administration in the New Mexico educational system.

RT: You mentioned that you were trained in the university for a teacher's degree. I assume you had some science, because there is a science requirement for FDA employment. So were you training as a teacher in science?

AT: I have a degree in biological sciences, and I was going to be a teacher in biology. I also have a minor in speech, and I had taken a lot of course work in chemistry. So I have a B.A., but with a emphasis in biological sciences, and, of course, a minor in education. So that was going to be my career until I got diverted.

Paul Hile is a very interesting individual to me, a very unique individual. In fact, I was reflecting recently on his qualities and how it inspired me through the years. He and I have been very close over the years, not only professionally, but socially, as well.

Just recently, if I might divert a little bit, we were at a company together doing some consulting work and making a presentation. He had the burden of making most of the presentation. We had spent I would say a week preparing for this presentation which involved advising the company of conclusions drawn over a period of about six months that Paul and some other people had been involved in assessing how this company was doing in terms of meeting FDA, not only current requirements, but future possible requirements.

We had to go back in time and develop a scenario as to why FDA did things the way they did in terms of enforcement. So that permitted us and actually required us to go back and write a brief history of FDA's regulation of food safety. Then we tried to incorporate that into a discussion to senior management at this major corporation about what FDA was currently doing and where FDA was going in terms of its future regulation of food products in the United States. It was very interesting. And to see him . . . I think he was probably on his feet for about eight hours during the two-day period, one evening from about 6:00 until 9:00 at night presenting to maybe four or five different groups of executives there. I just couldn't help but continue to be amazed at his grasp of the facts, as well as the manner in which he presented.

So I guess what I'm saying is from the time I was interviewed by him when I was twenty-two years old to now when I'm fifty-six, and in those intervening years,

it just has basically bolstered my attitude, I guess. He has been very helpful to me. So that's kind of diverting from what we were talking about.

But I did graduate from Highlands in 1960, and I got offered a job by FDA, and I started my career on June 20, 1960, in Denver as a GS-5, and I recall I was earning $3,900 a year. I'd gotten married and I had a child on the way, and we moved to Denver with twenty-five dollars. (Laughter) And no car. (Laughter) Well, I mean, those are the good old days.

RT: Well, it sounds like Paul did fill you with a lot of enthusiasm to embark on such a career with the risks of not having many resources to go over there to Denver.

AT: Well, fortunately, my wife's sister lived in Denver with her husband, who worked with the Air Force. They had a trailer in Aurora with an extra bedroom, and that's where we lived for about three months till we struck out on our own, with my wife's brother-in-law's 1948 Chevrolet that didn't have any brakes. (Laughter) But it was quite an interesting period of time. I don't know whether I really try to think about it too much. Things are a lot different now.

I was entered on duty at the same time there was another young man from Kansas who came in--I think his name was Dale Harper. He was very blonde, crew cut, and I was not blonde, and my hair was quite long, going back to the style of the Hispanic Americans in those days. So we had a contrast.

RT: Who was the district director at that time in Denver?

AT: Ralph Horst. He swore me in. Now, I walked into this big open area, and there must have been forty people in there. Many young inspectors. I think Denver District hired, let's say about twenty inspectors in a period of three months during those days. It was going through one of its crash hiring programs. So I walk into this environment, and, you know, many of these people come from all over the country.

I remember there was one other person from New Mexico. Maybe a couple of others. But the guy that I remember who's a long-time friend of mine now, Leroy Gomez, who was the regional director of Dallas before he retired, was there. He was from a small community in New Mexico also, but we kind of looked each other over, you know, sized each other up, and we didn't get too close at first.

I don't know how most people react when they're going to their first professional job after they graduate from college. You're just kind of thrown into this work atmosphere, and I guess some people fit in better than others. Frankly, I don't know. I never really thought about asking anybody, "How did you feel when you went into your first job?" Well, of course, I was apprehensive. First, I've never been out of New Mexico. And I was from a small town. Many people going to first jobs are from small towns. I don't know where you were from.

RT: A small town originally.

AT: And how far you had to go to get your first job, but there was a lot of activity going on in Denver at FDA. You had these old-timer FDAers and these young people coming in, trying to get into the system, and you had two different worlds in there, I think. And, now, with me, being where I was from, maybe a third little element there. So I always kept my mouth shut pretty much. I don't keep my mouth shut as much anymore. But in those days, I was very quiet and just kind of watching.

As it turned out, I kind of walked into kind of a hornets' nest, because there was a lot of stuff going on there. I think it's very important in how it has affected my personality in FDA in terms of integrity and just being conscious of who you are as an FDA inspector primarily. Well, there were a bunch of guys there that were kind of revolting against the administration in the Denver District at the time, which was, I think, part of the whole culture of the Food & Drug Administration in those years, where by God, you were going to do what you were asked to do. There was to be no apologies. You did it right, and you didn't ask any questions. Because they

really struck the fear of God into you--maybe it's not that bad--but basically you had to follow the party line, and if you wanted to do anything, you had to do it right. That required a lot of discipline. I think it required a lot of absorbing direction.

But, at the same time, you cultivated a sense of dedication and integrity. So maybe there was limited freedom of expression, but there were opportunities, I found, if you really tried and if you had the support of people who took an interest in you. That part of it is what I always felt has helped me. Because not only Paul, but other people in the organization, the supervisors . . . If they felt you were trying to do the right thing and working hard at it, they would help you. But they would try to weed you out if you weren't.

RT: At that time, do you remember the chief inspector?

AT: Yes. Leo Cramer was the chief inspector. A very nice gentleman. I didn't know too much about him, because when you walk in, you're twenty-two years old, you have all this going on, you know, they're running the organization, and you're trying to figure out what it's all about. So I knew very little about Leo. But the next chief inspector that came in was John Cox, and I got to know John a little better.

RT: In those days, there was more travel away from home than maybe is the case today. Was that a problem that you encountered, having to be away from home on assignment trips from your family?

AT: Well, it certainly was, because what they would require is for you to go out on the road two weeks, and then come back and stay in about two weeks, then go out two weeks. I think Denver was probably the largest district in terms of territory, because we had to travel all the way from southern New Mexico, that is the El Paso area, all the way to Idaho and Montana.

RT: Really to the Canadian line you might say.

AT: Almost, and there was a lot of driving involved. Of course, it took sometimes a day or more to get there, and then you had your assignments, and you were expected to come back with all the assignments completed and almost all reports written up except for the last one.

RT: The reports were written in the field then, weren't they?

AT: The reports were written at night, because you can't write reports during the day, because you're supposed to be working. So no overtime. I don't think I ever earned one penny of overtime in the Food & Drug Administration. Nobody told me to work overtime; I just did it, because that's the way it was expected. Because before I went out on my own, I'd go out with Paul and some other inspectors, some of which didn't impress me very much. But most of them worked at night and tried to make sure they got everything done. That was before the days where you could call into the district office too much, and there was no FTS or anything like that. So we would be asked to stop in at the Western Union at various towns along they way, and we'd pick up messages. I think the per diem at that time was nine dollars a day. So you stayed in a place for about six dollars. Then you got to twelve dollars a day, so then you got into a little better place, and . . .

RT: Now, during the two weeks that you were in the office, if you had many of your reports written in the field, what was the inspector's activities during the time in the office?

AT: Well, there were assignments around the Denver area. A lot of work involving filth at the time, Bob, sanitation. In fact, a very heavy emphasis on sanitation. The Denver territory was more an agricultural region with not very much

in terms of high tech until now. I guess they've got more medical device and pharmaceutical companies now. But in those days, it was mostly food, feed, and those kinds of industries.

RT: While you were at Denver, were you promoted? Did you rise in rank there?

AT: I think in about six months I became a GS-7. About three months after I got there, there was a pay raise to $4,040 a year. Then about six or seven months later, I got a GS-7. That was about the way it happened for most people.

Then in 1963--this was one of the greatest opportunities I had--I was asked to go to Salt Lake City to the resident post. In those days, you didn't apply for something. You were "asked to go." If you wanted to have a career, you went. So my wife said, "What's at Salt Lake City?" I said, "Well, I don't know. I've been over there. It's OK. It's a nice city. So let's go." So we did, and it was a great experience. Salt Lake City's a beautiful place. I was there in a two-person post. In those days, it was a two-man post, Bob, because there were no female inspectors.

RT: That's true.

AT: I don't even know whether they thought about recruiting women inspectors. There were some women in the laboratories, but Salt Lake City was a two-man post. The senior person was Harry Butts, who later came to Washington and basically was very involved in medical device enforcement activities at FDA headquarters. Harry still lives here in Sterling, Virginia.

RT: I didn't know he was still in the area.

AT: Yes. So I formed a very good relationship with Harry. He was older, and he helped me out. This was very important, because when two persons work in one

office, you've got to get along. Inspectors would come from Denver all the time to Salt Lake, because there was quite a bit of industry there, and we would kind of host these people coming. Many young people would come in and out of there. But we had the whole state of Utah and the southern part of Idaho to travel to. It was a great experience. Very rewarding.

I had trouble with a drug company one time. It complained about my "strong-arm tactics." I was going down there to collect some samples, and they weren't very cooperative. So I basically said, "Now, I'm entitled to come in here and get these samples." So they complained about me to the chief inspector in Denver, and at that time it was John Cox. John was a very notorious guy, a very strong-willed guy, and you kind of want to steer away from him if you value your hide. So you have to take a certain amount of abuse from John. I don't know whether you know him.

RT: Yes, I do know him--I did know him.

AT: I think he was kind of an example of some of the style in those days which was, "Here, I've been through this. I know what I'm doing. I'm up in the ranks here, and this is the way we do things around here." Without saying those words, that is the feeling you got, and there was kind of a culture there. You would hear stories about people from Washington, from the Bureau of Field Administration, saying, "This has got to be done. This has got to be done."

All the promotion recommendations . . . In fact, the one for me to go to Salt Lake City and even to become a GS-9 had to go to Washington to get blessed. Can you believe that? I mean, my supervisor and his boss, who was the chief inspector, couldn't make that decision. They had to go to Washington, and they had to prepare a very full report of what you'd done in detail and why you merited a promotion, and particularly why you merited transfer to a resident post, because they couldn't, I don't think, send people to the resident post that they didn't trust, because you were very independent out there. You weren't under somebody's direct administrative control.

So I saw the recommendation for my promotion to GS-9. I just kind of happened to find it, and it was quite interesting how much confidence they had to have in you. But John Cox was one individual who basically agreed that I should go to Salt Lake, so he trusted me, and we had that rapport I think.

Well, when John called the resident post to check about this complaint from this drug company, it seemed like I was guilty already. Well, Harry said to him, "John, this is a hell of a way to run a railroad, you know. Adam did what he had to do." (Laughter) And I don't know the whole story, but John backed off. I think this is important, because FDA people in the field will support their inspectors and others if they trust them. But they have to follow up on these kinds of complaints.

Some things it has taught me, and I didn't get into it . . . What was going on in Denver when I first walked in, there were a lot of people uptight about what was happening. And there was an investigation of the Denver District, where inspectors were suspected of falsifying reports and expense reports and goofing off a little. As it turned out, there were recorded interviews, like the one we're having here, around 1962, when Ken Lennington and Reo Duggan came to the district from FDA headquarters to conduct an "investigation" about the goings-on there, and interviewed everybody as to what they knew about it and tried to figure out, I guess, who was responsible for these allegations of misconduct.

Well, I walked in, and I guess my interview lasted about a minute, thirty seconds. They said, "Have you ever misused a government car?" I said, "Well, to tell you the truth, one time I did have to take it home because I forgot my badge, and I'm sorry about it." So they said basically, "Get out of here." I walked out, grateful that was the extent of their interest in me. Some people were interviewed for two hours. As a consequence, I don't know exactly what the decisions were, but many people in the Denver District were split up and some went to New York. They opened up the Dallas District office at the time. Some inspectors went there and to Minneapolis.

They basically broke up the clique that I think had formed in Denver with the old-timers who were disgruntled and some of the new people who were more free thinkers than I guess some people were comfortable with. So then there were two sets of people in the inspection staff there: one that was siding with these disgruntled old-timers, and the others were trying to do what Paul Hile was doing, that is, do their job and get it done OK. That's they way I look at it. I happened to be on the right side, the side of the angels. (Laughter)

RT: That was important during that Denver office problem. As I recall, even the leadership there at the time relied greatly on Washington advice to carry out some of the administrative functions. I'm thinking the district director. I don't know if that was something you were involved with or aware of?

AT: Well, the guy who replaced Ralph Horst was Sam Alfend, and he was a very strong-willed district director. A very strong-willed personality. You know, I feel Sam was willing to fight for the district and what was happening, whether it's personnel-wise or more importantly, I guess, his policies, the implementation of policy, because Washington developed policy, and set the tone, and gave the marching orders. The districts carried it out. So the districts, I think, were always under pressure to perform. But Sam would support the district and its staff.

RT: Yes, I'm sure that's true of Sam. I was thinking of his predecessor . . .

AT: Ralph Horst?

RT: Yes, as being someone that apparently called Washington for almost trivial decisions.

AT: Well, maybe that was the way things were done. And I think one of the things about maybe all organizations and its power, those people in Washington that were notorious in those days, like Kenneth Kirk, Kenneth Lennington and Allan Rayfield, they were powerful people. I wished I'd have been more aware of what was going on there, because it would have been an interesting thing, and maybe I'll discuss it with someone someday. But not only did they have to bless everything, but they were consulted on almost every administrative or regulatory decision that was made regarding field office operations.

(Interruption)

RT: Yes. You were saying at the end of the tape the need for consulting with some of the important officials at Washington.

AT: Yes, we've come a long way. Now the district offices have a lot of independence. But I think in those days, a lot of people had to go to Washington for advice, for concurrence, et cetera. I don't know how it was with other organizations in those days or maybe still is now where there was power in the central office. But, yes, some of these individuals like John Cox, however, as it turned out, I had no problems with him. Others did. In fact, soon after that John left, and another notorious guy came in as chief inspector, and that was . . . Oh, gosh.

RT: Was it Frank Clark?

AT: No, no, no. Joe North. Did you know Joe?

RT: Yes. I know of him.

AT: He was the hatchet man who came in to take care of all the problems in the Denver District. Thank God, Joe and I got along quite well. He came from New York. How do you have someone from New York come in with all the style of life there, including probably a much different management style, and come to a Denver office. But that's what happened, and there was a lot of stuff going on there.

Anyway, in 1965, I went from Salt Lake City to the Denver district conference, and a guy by the name of Monte Rentz was there. He was in charge of the FDA National Inspection Force. He was giving a talk, et cetera. A nice gentleman it seemed to me, you know. He didn't impress me as a kind of a hard character. But my supervisor kept saying to me, "Go talk to Monte." I said, "About what? I don't have anything to say to him. He doesn't know me from Adam, so . . ." I finally got around to saying hello, trying to talk to him. You know, what do you do? Being twenty-seven years old, and here's this guy from Washington. What can you say to him other than try to b.s. him, which I never like to do?

Well, as it turns out, there was a specific reason why he wanted to talk to me, and so all of a sudden I got a call from Joe North saying, "How would you like to go to Puerto Rico?" "What?" "Yes," he said, "let me know by tomorrow."

RT: They didn't give much time for such decisions, did they?

AT: Not much. So, to make a long story short, I went to Puerto Rico, to become a GS-11, and I was again the second man at that resident post. Puerto Rico is an island of thirty by one hundred miles isolated from everything. No FTS government phone system, nothing. I took off driving, and I went to New York to spend a couple weeks there to get orientation, because New York District was the head office for Puerto Rico in those days. I lived in Weems Clevenger's house for two weeks. Weems was the chief inspector of the New York District. Another character. You would run into characters all over, in those days, all the time. Maybe even in these days, but it's not the same. These guys were flamboyant.

RT: Weems was a unique individual, all right.

AT: So he treated me very well. I went out with his inspectors to do inspections of drug companies in New York City, which I had never done. I think he was just trying to size me up and all that. I don't know whether he had any say in whether I was going to go to Puerto Rico or not. Although the thing was I spoke Spanish, and I was a hard worker, and they trusted me. I think that's why they wanted me to go. So I went, and my wife came later. She was pregnant with our daughter, and our daughter was born in San Juan in 1965. I wish I hadn't gone at that time, because we had some problems with that delivery, because the way of life in San Juan, Puerto Rico, and its health care system was not equivalent to Salt Lake City's or probably any place in the United States. So if I had it to do over again, I wouldn't have gone, but it might have jeopardized my opportunity to go. Because they could have said, "No, you're going." And I said, "No, I'm not." So the choices were to go or to quit? I don't know what would have happened if I'd have said no.

RT: Well, I think some of the folks that I've known of, when they refused they were stymied in their careers thereafter.

AT: That's it. So I wasn't even thinking about that. But there was this drive to advance--because it was very difficult to get promoted. It wasn't an automatic thing. Now you get promoted to GS-12 as if nothing happened. You just have to kind of do the job, I think. You have to do a good job, but there was no big pressure. I probably shouldn't have gone, but I did. As a consequence, the experience in Puerto Rico was kind of mixed. It was a very positive professional experience for me--great. But in terms of personal experience, it was not that great. It was very difficult for my wife particularly. Oh, she adjusted very well.

RT: What kinds of investigational work did you get involved in down there? Was there much of a drug industry there?

AT: It was just beginning to develop. It's an interesting situation. You know, now there's about eighty people in the San Juan District. At that time, there were two of us, and there was a whole mix of industries. There was foods, and pharmaceuticals, and some medical devices coming in, a whole lot of imports. We basically did anything we felt we had to do, with very little guidance from New York. We had these work plans and all that, but basically you had to do what you had to do. So we did everything. We inspected some drug companies, medical device companies, food companies, and we went to the docks and hauled around and moved around bags of beans, and coffee, and such; and it was hard work. But it was an interesting experience for me in that I got into what I think probably is a foreign culture, and I had to communicate in Spanish, and it's helped me through the subsequent years of my professional life.

RT: Did you find any situations there that led to legal actions that you were involved in?

AT: Yes. There were mostly food companies that had insanitary conditions, rodent and insect filth, some type of contamination. So there were a number of seizures, some prosecutions. In those days, there was a feeling that the people in charge counted seizures, prosecutions, injunctions, and every time you got one, you'd get one point. So people were striving to find these violations. If you found them, you were a good inspector. If you didn't, you weren't. I guess that's the life of the investigator. You just can't spend thirty years doing investigations or inspections and not come up with anything. So there was quite a bit of activity, particularly in the food area.

In those days, FDA's regulation of the drug industry was not quite what it is today. Inspectors weren't as sophisticated in terms of their capability of analyzing

and assessing the situation in terms of good manufacturing practices, which is what you have now, that being a very sophisticated, fine-tuned way of finding out what's going on in a drug company or medical device company or, for that matter, a food company that has a complex process of production. We've come a long way in those years.

But for me, it was quite interesting, and about a year later, after being in there, three other guys came into Puerto Rico, Roman Longoria, Ed Fry, and Terry Musson. We developed some relationships there, and things were going along well. After I'd been there two and a half years, I got a little itchy, and I started wondering . . . I've got to get promoted to GS-12, and there was no way I could get a promotion there. So I don't know how it happened, but there was a vacancy in headquarters, and in 1967 I got selected to go work in the Field Inspection Branch with Don Martin, whom I had met in Denver District four years previously when he was a supervisory investigator, and now he was the head of the national office for all inspections. I don't know whether that's when I met you, Bob. When did you come into FDA?

RT: I came in in 1962, so perhaps that was our first contact.

AT: Yes. Well, I came into this organization of five people, called the Field Inspection Branch, and now it's the Division of Field Investigations, which has a staff of over fifty people.

RT: It's a good-sized staff certainly.

AT: Yes. But we were responsible for developing inspectional guidance, inspectional training, fire fighting on issues involving inspections, and it was quite an interesting time for me, and it was enriching. Because I could be involved in just about anything. I kind of was a jack of all trades, with whatever was going on in the

field, where inspectors were needed help, helping to develop training courses, etc. By that time, I think Paul Hile was in headquarters also. Harris Kenyon--wasn't he the field liaison officer?

RT: I think that was his role.

AT: I don't know exactly where DFSR (Division of Federal-State Relations) was in that hierarchy in 1965.

RT: Well, we were still a part of the office of the commissioner. Then when Paul Hile set up the Executive Director for Regional Operations, or the EDRO organization, the Federal-State Relations staff was brought into that organization and became a part of the field administrative structure. There were some advantages to that, because before we were just kind of a headquarters staff without a real connection with the field, and that was helpful to be a part of the field organization.

AT: Well, then were you in a division at that time?

RT: Well, it was an office as part of the commissioner's staff until the EDRO reorganization.

AT: What was interesting to me was we had a staff representing field inspectors, and we had another staff representing field analysts and laboratories, and we would cooperate and talk to each other. Hy Eiduson was the director of the Field Sciences Branch; Donald Martin was in charge of the Field Inspection Branch; and then there was Charlie Armstrong. He was . . . I forget his title. Come to think of it. I remember Glenn Kilpatrick was in charge of Federal-State Relations.

So in about 1972, the organization was called the Office of the Executive Director for Regional Operations, and Paul Hile was the director of that office. He

needed a special assistant, so he asked me to come and work with him. I remember going to staff meetings, and here was Charlie Armstrong, Hy Eiduson, Don Martin, Glenn Kilpatrick, Paul Hile, myself, and I think Ron Ottes. It was really great.

Those days seem to me like they were much more pleasant and productive, with more esprit de corps, more kind of a family situation where everybody knew each other, and they were talking pleasant. Yes, there was a lot of stress and all, but there was not a lot of back-biting going on or not a whole lot of personnel management issues that I was aware of anyway. Undoubtedly there were, but it wasn't on the surface. There wasn't a lot of unhappiness is what I'm trying to tell you--on the surface anyway. There were not a lot of disgruntled people going around. Everybody was pretty much hard-charging. Just a very nice working environment. I don't see that happening now.

So that's what happened. I got into a lot of liaison with the field and the headquarters bureaus. As special assistant to Paul, I would do a lot of ground work to track down things, and special assignments, which exposed me to a lot of people in headquarters. That really helped me, because I was talking to the bureaus at that time about various issues that affected the field. I think I cultivated a degree of trust in many people in the agency at the time, because I would go around and talk to them, and I wouldn't sit at my desk and wait for things to come to me, because I liked to get out and talk to these people. I cultivated a lot of friends.

RT: So you were in headquarters in that position until you went out to the field as a district director?

AT: Right. Yes. In 1973, after having been a special assistant with Paul for about a year or so, I kept getting calls from Maurice Kinslow, who was the regional director of Atlanta District, and Dick Dawson, who was director of investigations in Atlanta District. It just so happened that the Atlanta region had grown so much in terms of industry that they decided to create three sections from what was previously the

Atlanta District. I didn't know Maurice Kinslow, but there was another character for you.

RT: He was an unusual person in some respects.

AT: He had been the associate commissioner for program coordination, a high-level position in the agency, and I never knew why, but all of a sudden he was the Atlanta regional director. I guess maybe they felt they didn't need an associate commissioner for program coordination.

RT: I don't know. I know that Maurice had served--one of the only persons I believe that had gone over and served on the Hill for a time. Whether his experience there had helped that appointment, I don't know.

AT: I think he was also involved prior to that in the Office of Legislative Affairs.

RT: I believe he was.

AT: So I didn't know him. But Dawson and I were friends, because he had been an inspector, and we ran into each other along the way, and he kept telling me, "We want you to come down to Florida where we're opening up a new section." I said, "No, no, no." Finally, I got to the point where I said, "Well, I'll talk to Paul about this." And I said, "Paul, look. These guys are calling me and telling me they want me to come to Florida." There was no announced vacancy. I said, "What do you think?" And he said, "Well," he says, "what do you think?" I said, "I don't know. Florida. What do I know about Florida? It's a spit of sand somewhere. It might break off and float away someday." (Laughter) So he said, "Look. Why don't you just go down there and make a visit, check it out."

So I went down there, and I walked into this place, and they had opened up, I think, in 1972, the end of 1972, and they had three supervisory inspectors and about twenty or thirty new inspectors, plus a number of other older inspectors. As I walked in there and I started talking to people, of course, they didn't know who I was and what I was doing there. Although they probably knew something was cooking. I said, "Well, I'm here for a visit. I'm from the EDRO. I'm just kind of making a visit." Well, I fell in love with the place to make a long story short. I transferred down there on April 1, 1973.

RT: And that was to Orlando?

AT: To Orlando Section.

RT: Now, you mentioned they were setting up three separate units. Where were the other two going to be?

AT: Nashville and Atlanta.

RT: And at that time, they were only sections rather than districts.

AT: The idea was that they had a Director of Investigations, which was Dawson, who was in charge of management of all inspectional and investigational activities in the region, and three section chiefs, who were responsible for taking care of all the inspectional activities in the three sections, and Orlando was the main office for Florida. It was an experiment. I don't know whether it had ever been tried before, but they didn't want to set up the districts in those places, because they wanted to keep this hierarchy. So we went into it.

For five years, it was really a struggle in terms of management of the section, because there were only three supervisors and myself, and no chief inspector, and no

compliance branch director, no administrative officer, no management structure like there is now. So I got involved in managing everything, that is inspections, compliance, et cetera. There was no laboratory. The laboratories were in Atlanta. All the administrative work, data processing, program planning. I was responsible for everything basically.

RT: In retrospect, would you have any view as to the desirability of locating that section at Orlando as perhaps compared to Miami? I'm thinking of import activity.

AT: There had been a study made under Kinslow's direction which indicated that the central Florida area was growing in terms of population and industry, and because it was central location as compared to the main population centers of Miami, Tampa, and Jacksonville, with the state capital being in Tallahassee. Orlando was centrally located. Whether I would have made that decision myself, I don't know. But I probably would have located the section office and later the district offices in the Miami area.

RT: Now, you mentioned that there was no laboratory, and, of course, it's very expensive to set up laboratories in many locations. In fact, the agency has moved to more specialized laboratories in recent years. Did that create any serious problems in having a lab in another location for your Orlando operations?

AT: It created some problems. Serious problems? They were some significant problems in terms of coordination between the laboratory and the district, as well as the other two districts or sections, as to whose samples have priority. So when you're in a regular district, you manage not only the inspections, but also the samples and the analyses, and you are sitting right there at the same place discussing the issues and priorities, and you can make decisions. So we went through a period of a number of years trying to design a way to be sure that the priorities were handled

properly. Well, logistically, how do you get samples from Miami to Atlanta? What evolved was I think a very effective system of getting samples planned, organized, collected, submitted, and analyzed on pretty much a timely basis probably as well as could be done if there had been a laboratory in Florida.

RT: Was your liaison with regard to those problems with Mr. Kinslow or with the chief of the laboratory at Atlanta?

AT: I try to cut out management wherever I can, because I want to deal with the people responsible, and I'd only go to Kinslow or Dawson if there was an issue or a problem or I need support for one thing or another. But I found that going directly to the laboratory, or in fact, the supervisory inspectors going directly to the supervisory analysts was the way to get things done. We tried not to elevate things to even the branch director's level or the laboratory director's level. Very seldom would I have a need to talk with the laboratory director about a problem. So even more seldom would I go to Kinslow or Dawson to resolve problems or get them involved in anything of this nature.

RT: Let's see. Who was the regional laboratory director?

AT: Coleman Seward.

RT: Coleman Seward, yes.

AT: He was the laboratory director in Atlanta. They were developing a laboratory, and I think Atlanta is probably one of the best laboratories around, as far as I can tell now.

RT: Now, with regard to the director of investigations. While you had a good personal rapport with Mr. Dawson, did that create difficulties in terms of the direction of investigations being centered in Atlanta rather than at the three points, or at least at Orlando, I'll just say?

AT: Fortunately, Dick allowed me to operate very independently, which I want to get into, because it's a very important part of what I think has evolved historically in the enforcement posture of the agency. There was a lot of enforcement work going on, and Dick would basically oversee and get involved from time to time, but basically left us on our own. That whole structure later changed.

They created district offices in Orlando, Nashville, and Atlanta in about, I would say, 1978, after a lot of pressure from me frankly, because I said, "Look, we need a chief inspector here, and we need a compliance branch director." So I got there in '73. I think it was in '78 that they finally agreed to let us have chief inspectors to help manage that part of the operation. Two years later they allowed compliance branch directors to come in.

We had one compliance officer in the district when we started, Jim Dupre. He lived across the street from me, so he would take home two briefcases full of work, and he was the hardest worker I've ever seen. He worked long hours. Well, now I think there are about five or six compliance officers in Orlando, but he really busted himself. There were a lot of actions. So they would send compliance officers from Atlanta down to help us frequently. They had a lot of people coming in there.

I finally persuaded them that they ought to make this office more of a regular district office. So it finally got there, but it took a lot of work. I just pushed all the time trying to get them to change things. I don't know frankly--maybe next time I see Maurice I'll talk to him about this--what their mindset was, whether they had said, "Well, this is our organization. We've set it up as we want it. And we will never change it, because it's not what we envisioned." But they've changed it.

Dawson left. He became the director of Division of Field Investigations in FDA headquarters, I guess beginning around 1980.

RT: Probably about that time, yes.

AT: And so they eliminated that position in the Atlanta region. It was no longer necessary. He and I remained friends and are still friends. He's now over there in the FAO in Rome, the Food and Agriculture Organization of the United Nations. He's been there for many years now, and basically, FAO has a food safety unit that helps developing countries strengthen their food safety programs, and Dick has been very, very instrumental in that program over the years. I guess now fifteen years. But when he left, it just created an opportunity to have a different organizational structure, and Kinslow was still the regional director, and we proceeded. Much of the growing pains then were over, and we continued to operate.

Florida's population increased dramatically. You mentioned imports. I think imports increased about ten-fold over a twenty-year period of time in Florida. One of the biggest pressures I had was to have the staff necessary to manage these imports.

RT: I suppose you must have had to maintain a staff--kind of a resident staff--down at Miami, didn't you? A substation or something?

AT: Well, there had been a resident post in Miami, but it was never fully staffed. So I just kept pressuring to get more people down there. I had to transfer some young inspectors from Orlando to Miami. They didn't want to go. But we were traveling them so much to Miami, it was like four or five people at a time from Orlando going to Miami. It got to the point where there was a lot of cost involved. So we started asking these people to go and then basically transferring them. Some would go voluntarily and others would not. Some quit. Because when you're in

Orlando, and you're living in Orlando as a young person, it's a nice atmosphere. It's very pleasant. No big problems, but if you go to Miami, you get into this whole different culture. That was in the days when the Cuban immigrants were coming in. The automobile traffic was tremendous. The cost of living was very high. There was a lot of stress on you because there was a lot of industry there, and you had to really work hard there.

RT: Now, during this same period of increased imports, was there a similar increase in the device industry in Florida?

AT: Yes. That was one of the evolving industries, and there was a substantial amount of medical device work to be done. At this point, what I'd like to do is get into some of those issues on enforcement, because I think it really had something to do with the way FDA has developed and how it evolved some of its compliance policies later.

RT: Good.

AT: I'd just like to mention a few things that the Orlando District got involved in during those years. I think we're quite instrumental in shaping some of the things that FDA is doing now. This is just my opinion. But the Orlando District was the first district to get involved in the regulation of plasma centers, blood products, in the 1974-75 era. I remember . . .

(Interruption)

RT: This afternoon, August 3, 1995, we are continuing a recording of an FDA oral history interview with Adam Trujillo, the initial portion of which was recorded on March 16, 1995.

I'm picking up on an area of lapse in the tape before. I think our discussion was turning to matters relating to the Bureau of Biologics. So let's continue along that line if you would, regarding your experience in that activity.

AT: Just before we got into this subject and the whole area of FDA enforcement, I said that the Orlando District was early involved in the regulation of the plasma centers and that program expanded in the 1970s.

Prior to that, as you recall, there was a Bureau of Biologics which was located in FDA, but before coming to FDA, they had been in the NIH as the Division of Biologics Standards. There was a reorganization, and they came into FDA, and it was their responsibility to go out and make inspections of blood product manufacturers, many of which required licensing before they could operate.

Traditional FDA inspectors in district offices had not been involved in inspections of those industries until, I believe it was in 1974 or '75, when we were advised of a death of a donor in a plasma center in Tampa, Florida. We were able to persuade the Bureau of Biologics through the Office of the Executive Director of Regional Operations in FDA headquarters that we should become involved in making an inspection of that plasma center, and sure enough, we did. We went in there with the Bureau of Biologics inspector and were able to document some serious deficiencies where they were overbleeding donors.

One thing led to another, and during the period of about four or five years, we then managed to inspect almost every plasma center in Florida, and found out that they had some really bad practices in terms of not only donor protection--that is overbleeding of donors and taking care of donors and all that--as well as potentially significant quality control deficiencies in terms of, at that time, the question of hepatitis contamination of blood. We had a number of injunctions against plasma centers in Florida. They, as far as I know, were the first times that we would take on that industry and take it to court.

My own opinion is that they had been under-regulated and that there were a number of characters in the industry--not only in Florida, but in maybe other parts of the country as it turns out--that were primarily in the business of selling blood. Of course, the donors would come from economically disadvantaged segments of society in Florida, Southern California, perhaps in Texas, and elsewhere. So what you have here are clients and people who may be not the healthiest, providing blood, a very important, as it turns out, not only biologic but a drug, and under questionable practices. We felt that many of the plasma centers were not in compliance.

So that led to a number of injunctions. In fact, there was a large blood bank, the John Elliott Blood Bank in Miami, that I believe supplied maybe half the blood in Miami, where we found some significant problems, and this was whole blood that was to be transfused.

RT: In that investigation, you mentioned hepatitis being a problem. Was HIV a concern at that time?

AT: Not at the time. But later on it developed that HIV was a principal issue. By the time that the HIV and AIDS problems occurred, I think the agency was handling blood products in a different way than they were in the early 1970s or before. I believe the work of the Orlando District had much to do with this.

Then we got started into inspecting the regular blood banks. There are small blood banks all over the country, in hospitals and other places, and they are a vital source of blood for patients. If you compare what was going on in early 1970 to now, you'll see a tremendous difference. Now FDA and the industry has been through a lot of transformations. You know, the American Red Cross even got into some difficulties over some years, which I think they're still trying to satisfy FDA's regulatory requirements.

So we were very proud of the fact that we were the first district office to really get into this field where we had not traditionally been involved as part of FDA field operations.

RT: Was that in part because of a concentration of this kind of laboratory and sales of blood products in Florida?

AT: I think that's part of it. As I said, these indigent people probably seek parts of the country where they can live more easily, and certain parts of certain cities in Florida seem to attract a certain element. So part of their way of surviving was to sell blood. That was one reason, but the other reason was the enforcement attitude of the Orlando District, in that it wanted to take on new initiatives. The people there were very concerned about what was going on in the industries that we regulated, and we had an enforcement attitude that perhaps in some other districts in those days wasn't as prevalent. Now it's become more popular to be "enforcement minded." But back in the seventies and eighties, the Orlando District was quite rigorous in its mission.

Which now leads me to medical devices. You know, the Medical Device Amendments of 1976 caused a tremendous change in the way that FDA regulates the medical device industry. Of course, since then, there have been other amendments, and today you'll see that FDA has really been very aggressive with the medical device industry. There may be a number of reasons. It's a relatively new industry as compared to drugs or foods, and evolving over some years with many small manufacturers, and perhaps not too many of them, at least in those days, fully aware of what FDA expected in terms of GMPs. There were no GMPs to speak of in those days.

So we ran into a situation, in Miami again, with heart pacemakers manufactured by a large manufacturer. There were some failures being exhibited of pacers that were already implanted in patients. We began to make an investigation of the

situation. Our investigators got in there with some Bureau of Medical Devices technical people and some national engineer experts, one of which was Fred Hooten, who then later became very active in the Center for Devices and Radiological Health in developing new approaches to GMPs for medical devices. But in this situation, we were in this plant for over a year off and on.

RT: Was that the Cordis . . . ?

AT: That was the Cordis Company. I believe they recalled over 100,000 heart pacers. We went to court and had a very difficult time. It was a very unique court case where the court called in a "master" as in a technical expert to hear the arguments, and there was a lot of testimony on both sides. And even though FDA didn't succeed in getting the injunction, we were successful in getting the company to voluntarily change their practices to make sure that they were in compliance with good manufacturing practices (GMPs) as we knew them and mostly applied to drugs in those days.

RT: Now this particular firm's device caused some deaths or was it primarily a question of reliability?

AT: It was primarily a question of reliability involving the recalls that took place, and the question about what do you do when a pacer is implanted in a patient. What are the benefits and pros and cons of recalling? Or what is it you do with that particular device? The physician has to monitor it, especially if the product is not of reliable quality.

Well, we felt that incident, which again it was in the early seventies, and I believe it was recognized in congressional hearings, and led in part to the passage of the Medical Device Amendments of 1976, and I think subsequently to the development of GMPs for medical devices. Now I'm not saying that that incident

itself was the reason why this law got passed; but it was a significant incident that had some bearing on FDA's new direction in terms of regulation of medical devices.

RT: Did the congressional attention involve what the agency was doing or was it more in terms of some publicity about this particular firm?

AT: Well, the Congress had held hearings in the past about medical devices. As you know, sometimes it takes some years to develop new legislation and often problem areas surfaced. So this Cordis situation was one more that added to the need for better regulation of the medical device industry. Now what you have is an evolving process where new GMPs are being developed. Today, there is even greater attention being given to being more stringent and more specific. FDA has recently issued a proposed regulation on GMPs for medical devices which incorporates something called ISO-9000 concepts of quality systems for the first time in an FDA regulation. This ISO system is something being used worldwide but primarily in Europe to provide some direction to companies that are manufacturing a wide range of products and to help them institute quality systems.

RT: The ISO is an acronym. What does that stand for?

AT: ISO basically means International Standards Organization out of Geneva, but it's been evolving over the last I would say twenty years or more. It's an attempt by the international community to develop uniform standards that can be used worldwide.

RT: I think that that may be of interest to someone that would review this interview and not be familiar with that term.

AT: So other things that were happening in Miami I want to mention which I think were significant: One had to do with some snake venom that was being promoted by the Miami Serpentarium in Miami as a cure for a number of diseases, including one known as ALS. I forget the technical term for it, but you've heard of Lou Gehrig Disease? This is what it is. In this case, patients would come to the Miami Serpentarium and get treated.

RT: Was that firm also involved in merchandising or processing snake venom, like rattlesnake and other poisonous snake venom?

AT: Yes. They would use rattlesnakes and perhaps some other reptiles and process the venom, and then patients would come, and they would get treated. They had been doing that for twenty years under the . . . I would say guise of humanitarian concerns. We felt that they were in violation of the FDA law, but it was difficult to prove, because they weren't shipping products in interstate commerce.

RT: So were Florida regulatory officials concerned or had they taken any oversight on this particular operation?

AT: We tried to involve the Florida health authorities, but frankly, we had very little success. Although they were supportive, it was very, very difficult for them also. I think the question then boiled down to, at what point does FDA take action against an institution that may be treating patients that have serious diseases, like cancer, ALS, or some other disease that perhaps there is no cure for. Particularly if there is no interstate commerce involved in the finished product, for which FDA has the principal responsibility. Or, where is the line between the social and medical concerns versus violations of federal law?

RT: In this case, were patients or clients coming to Miami rather than receiving treatments after the venom or whatever product had been shipped in interstate commerce?

AT: Yes. As I said, the patients would come to Miami because they were being enticed to come, and they were being treated. After a long investigation, we were able to go to court and say this really is not a medical practice which should be exempt from FDA regulation; it's a commercial practice which should be subject to FDA regulation. Because the empty vials moved in interstate commerce, we were able to successfully demonstrate that this was under our jurisdiction, and we closed the place down.

RT: Were there other areas of regulatory concern?

AT: We got into some of the products involving cancer cures, Laetrile, Krebiozon, and all those things seemed to happen in Florida, I think partially because of the nature of Florida's population. It just seems to be more prevalent there, and maybe some parts of California also were similar with regard to these kinds of problems. We were feeling at the time that we had to investigate these matters for public health and consumer protection purposes. So there was an enforcement attitude there that we felt that was very, very much necessary.

I recall in 1982 . . . Who was the commissioner then?

RT: Well, I'm not sure. Would it have been Dr. Charles Edwards?

AT: I believe it was Arthur Hull Hayes. He asked the district directors for opinions about enforcement. I sent him an eight-page memo saying, "Here's what I see as a problem involving the centers, staffing, and enforcement philosophy, and all that, and here's what I think you should do." I never got an answer, and don't

know what impact it had. This whole effort was for the commissioner to try to get everybody's point of view. It may have had some significant effect, but I don't know. But Commissioner Kessler came in, what, 1990? He didn't invent enforcement. A lot of people out there were involved in enforcement, but I think some of them went too far the voluntary compliance way and then the generic drug scandal hit them right in the face. I'd like to talk a little bit about that.

In the mid and late seventies, we were inspecting a generic drug company in Florida, and we got indications that they knew we were coming. So, accustomed as they were to ferreting things out, the district inspectors began to make calls trying to find out who's saying what to whom and why the company seemed to know we're coming, which is really a big departure from the way we do business. FDA doesn't announce when they're going to make inspections.

So one thing led to another, and I think some of my staff felt that some people in the Bureau of Drugs were stonewalling. We knew there had been meetings with the company, but the Bureau didn't want to give us copies of memos of meetings or talk too much about it, so I wrote a memo to the bureau director, saying, "We understand this and that is happening. We hear this. Here's what information we have, and we haven't had any feedback. I want to bring this to your attention so you can let us know . . . We need your help."

Well, there was an investigation made of the Office of Generic Drugs. A few months later I got told in writing that there was nothing to it, that everything was basically fine. There was no collusion between the Office of Generic Drugs and this company and not to worry about it. I think I still have a copy of that memo somewhere. Then I got a little private note in handwriting from the bureau director saying that I needed to mend fences, and that it wasn't perceived as proper for me to be raising these issues. I'm paraphrasing.

But there was something going on there, Bob, and here's where you have this gut feeling. And sure enough, there were some problems in the generic drug industry. There was too close of a relationship between some of these people in the

bureau and the industry we were regulating. Some years later when the whole generic scandal happened, there were investigations, and quite a number of FDA people got chastised, and some got hurt. The image of the FDA suffered tremendously in the mid-eighties. Then there was a congressional investigation about this, and I recall seeing a chronology of events, and the first piece was my memo to the center director back in the seventies, which means the agency knew something was wrong, but they didn't take the action. So what happened is they had to suffer a number of years of investigation and criticism, which I think might have been avoided.

In my opinion--and I don't know everything there is to know about this--the FDA let the generic drug industry evolve without adequate oversight. FDA had worked so hard with the ethical manufacturers, the brand name manufacturers over a period of time . . . If you remember the Intensified Drug Inspection Program (IDIP), the whole evolvement of GMPs (Good Manufacturing Practices). It seemed to me like FDA had really tried to work with the industry over a period of many years to make sure they understood FDA's point of view about GMPs, and to a large degree, I think it was quite successful.

Not so, in my opinion, with the generic drug industry. They just appeared from all over after the Patent Term Restoration Act which basically promoted generics. Some people have said there were reasons for Congress to protect the generic drug industry, because they were promoting the need for generics in the United States because of the cost.

RT: Do you suppose that part of it might be because, with regard to the ethical drug industry, or the developers and researchers, FDA got more focused on the review of NDAs (New Drug Applications) for prescription drugs, and that degree of interest didn't transcend to the generic industry?

AT: When you have some so-called fly-by-night operations spring into an industry which is so important as was the generic drugs, I can't condemn the entire industry or most of the people in it, but there were some characters. I think I've seen figures that there were more than twenty indictments over a period of some years, and there still is investigation going on. Quite a number of people have been hit in the generic drug industry for fraud.

My feeling is this: I think if we'd have been on top of it in the seventies and eighties, early eighties, it wouldn't have hit us so badly. I still say "us," because I kind of slip into it. I'm no longer with the FDA, but I say "us." And it happened because of failure on the part of FDA to emphasize the need for enforcement. I think in those years, some districts, and maybe the culture in the organization, was more toward voluntary compliance. It didn't happen that way in the Orlando District, and it didn't happen that way in my own mentality. Maybe I was considered a little bit of a maverick in that I wouldn't go along with that frame of reference. I hadn't been trained that way. How can you change your mentality, your approach just because there's a new administration or a new commissioner? It's not easy. But some, I think, were kind of laid back, and they didn't push enforcement.

RT: I believe after you served as director of Orlando District, you did come to headquarters. Can you relate some information about that: when you came in and what you became involved in at the headquarters offices?

AT: Yes. As it turns out, Bob, around 1983 and '84, I got involved in something called the Senior Executive Service Executive Development Program which was a program where they'd take people from the various Department of Health and Human Services agencies and provide training opportunities for them in executive development. So I was able to serve assignments with the CDC, with the Pan American Health Organization in Washington, D.C., in the Office of Regulatory

Affairs in FDA, and with the department itself. That was over a period of two years--not full time, but maybe with three-month assignments.

When I had completed the program, I felt that I needed to move on. So I talked to Paul Hile, and he arranged for me to be transferred to FDA headquarters to become the deputy director of the Office of Enforcement in 1985. It was a good move for me. I had been twelve years in Florida, and now I had an opportunity to come and try to do something different at the headquarters level.

RT: You were deputy then to whom?

AT: To Merv Shumate.

RT: Oh, Merv Shumate.

AT: Merv and I worked together for some time. He was basically an institution in the FDA and had been in that job for quite a long time, and everybody knew Merv. A year later, Paul retired as the associate commissioner for regulatory affairs, and Merv Shumate retired also. So they were gone, and new people came in. In the interim, while they were trying to fill the job of director of Office of Enforcement, I was the acting director for almost two years.

RT: Were there any particular episodes in enforcement during that period about which you'd like to comment?

AT: Well, I think I should mention maybe two initiatives. First, there have been many times where there has been concern or criticism about the lack of cooperation between the field and FDA headquarters in regulatory matters and enforcement, and in the past, there has been a "we" and "they" attitude in some instances.

One of the things that I felt was that there ought to be a better understanding on the part of the FDA centers about the roll of enforcement and the roll of the field in the mission of the Food & Drug Administration. So I proposed and it was accepted that there be a series of seminars or workshops for center scientists. There were five centers as you know, for foods, drugs, pharmaceuticals, biologics, medical devices, and veterinary products. So the idea was to get these people together and try to provide them some orientation about the enforcement policy and processes of the agency. FDA is a law enforcement and consumer protection organization historically. All I was trying to do was to provide center scientists with that orientation, and we had set up a series of meetings.

Well, this one center director, when he introduced a subject, we had some lawyers in there and some other people. There were about let's say fifty scientists sitting in the room. He says, "Well, we're here to hear about enforcement, and sitting in the back is Trujillo. He has a number of notches on his gun, and I'm sure he'll tell you all about it." So he gives this preliminary kind of greeting and basically doesn't really support too much what the seminar's about, but he kind of reluctantly says it's important. Then he walks out. I'm next to talk, and he's already gone. So I couldn't get my two cents in so he could hear it too, see. (Laughter)

So I think the whole thing was successful over a period of maybe a year. There were a number of meetings like that. I hope the center scientists gained an appreciation. Well, if they didn't in '86, they have it now. (Laughter)

It was quite an interesting experience, because here I had the opportunity to deal with all the centers, and the Office of General Counsel, and all the field offices on some of the major enforcement initiatives that were going on. Most of the significant enforcement actions would come through the Office of Enforcement. All the regulations development was still there at the time, which now has been transferred to the Office of Policy. All the compliance policy issues were being coordinated out of the Office of Enforcement. So to me it was quite an interesting opportunity to become involved in the agency's overall enforcement policies.

One of the things that I tried to do was provide more emphasis to enforcement, to allow for better coordination between the centers and the field on enforcement issues. One of the most significant initiatives was the FDA action plan in those years. There was one aspect of it that had to do with enforcement processes. We went through a long period of time trying to analyze these issues and streamline enforcement. A lot of people resented this action plan, because it tied up a lot of resources trying to develop these strategies.

RT: Was that an initiative of one of the commissioners?

AT: Dr. Young.

RT: Yes, Dr. Frank Young.

AT: He had a number of issues, but enforcement was one of them. Basically, the centers, the Office of General Counsel, and the entire institution got involved in determining how you can improve enforcement. And we came up with a plan to streamline, cut out duplication, and speed things up. That was before Kessler came, so there was emphasis on enforcement. I was quite proud of my role in that. It didn't take to the degree the generic drug scandal forced us into later years.

RT: Well, you've cited Dr. Young. Prior to his tenure, do you recall other commissioners that you believe were enforcement oriented?

AT: You know, Paul Hile and I had to go through that question recently, and we found copies of statements issued by various commissioners over the years on enforcement philosophy, which I would be happy to share with you. Yes, there were statements made, often as a result of incidents that happened where commissioners felt it necessary to articulate what the agency's primary role is, and that is as a

scientific law enforcement agency. Product review and approval is important, but FDA has a mandate to enforce a law. Some commissioners have openly expressed interest in FDA enforcement. Dr. Young did, and now Dr. Kessler. He came in at the right time. Whether his personality was that way to start with, I don't know. Dr. Kessler came in when the agency had the generic drug industry problem. He took on the orange juice industry to correct labeling practices and made a big splash of it.

Now we have a corps of criminal investigators in FDA to ferret out fraud. That came in after the generic drug scandal and investigations by the Office of Inspector General in the department, and Congressman Dingell's investigation that concluded FDA didn't know how to make criminal investigations. Although many of us thought that we knew how to make criminal investigations, people from the outside--and I guess they convinced Kessler--felt, no. So FDA hired about a hundred special agents, criminal investigators. Well, maybe that was a necessary part of the evolvement of the Food & Drug Administration. But I still wonder whether the same thing could have been accomplished without that. Because these people have special credentials, and they have a different attitude, I think, than what the FDA investigators had when they regulate the industry.

In my opinion, FDA should be perceived as a consumer protection agency, and law enforcement is necessary, but you've got to go in there with a professional approach. I think for the most part that you'll find people in industry want to comply. It's a challenge to find those who aren't, whose primary motive is something else. Whether FDA investigators have traditionally not had the capability to find fraud, I don't know, but I think they did. Obviously others felt differently. Whether it was done for political reasons or not, I don't know. We were forced to accept this new mentality of criminal investigation. Although through the years, FDA has been very effective in terms of finding out these problems and bringing about correction.

So what the current attitude is of the traditional field force about these criminal investigators, I don't know. Maybe they're more accepted now. Maybe

there's a lot of cooperation between traditional FDA investigators and the special agents. Maybe it's an exciting thing to get these criminal investigations going. I'm afraid of going too far overboard where FDA may be perceived as primarily a criminal investigation kind of organization instead of a professional law enforcement organization that has the best interests of the American public as well as American business in mind. This is what I'd like to lead into.

RT: OK. Of course, the criminal investigators were the first of our field personnel that carried sidearms, I believe. Isn't that correct? I don't know whether that's another inference of more of a crime orientation than our people who have not carried firearms in the past.

AT: Yes, the weapons . . . Although by law FDA investigators were entitled to carry weapons under certain circumstances, that never happened. It's something that the FDA traditionally stayed away from. Although back in the sixties when FDA was involved in the investigation of illegal sale of barbiturates and amphetamines, I personally--and others I know--were involved in these kinds of investigations. Those types of investigations were dangerous, and the only thing you had to protect you was one of these little recorders called a mini-phone that you would wear if you went into a bar. It was supposed to transmit the message outside to whoever was listening, some of your peers.

I walked into a bar in Salt Lake City in 1964 to try to buy amphetamines. They didn't know me from Adam in there. So I started having a beer, and somebody came up to me and said, "Say, where are you from?" So he put his hand on my shoulder and he slid it down the back, and I had this strap with the mini-phone like a cigarette case right next to my chest. Fortunately, he didn't detect that. But I don't know what would have happened to me if he'd have found out that I was wearing that thing.

I go outside to the government car--I had the sense to have an unmarked car--where another inspector was waiting. I said, "Did you hear that?" And he says, "What?" He didn't hear a thing. So the mini-phone didn't work. I decided then and there, I don't want this. At that time, some of our inspectors involved in those kinds of investigations went into what was a newly formed organization called the Bureau of Narcotics and Dangerous Drugs, and some of our investigators went in there and started working with them. They tried to recruit me in Denver during those years, Bob. I walked into the Bureau of Narcotics, I think it was called at first, right?

RT: Yes.

AT: And I was talking to these guys there at the federal building in Denver, and they said, "Well, where are you from?" And I said, "Las Vegas, New Mexico." "Oh, do you know such-and-such and such-and-such?" I said, "Yes, I think I've . . ." "Well, they're in the pen now." They were old acquaintances, and I knew these guys. So luckily, it could have been me, I guess, involved in those things. But those guys from the Bureau of Narcotics were hard characters. I didn't want anything to do with them. So I said, "No, thank you. I don't think I want to work with you."

RT: Now, Adam, I know that through your management career, at least, you've been active in equal opportunity for employees, perhaps particularly Hispanic-origin staff. Do you have any thing you want to mention about how the agency is moving in a positive way in that direction?

AT: Yes. I'd like to talk about that as well as one more item, and that's international activities.

In terms of equal employment opportunity, affirmative action, which is now being kind of looked at again as something that's not necessary by some people in this country. I've always felt, and maybe naively so, that one person is as good as

another, but sometimes doesn't have the same circumstances or maybe privileges or opportunities. That applied to a lot of Americans, not only Hispanics, or blacks, or other minorities, or to women. A lot has to do with culture and how the predominant society accepts others, and how you had to blend in. Did you come into this country and try to adjust, and conform, and become accepted, and get into the mainstream?

I can't figure it out still why there is this resistance on the part of some people to allowing others to become a part of the system. I guess it has to do with power and giving up power. I guess I'm talking primarily about white males. If you look at today's polls, you'll see in corporate America very few women and minorities at top levels.

Where I'm from, Hispanics are not the minority, and some people--maybe I don't have to say this--don't understand that there were Hispanics in this country before there were Anglo-Saxons. The Spanish colonized Santa Fe, New Mexico, in 1610, before the Pilgrims. So I come from a group of people that felt they came in a long time ago. Unfortunately they displaced Native Americans, but maybe lived in harmony with Native Americans more so than any place else in this country. You'll still see in New Mexico a lot of harmony between Native Americans, whether it's Pueblo Indians, Apache, Hispanics, and Anglos, more than you would see in any part of the country. I think you're from South Dakota or in that part? Do you know what's happened to the Sioux Indian and to the Cherokee? And before that, in the east and the Atlantic coast and all that.

RT: Yes. In government, in the Food & Drug Administration, in those earlier times, there were real hurdles for members of minorities that are now not as severe.

AT: I've always been very fortunate in that I've never felt directly discriminated against. Maybe there had been some subtle discrimination and maybe I won't admit it, but I've always been very fortunate. One reason is because I won't accept it. I

will fight it every way that I can. Hopefully I'll never get to the point where I have to directly confront someone because of what I perceive to be discrimination. But that's me, and I'm lucky. But I know other minorities, Hispanics and blacks primarily, they just haven't had the same opportunities. I don't know whether it's improving or not, Bob. I think it's improved somewhat in the Food & Drug Administration, and I believe that most people I've met in the Food & Drug Administration do not discriminate openly.

But, like any other organization, I think some people are more comfortable with other people that are like them. So I have tried over the years to try to sensitize people about that. In 1972 and 1982, I went out on the record on it. In 1982, after some frustration--not for me, but for what I perceived as a lack of attention to Hispanic concerns and the involvement of Hispanics in the agency, Leroy Gomez, who was a district director also, and I sent a memo to the commissioner saying, "Look, this is wrong. A very small percentage of people in this agency are Hispanics--1.2 percent or something. There's virtually few, if any--maybe not any--in higher management, and this is wrong. You've got to do something about this."

And so, fortunately, we were listened to, and the deputy commissioner, Mark Novitch, took an interest. Gerry Meyer, who was the associate commissioner for management, took an interest. Paul Hile, who was the associate commissioner for regulatory affairs in charge of the field, took an interest.

One thing led to another, and there was a major recruitment effort. It happened that FDA was able to hire two or three hundred people for a period of time in 1982. I think it had to do with bioresearch. So there was a special effort made, and we recruited about fifty Hispanics, especially field investigators, into the agency. Since then there has been some gradual improvement in affirmative action involving hispanics, blacks, and women. When Paul Hile was the associate commissioner for regulatory affairs, there were two black regional directors, George White and Lloyd Claiborne.

So unfortunately, at some times during my career, I had to speak up about this, and I think I got the reputation of being somewhat of a maverick, whether it's on enforcement or on this issue. I think some people looked at me that way instead of the way that I felt I was in terms of being a career FDAer interested in the agency's mission. So how do you decide when people look at you in ways other than the way you perceive yourself? Yes, I pushed, but I didn't do it outside the system. I did it within the system and hopefully in a positive and constructive way. We were able to make some improvements. But I know there's a lot of frustration on the part of Hispanics and blacks inside FDA.

I'm not even talking about Native Americans. Where do they fit in? When are they ever going to become a part of this society? Do they really want to in the first place? Does anybody want them to? Is anyone wanting to involve them in the way this country works? Well, a lot of people say yes--lip service, I think. I think some people feel threatened by people that aren't like them. And some people feel like they've got all the answers and they understand it, and nobody else does, particularly somebody with a different color of skin. And I'm not bitter about this. I'm just looking at it the way I think it is. If they're women, well, some would say, they don't belong in corporate management. FDA now has a number of women executives.

RT: And certainly quite a number of investigators.

AT: Oh, many of them are female investigators now. So FDA's come a long way. Sometimes you can't fight this by confrontation. Minorities have had to confront institutions forever. When Leroy Gomez and I left the agency, there were no remaining Hispanic SESers. Now there's one, the regional director in Dallas, Ed Esparza. I mean, you can't go through your life fighting on this issue and having it consume you. But I certainly don't want my children and grandchildren having to face those kinds of problems in this country. I think it's a mistake. Here's why. This

world is not predominantly white, but the power structure is white in many instances, whether it's in Europe or here.

RT: Well, I think the population predictions are that there will be many more minority folks in the United States in the future than there will be whites. The Caucasian white may become a minority in time.

AT: Things are changing. Demographics are changing, and it's inevitable. Hispanics are going to be the largest minority in this country. I've seen some estimates like twenty million, thirty million. Blacks are becoming smaller percentage wise compared to the Hispanics. Asian Americans are on the increase.

RT: Well, the Food & Drug Administration, I think, is recognizing that in the sense that in recent years, before I retired, there were some seminars on ethnic awareness designed to develop on the part of managers in the agency a better understanding of ethnic differences so that in management style there's not inadvertent offenses of staff. That can happen. Claudette Guilford in one of the sessions made a revelation to me. She said that, "You folks often use the term 'gals' for women when you're addressing black women, and that's very offensive, since to some, that term means a woman of less than the highest virtue." That was something that I don't think any of us were aware of.

AT: Well, you have to be careful how you approach people no matter who it is. I mean, you've got to be respectful; you've got to be in tune with where they may be coming from; and you can't overshadow that other person's personality. The thing is people who are in power tend to act that way, and they give the orders.

Well, I'm going to go back to my formative years. My upbringing had to do with respect of my grandparents, and my parents, and peers around. At the same time, I probably have had to go through things a lot of people haven't gone through,

and that is conflict in my growing up because of having to be able to deal with confrontation in society.

In my environment, when I was young, people would get physically threatening. This whole culture of let's say black, urban blacks, and in my experience, Mexican Americans, living in a society where there was a lot of frustration, anger, no hope, very little education, not much counseling, a lot of rejection, not much acceptance, not much awareness of what's out there. So you grow up in a situation where you're fighting all the time, sometimes physical violence, and you know nothing else. You can see it in the urban areas now, people killing each other off. You know, guns being the way to settle things.

RT: I want to digress a moment, Adam, because I would like to get this in the interview. You were active in government with PAHO (Pan American Health Organization), and that was while you were with FDA. Would you like to go into a little of what is PAHO in terms of their interest in food and drug related matters? What did you do with and for them?

AT: Well, I think it's a good point to get into because it has to do with diversity also. You know, the Pan American Health Organization is an office of the World Health Organization (WHO), and the WHO headquarters is in Geneva. PAHO has their headquarters in Washington. They're basically responsible for trying to improve the public health of the Americas. But PAHO has been around since 1906, which was when FDA basically became an entity. So PAHO predates WHO. I was interested in PAHO back in 1983 when I first served an assignment there when I was in the SES candidate development program trying to go in there and help them strengthen food protection programs in the Americas. I traveled over a period of time with PAHO or the Food and Agricultural Organization (FAO) of the UN to about twelve countries in Latin America trying to assess where they were in terms

of food safety or drug quality programs and to help them find new ways to develop better programs.

It's been very interesting. I went back to PAHO for a year and about a quarter in 1991. The FDA allowed me to go and spend time with PAHO, and I again worked with them to try to define how to better help these countries.

(Interruption)

AT: My interest in PAHO has been because as a Hispanic-American, I felt that I could contribute to cultivating better understanding between the FDA and these Latin American countries in terms of food protection and pharmaceutical quality and all that. But more importantly to me is helping cultivate better relationships overall between the U.S. and some of these countries. So I've been involved heavily over the years in this kind of thing. Right now, as a consultant, my primary goal has been to try to reach out and develop some business relationships with Latin America, particularly between Mexico and the U.S., to do two things: help them understand FDA requirements to export products here, and secondarily, to help U.S. companies understand what's going on in Latin America and help them do business there.

RT: A few years ago there was a Chilean grape problem, and I was wondering, would you suggest that the problems with imported products relate primarily to pesticides and indirect additives, or is it sanitation, or combinations of those sorts of things?

AT: There's a mix of things. A lot of sanitation problems and labeling. I have statistics from FDA about detentions of imports going back in time, from all over the world, not only Latin America. I think what it boils down to for me is that many of these countries don't have the infrastructure, resources, awareness, understanding, or capabilities, or the sanitation or quality systems in place to ensure that their products

meet FDA requirements. Not only FDA requirements, but European requirements and Japanese requirements or other countries who have over time implemented more stringent requirements for imported products.

RT: Would you describe the Pan-American countries as having any more of these kinds of problems than other parts of the world? How do they rate?

AT: I've never been to the Asian countries, but I see there's a lot of FDA detentions of imports from India, China, Thailand, and Indonesia. So I have no direct frame of reference; although I sense that some of the conditions in India, for example, shrimp harvesting, is kind of a cottage industry, and there's not a whole lot of control.

In terms of pesticide residues, what's happened in Mexico primarily and some other countries is that, despite the fact that their producers, and many of them are small producers, are aware that they shouldn't be using certain pesticides, but there comes a time when they have nothing else, so they apply these pesticides which are not permitted in these crops in this country, and it shows up in residue. So it's having an effect on the import detentions, and it seems like it's a consistent problem and never goes away in some countries.

So sanitation, pesticide residues, bacterial contamination such as salmonella, in some instances chemical contaminants lead to FDA detentions. I got very involved with PAHO during the cholera epidemic in 1991, and I went to about six, seven countries, including all Central American countries, to help them devise better systems to assure that there is no cholera transmitted in foods, particularly in exported foods, foods exported to the U.S. I mean, this cholera problem had a big impact on some Peruvian and Ecuadorian exporters, particularly with fishery products.

So the conditions in these countries are such that you can't have the same systems in place in these countries because they don't have the infrastructure or

resources or, in my opinion, the awareness or information. So all I try to do is provide information. I just got a fax here from the American Chamber of Commerce in Mexico which wants to know about FDA requirements for imported products. So I try to provide that information to countries. I've done a lot of speaking in conferences in Mexico and other places trying to help them understand the rules of the game.

RT: When you were with FDA, were you doing this education with foreign governments or with foreign industries?

AT: Primarily with foreign governments.

RT: And now as a consultant, of course, you're probably working more with the import industry?

AT: Yes. Right now, in my view, if some of these countries are going to change, it has to be the private sector that's going to change with the help and commitment of government. But in many of these countries, there's little stability in terms of the bureaucracy. So if they get programs going and four years later, six years later, they sweep all these top people out and new people come in, and so there's not an FDA-like mentality in some of these countries. They don't have a permanent corps of people who can carry out these programs over time like we do in FDA. So I think I'm going to focus on the private sector, because they've got the most to gain and lose.

RT: Adam, when did you retire from FDA?

AT: I retired on April 3, 1993.

RT: And then, of course, now you're in consulting with some other former FDA persons, and you're in the Phoenix Regulatory . . . What is it?

AT: Phoenix Regulatory Associates, Ltd.

RT: Right. So you're still working in the food and drug field, but with industry.

AT: Yes, primarily with industry. I'm working here at Phoenix, but I'm not an employee. I'm an independent consultant and associate of Phoenix.

RT: Looking back now, you were with FDA for thirty-two years, and, of course, during that time, you saw many commissioners, and in more recent times with greater frequency, come and go. As a former employee and a person on the outside now sort of looking back in, do you have any impressions that you care to share about either where the agency's going or what changes come to your mind that might be indicated? Of course, with the new Congress and so on, there's some reorientation already that may impact all of federal government. We don't know about that yet entirely. Do you have any sort of closing thoughts that you'd like to share?

AT: Yes, two. One is that I think the FDA should become somehow more cooperative with the American private sector. I know that there needs to be a lot of arms length, hands off, and there needs to be more attention to that. What is the FDA's proper role in terms of its relationship with the industry that it regulates in the United States? And it seems to me that they ought to find ways to get more cooperation or understanding flowing back and forth. There's a lot of it already. But as I mentioned with the generic drug industry, not enough.

RT: Are you suggesting a return to voluntary compliance?

AT: No. I'm suggesting that there ought to be more understanding between the FDA and industry at all levels about what both organizations or institutions are trying to achieve in terms of product quality and consumer protection, and--here's maybe where FDA would have problems--how can you support the development of the U.S. industry? Because we're in a competitive world.

I was going to say in terms of my orientation about minorities and my grandchildren, if we in the United States don't involve minorities in doing business, whether it's government or the private sector, we are going to miss the boat when it comes to future years in terms of competing in international trade. If we get to that point where we can't compete as a number one country, it's not going to be good for anybody--not the whites, not the blacks, not the browns, not the yellows, or anybody else. So I think we ought to strengthen the institutions and involve all the people in helping this country get to where it has to go for the good of everybody.

I think that's the same for business. If the government has to support American business, it's in a competitive world that they have to deal. So that's where I think FDA needs to focus a little bit more on that, even though they don't have a mandate to do that.

RT: Well, of course, one of the inferred conflicts of interest that has sometimes been made about USDA is that it's an industry supportive agency, and yet it has a regulatory role.

AT: There may be. That's why you have to be very careful. You don't want to step over the line, and the generic drug scandal showed us that. What is a proper line? I think it has to be a policy question in the United States as to what is the proper role for federal regulatory agencies in terms of its regulation of the private sector. The EPA is getting a lot of pressure, and right now OSHA is going to get a lot of pressure. USDA has had a whole different philosophy behind them, and

they're under attack. Some people want to take foods away from FDA and give them to USDA. I think that would be a mistake.

RT: Well, do any further thoughts come to mind regarding your views of FDA's need to change its course in the future?

AT: Well, you were asking me about where FDA ought to be going, and I mentioned about the relationship with the private sector, and I want to mention very quickly one reason why I say this. I spent a year in something called the President's Executive Exchange Program in 1990, where I went away for a year with twenty-five colleagues, half from the government sector and half from the private sector. I went to the private sector, and the people from the industry came to the government, and it was a tremendous experience. This program has been disbanded because of some alleged problems.

But I spent a year with the American Cyanamid Corporation in Princeton, New Jersey, in their agricultural research division, and my project was to help them understand public perceptions about agricultural chemicals. It was one of the best experiences I've ever had. By getting into this environment with business in this country, I think more government executives and government managers would have some opportunities to understand what the private sector is doing out there and why, and they're not all crooks. It helps the private sector understand that not all government employees are lazy. I think there is a gap between the two that somehow ought to be brought closer.

It seems that is a way to do it. But, unfortunately, with resources the way they are, maybe it's not going to happen. But something ought to be done to provide a better understanding between the private sector and the government sector in this country so that we work towards common goals. In the meantime, there is a lot of distrust. So, I guess, historically my attitude has been that you trust, but you verify.

In other words, you've got to have this acceptance between the two sectors in order to keep this country great. I would encourage this to happen.

I'd like to finish with a statement about FDA's international role. Before I left FDA, I tried to persuade some people in FDA that they ought to open up an office in Brussels. Well, no, they felt this was premature. So in the last year that I was in FDA, I tried to emphasize the need for getting the agency more aware of what the role should be in terms of international enforcement and regulatory activities, and I think I was able to stimulate some thinking.

A number of meetings and conferences and groups were formed, and I think there's now more emphasis on enforcement in FDA's international harmonization program. But I think that the mentality of the agency is now more international. You see it by the emphasis on foreign inspections and more dialogue with foreign governments.

FDA still doesn't do enough to share information with foreign governments and foreign exporters or participate in international regulatory efforts. But I think they're trying to find ways to emphasize this now. It's absolutely mandatory for two reasons: to ensure the quality of products that are imported in this country, as well as be able to compete internationally in exports. Somehow I think FDA needs to focus more on that, even though there's a considerable amount going on right now. Specific initiatives, such as the one with Russia, are evolving, probably for political reasons.

But there ought to be more in Mexico and Latin America, for example, because that region is dynamic, it's growing, it can go one way or the other. I mean, you don't want it to go back to the dictatorships. You've got to get more dialogue going, create better understanding, and get involved in more of a neighborly way. That's basically where my platform is. I don't know what I can do about it.

RT: OK. Well, that's good. We've covered quite a broad area of activities, Adam. Are there any other thoughts that come to you that you'd like to add to the transcript?

AT: Well, other than to say that this is a very interesting experience for me and I appreciate you coming by. Hopefully there can be a way to make something useful out of this, as well as all the other FDA history work that you and Ron Ottes and others have been involved in over some years. To me it's important for the FDA as an institution to survive and to always be a proud organization, and the people in it, and they're getting crunched right now, to maintain this sense of a commitment and urgency. I don't know where they are now in terms of their attitudes and how things are going for them in terms of morale and the reduction in budget and all that. I sense that it's not healthy, and I wish that there were some things that could be done, some way for this historical perspective that you are working on to make a difference in the current activities of the Food & Drug Administration.

RT: Well, of course, one of the initiatives that the current commissioner is taking is to consider the regulation of tobacco products, and that's quite a departure from anything that's been done heretofore. It looks like that may be blunted now by the changes of politics at the national level. Do you have any impression about those kinds of things? Should the agency keep more in line with its traditional role in food and drug control?

AT: Turn it off a minute.

(Interruption)

AT: I was saying that I felt that in terms of the current political environment, I think the FDA should drop this thing about tobacco. Maybe somebody needs to take

care of it, but I don't think it's FDA. I think they ought to look ahead and think about how is FDA going to survive as a strong institution, and in view of the current anti-regulatory climate in some parts, there is going to be a battle in the next two years. I think there's going to be a strong support for the FDA. Hopefully, the Senate will be a little more rational. But certainly, it's going to slow down FDA's enforcement role probably--regulatory role overall.

There are some important regulations coming, and the big question is how much regulation is too much? And how much do you let the industry take care of things? Consistently what we've found is that there's always some problems, some issues, some incidents, and like the generic drugs scandal again, you just can't get away from it. So I think what FDA ought to do is try to persuade the policymakers how important a role it has in terms of consumer protection, and in terms of fostering a better climate for the private sector, including how FDA could be involved in that, even though it's a regulatory agency.

I don't know how you do that, Bob, but I think that's the way it ought to go. Because you can't live isolated from what the problems are in this country, and FDA, as fine an institution as it is, shouldn't be constantly perceived as anti-business.

RT: Well, that sounds like a judicious path for the immediate future in view of the national political scene.

Adam, I want to thank you for this interview. We appreciate your participating in the FDA oral history program so that your experiences can be shared with those interested in reviewing FDA's history at the National Library of Medicine.

AT: Thank you very much, Bob. It's been a pleasure.