History

of the

U.S. Food and Drug Administration

Interviewee: **Michael C. Olson**

Interviewer: **Robert Tucker**

Date: **July 27, 2004**

Place: **Rockville, MD**

Interview with Michael C. Olson

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TAPE 1, SIDE A

This is another in the series of FDA oral history interviews. Today, July 27, 2004, the interview is with Michael C. Olson, Director, Division of Genome Science, Office of Regional Operations.

Bob Tucker: Mike, as we begin the interview . . . Oh, pardon me.

The interview is taking place in the Parklawn Building, Rockville, Maryland. Robert Tucker is conducting the interview with Miss [unclear].

Mike, as we begin these interviews, we like to briefly cover your personal history, where you were born, educated, and any career experience you might have had prior to joining the Food and Drug Administration.

Michael C. Olson: Okay. I was actually born in Chicago, Illinois. I'm a southsider, White Sox fan. I lived there for ten years. We moved from the south side of Chicago to Brooklyn, New York, from the fireplace to the fire, from the frying pan into the fire. I went to schools in New York, graduated Brooklyn Technical High School, which was a special [unclear] high school in New York. I got a

bachelor of science degree in chemistry from Brooklyn College. And before I came down here, I did all the coursework for an MBA, master of business administration and management, at New York University.

Prior to FDA, when I graduated college, I tried very hard to get jobs, and I think I sent twenty resumes out.

Tucker: What year did you graduate from Brooklyn.

Olson: Brooklyn? January '69.

Tucker: That was Brooklyn . . .

Olson: College.

Tucker: College.

Olson: Yes. I went the four-and-a-half-year plan.

And then, when I graduated, I got one of these books and I sent twenty or thirty letters out to chemical companies for jobs as a chemist. And it was funny. I got back twenty to thirty rejections.

I couldn't figure out what was going on, so I went to a headhunter in New York. He took one look and looked at my draft status. It was a 2S, which is a reservist, and he asked one question. He said, "Have you been on active duty yet?" I said, "No." He says, "Goodbye. You can come back and see me after you've gone on active duty."

So, then I started -- so I actually went to Metropolitan Life Insurance and became a life underwriter. I was training for that. I did that for about four months.

My goal was to not be a life underwriter. It was simply to have a job.

Then I got my notice to go on active duty, so in '60 . . . Actually, in July of '69, right after about four days after we landed on the moon, I went to, got on a bus, went down to Fort Dix, New Jersey, went through basic training there, then went up to Fort Devins for my advanced, you know, AIT, and came out end of November.

Tucker: Where was Fort Devins?

Olson: Fort Devins, Massachusetts.

Well, the interesting story is how I got into the government.

Right after I graduated, I had FDA in the back of my mind, and the reason I had it there, when I was in college, somebody had told me, there's this thing called FDA, and they give draft deferments. So that kind of clicked FDA in my mind. All I ever remember hearing about FDA was cranberries, the great cranberry crisis at Thanksgiving. So after I got out of school, even though I was a reserve . . . I actually joined the Reserves a month before I graduated, so I didn't need a draft deferment. FDA was still on my mind, so I actually went down to the Brooklyn office probably in March. I graduated in January. About March. Met a personnel person. Her name was actually Georgia Peachy. And, you know, I said I was interested. Did they

have a lab there? She said yes. But she said they hadn't hired in a long time, but they were hiring investigators. I did not know what an investigator was. She gave me the brief three sentences, and that just wasn't for me. In retrospect, it's exactly what I like doing. Even though I started, I have a degree in chemistry, I [unclear] electrical engineering. I have an engineering mentality. I love to look at things and see the way they work, so I had a [unclear] as an investigator. But I figured, I had a degree in chemistry, I wanted to be a bench chemist, so I told her I wasn't interested in an investigator. She says, well, she heard that -- and I think at that time, it was BDAC BONAD, Bureau of Narcotics and Dangerous Drugs, had split off under Justice, and she said she heard that, she remembered they were setting up, they were split off from FDA, too, and they were setting up a lab in Manhattan. So she told me to go see Tony Ramano, the lab director.

So I got on the subway and went up to Manhattan, found the lab, and there was Tony Ramano, the lab director, painting the walls, which is kind of interesting. So he's in there painting the walls and he's talking to me, kind of interviewing me. And so I told him I graduated and everything else, and he said that at that time, since he was just setting up a new laboratory, he really could not afford to take on somebody brand new, with no experience because he

just didn't have time to set up any kind of training program. And he said, "Why don't you try FDA?" and I said, "Well, I've already been down there. They weren't hiring." He says, "Well, Abe Kleks is the lab director." So he gave me Abe's name, so now I got on the phone. Now when I called in to FDA, I could now say, "Can I speak to Abe Kleks?" The secretary would naturally say, "Well, who are you?" and I'd say, "I'm Mike Olson. Tony Ramano told me to call Abe." And Tony had worked for FDA. So that was my opening to Abe Kleks.

So I got in to Abe and, amazingly enough, on the phone, we hit it off. I would call him about once a month; we'd talk for a half an hour.

And then, while I was a life insurance underwriter, it was probably about May, they called up real quick and said, "Come down. Come for an interview." So I went down to FDA, took a day off, went down to FDA, spent a whole day just being shown around the laboratory, talking to people.

Tucker: Was FDA located at the Bush Terminal then?

Olson: Yes. It was at Bush Terminal on Third Avenue and 30th Street.

Tucker: In Brooklyn.

Olson: In Brooklyn.

And met so many people, it was scary. Left and never heard a word, which I always say is typical of FDA. Never

heard a word.

Then I go into basic training in the Army, and my dad gets a call in August. "This is FDA. We can hire. We want to hire Mike." My dad basically said, "Well, you can't. He's in basic training right now." Then my dad also said it wouldn't be fair not to. He knew I wanted to get into FDA. He said, "[unclear]. He's doing his military service." They said, "Yes, you're right." And the only dilemma they had was swearing me into civil service because they had to make the offer to be sworn in.

Actually, in the military, the oath an officer takes to become an officer is the Civil Service Oath, and they can give the oath. So in my sixth week of basic training, I was called into my company commander's office. I put my hand up, he swore me into the Civil Service, told me to drop down and give him twenty, and then I was an FDA employee on leave without pay, and I stayed on leave without pay for another ten weeks. So when I got out of the Army active duty, then about a week or two later I started at FDA [unclear] something like December. I always say December 1, 1969.

Tucker: Now, were you in the service just for the basic period, basic training?

Olson: Yes. This is after [unclear]. Right.

Tucker: That worked out quite well, then.

Olson: Yes. And I [unclear] to go to Vietnam.

Tucker: So, then you came into the laboratory at FDA at what grade level?

Olson: GS-7. And the reason I started at that, I was not the superior student. I am one of those people that people hate. You know, there's a lot of people that freeze up on tests. I do the opposite. I'm a test taker. I do well on tests. I test out very well. So I had taken the GRE [Graduate Record Examination] test for chemistry, and one of the requirements to get a 7 versus a 5, either I could have like a 3.5 index or score over 600 on the GRE chemistry test, and I scored better than that on the GRE chemistry test, which was the hardest test I ever took in my life.

Tucker: Who was chief chemist at that time?

Olson: The chief chemist was Abe Kleks. Abe Kleks was the chief chemist, the district director was Bob Martin, and the regional director was Weems Clevenger.

Tucker: So, George Schwartzman.

Olson: George Schwartzman left. No, he had left.

Tucker: Oh, I see.

Olson: And George went on to CDER [Center for Drug Evaluation and Research].

Tucker: So, in the early time there in the laboratory, did they give you a lot of training and orientation, or did you just kind of get into basic work?

Olson: Well, I went through the full training program. Actually, back then it was about a six-, seven-month training program, never touched real samples in training. It took me probably about eleven months to get out of training because there were three of us: myself, Bruce Goldwitz, and Marty Woodhouse. We were the training class of ’69. They actually got there before me because they started right about when I sworn in. I was in the military. I had about a two-month delay. And what they did a lot of back then was, we would be in training and then something would happen and they needed us. So they’d pull us out of training and really quick train us on an enamel system. We’d go do that for maybe a month. So in training, I remember I spent some time on dinnerware, basically doing dinnerware, lead in dinnerware. They just got flooded with samples. So they’d pull us out of training, we’d do samples, and then, once we were done, we would go back and continue the training program.

Tucker: You had mentioned [unclear] lead in it, and that lead was . . .

Olson: Lead cadmium in dinnerware.

Tucker: And was that, some of that from Mexico or . . .

Olson: Everywhere. New York is a huge, well, everyone knows it’s a huge port, so dinnerware pours through New York

from all over the world. And back then we were doing a fair amount of dinnerware work.

I think I also, I worked on the tuna crisis, the infamous mercury in tuna, which was either ’70 or ’71, and I can’t remember if I was in training or not. And I got pulled out of training to work on mercury in tuna, and that’s when -- the [unclear] commissioner was that they found mercury in tuna, and he made a commitment that we would test every lot of tuna coming in the country. And, again, New York’s a massive port. And back then, there wasn’t a lot of movement of samples around like we do nowadays. You know, we’ll move, if a lab gets flooded, we’ll ship it somewhere else. Back then, basically the whole laboratory supported the whole district. So we got thousands of samples. We actually worked for two months in New York twenty-four hours a day, seven days a week.

Tucker: Do you recall who the commissioner was that made that?

Olson: No, no. It could have been Edwards maybe back then.

Tucker: Now, were there seizure or injunction actions arising out of [unclear]?

Olson: No. These were all imports. Imported tuna [unclear]. And we found a fair number of . . . As a matter of fact, tuna, you know, we would get violations out of it

and have to check, analyze it.

Swordfish was all violations. As a matter of fact, during that time, we must have run 200 samples of swordfish. I think one popped up not violative, and we had to go back and reanalyze it. We just couldn't believe that it was not violative.

Tucker: [unclear] were denied entry into our country. What disposition happened the most? Were they sent back?

Olson: My guess is most of them were sent back.

Tucker: Where they originated?

Olson: Yes. But we would get in . . . I mean, I love tuna, so I actually learned to hate it.

We would get in number ten cans of tuna, and number ten are institutional size. And we had to composite twelve cans. They were about five or six pounds each. So we got to actually composite seventy-two pounds of tuna with big Hobart mixers. And after you ran in there and just chopped them and chopped them and blended them, ground them, it looked like tuna ice cream. It had the same consistency of ice cream. And then we would just have to pour that down the drain and put the next one in. And we just, we worked around the clock. It was actually very hard work.

But [unclear] composites, [unclear] your composites. The machine will kick out little bits of tuna here and there. They would stick to the wall and they'd begin to

rot. Pretty soon you get this rotten smell of tuna.

For some crazy reason, I had volunteered for the midnight-to-eight shift, because I had always wanted to work midnight to eight and try it. So I think I spent six weeks on a midnight-to-eight shift. And it actually, it's one of the, for an early experience, it was one of the smoothest things I've ever seen. I mean, it was done very nicely. We worked around the clock. We had a half-hour overlap on each end. It was just a continuous analysis. And we didn't, we just didn't run our own sample. I mean, I might start the samples digesting, and the next shift comes in, and they know exactly where I was, because we'd do about five or six samples at a pop. I mean, they would take over from there. It was very nicely done.

Tucker: After that experience, what else did you get into in New York?

Olson: Well, when I was in training in drugs, there was the big syrup of ipecac caper, and that was about 1970; it would have been '70. And syrup of ipecac is an emetic; you know, it makes people vomit. And it was something with, I think it had ephedrine or epinephrine or something, and it was somehow adulterated. They had not put the active ingredient, so it actually failed. And it was used to help that because people take syrup of ipecac because they're supposed to throw up because they've consumed something, so

if it doesn't have active ingredient, it won't make them throw up. It's very serious. And I remember that our lab, the lab was filled with samples. There were drugs, I mean, and there were hundreds of samples involved. And it was interesting because that's one thing I didn't get involved in.

And I always thought it was a very funny feeling. Here you are training, you're kind of rerunning. Basically, I would just rerun samples other people had run already, and, you know, very calmly. You know, you're in training and the people around you are running around like chickens without heads, trying to keep track. And back then, we didn't have the data systems we have, so it's just amazing, equipment everywhere, people running samples.

I do remember that they had tried to backtrack on the manufacturer and then found out it was a post office box in Canada that was the source of this product.

There were people who were involved. They actually got people because I remember when I was leaving New York in '75, five years later, that they were going to trial on syrup of ipecac. I don't know what the outcome of that was.

Tucker: So this was a Canadian import. What would they be prosecuting?

Olson: I don't know. That's -- I don't remember who.

Tucker: The distributor perhaps?

Olson: Yes, yes. It went up to somebody. Yes. And it was a domestic case.

Tucker: Now, was there any involvement with ipecac from domestic pharmaceutical sources?

Olson: No, I don't think so. I think it was just one whatever. Again, I'm a little hazy because I don't . . . You know, I was in the lab when they were doing all this, but I never picked up on a lot of the fine points of exactly what the particulars of the case were. [unclear] chemist.

Tucker: Had injuries been caused?

Olson: Oh, yes, yes, there were. I found out.

Tucker: Any deaths?

Olson: I don't think so. I think there were injuries because people who were taking it and it had no effect. As a matter of fact, I think [unclear] Jim Nelson, who worked in the lab in New York, actually, he had, Jim had, Jim, gosh, had eight kids or something and actually had to use syrup of ipecac on one of the kids and it didn't work. I don't remember who one of the index cases was, though.

Tucker: That's interesting.

Now, you mentioned drugs. Did you get into other kinds of pharmaceutical product exams?

Olson: Me personally? Yes, yes. Working in New York, I mean, if you look back, I'm happy I went to the lab and I'm happy I started in the lab. It's an amazing experience.

Brooklyn College actually was a fairly good school. I mean, it produces a lot of -- most people go to graduate school, medical school, and it gives you, I think, a good theoretical basis for chemistry, so I know a lot of theory. What the training program in FDA did was allow me to apply it, so I actually had both pieces. I'm a pretty good applications chemist, but I also understand an awful lot of the theory behind it.

Tucker: While you were in New York as a chemist, were you ever assigned to go out with an investigator to get some sampling?

Olson: Yes. Actually, inspections. I did a -- in training, we tried to . . . Actually, me, Marty, and Bruce wanted to know what investigators did, so Albert King was our training supervisor. And we talked to Al. We said, "You know, Al, it would really be a good idea" -- again, we were very manipulative New Yorkers. We said, "It would be a good idea if we just saw what the investigators do." So Gerstenberg was DIB [Director of Investigations]. George Gerstenberg was DIB back then, and they kind of talked him into, you know, why don't you go on some training inspections?

Tucker: What was Gerstenberg's position?

Olson: DIB.

So these were just training inspections, which means we

really -- I'm not even sure we would sign the form, just, we were just there for just a, we're not even investigator training, just kind of observing. So I did one or two of those. And it was a shame because I was the first one to go out. And then when George was [unclear], George was very interested in doing it, Gerstenberg. And then he came back to the lab and asked one of the other trainees . . . He was trying to get good inspections, too. It would be a lot to see, and I guess at [unclear] felt insecure about himself, so he said he hadn't had enough notice. Meanwhile, we're in training. Give me a break. What are we doing that's so important? We're reanalyzing samples [unclear]. So that kind of stopped that. I was probably the only one that did go out.

And then about three years after this, when I was in the drug group, I actually went out and did an inspection of a firm under injunction, and it was over in Jersey. I don't remember the name of the firm, but they were under an injunction and they wanted someone to go in and re-inspect the laboratory. And I'd never done that. It was kind of neat. They handed me like a list of a hundred questions you could ask of a drug inspection. So I kind of went over that list and pretty much made up my mind what I needed to do. We headed up the inspection. I can't remember the name of the investigator. And he kind of taught me the [unclear]

and he'd gone in the laboratory and had ripped them apart, but he said he really, he didn't really know too much what he was doing. He said the whole plant was a mess. So he really wanted me to kind of give them a good look-see. He tried to get them on validation. I remember that.

So I went and did an inspection, and I've always used it as an example of a precursor to . . . And I have the utmost respect for investigators, I always have; they know an incredible amount of stuff; but they just, they can't know that much about lab operations. And things they'll see that they call significant really scientifically aren't, and things they don't think are significant can be.

And when I was inspecting this laboratory, it was interesting. They'd hired a new lab director, an Indian fellow, Ph.D., and he had gone through and calibrated everything. So one of the things they gotten them on was this big floor centrifuge that every laboratory back then had. And there's a dial indicator on the top that's just -- some people think it measures in rpm's, but it really doesn't. It's just numerical gauges. So they had not calibrated that so that you'd know that a certain reading on the gauge meant so many rpm's, and there's devices you can do that to measure that. And then the USP [United States Pharmacopeia] would say centrifuge at 600 rpm or [unclear] or whatever. So walking through the laboratory, you know,

this guy is falling over himself looking. You know, he calibrated every thermometer. You name it, it was calibrated.

Well, I'm going through and he'd put little signs, little calibration charts, on each one. There was a big floor centrifuge sitting there and it doesn't have a chart on it, and I really went through a dilemma. I said to myself, "Should I mention this?" Now, you've got to understand where I'm coming from. All our floor centrifuges in our laboratories in Brooklyn, not only were they not calibrated, generally the dials were broken off. So we were just put it in the centrifuge and turn it up, which, believe me, scientifically works. So I did. I tried to very softly tell the guy, "I think you missed one," and he almost had a heart attack. I was trying to [unclear] take it easy.

Then we were over looking at one of the . . . You know, the thing I was more interested in actually was the instrumentation, you know, what do they use, methods they use, and he was using a Beckman DK2A, which is the old single-point spectrophotometer. You dial in a wavelength and measure at one point. It was really the science at the time. And the investigator had gotten them because he didn't have matched cells. You buy cells for [unclear], had to be manufactured, so they come in pairs, so your reference and your sample cell are the same thickness, which affects

the UV absorbance. There's a problem. I'm not even sure it's percent error. You know, you can get a volume of one-centimeter cell. Again, in New York, these cells were very expensive, maybe back then, they're $50, $60 a pair. I don't know of any analyst in New York who had matched cells. If you broke one cell, you'd test the other cell and [unclear] another one-centimeter cell, so they became "unmatched." It wasn't, it's not that big a deal. So he'd gotten [unclear] cells weren't matched.

So they had their two-way sitting there, and I pulled out the samples, and it had a huge crack down the face that the light comes from. Now, but it was funny because it wasn't leaking, but there was a huge crack. So I just looked at it, and then I looked at this lab director, and he said, "I'll throw it away." Now, the investigator hadn't [unclear] at that point, and he looked puzzled. And I told the guy, "Throw it away now," because I knew what he was going to do. So he threw it in the trashcan. And I told the lab director, I said, "Step on it." So he stuck his foot in there and stepped on it and crushed it. And the investigator was just, he was flabbergasted, you know. But being a good investigator, he never really said anything to me in front of the lab director.

When we were alone, he goes, "What was that all about?" He said, "What's the big deal?" He says, "They weren't

matched cells." I said, "Well, actually, the big deal, the fact that they weren't matched cells is not a big deal." I said, "I'm not sure I would even say to them." I said, I explained to him the crack. I said, "The crack gives you spurious results in refraction, reflection, the UV light and everything," and he didn't know that. That's just an example of what having lab people on inspections can do for you.

Tucker: This observation you're making, did that fact later lead to more the joint investigator and chemist [unclear]?

Olson: Yes, by me. When I came here, Richard Baldwin, my predecessor, was not -- Richard big on having analysts go out on inspections. I was, and I've pushed that since I've been here so that . . . And I use that example. And I don't do it to make someone look foolish, but it's just a different set of eyes. And analysts that go in the laboratory will look at different things. Investigators have been trained to look at validation. They'll simply ask the question, "Is this validated, is that validated?" We'll go deeper than that.

A lot of it is basic science: What are you doing? How are you handling things? Analysts can look at spectra, they can look at chromatograms, and they can tell if the chromatogram is unusually clean. Should it be that clean?

What kind of cleanup are you doing? I mean, there's a lot of things analysts can pick up on.

And investigators [unclear] they haven't worked in a laboratory. They just, you know, they're very well-rounded in a lot of different areas.

Tucker: Well, in a way, we're maybe getting ahead of it, but this is interesting to know, that you were involved in the design of the team approach.

Now, you're still in New York. Was there anything else that you'd like to cover during that period?

Olson: Yes. Bon Vivant happened in New York. [unclear]. [unclear] in the very early '70s, and that was significant. It was the vichyssoise, potato soup, and I forgot the name of the person, but somebody had died. [unclear] soup, and they opened up the can of soup and . . .

Tucker: It's cold potato soup.

Olson: Cold potato soup. And the wife got really sick, and the husband, I think, was paralyzed. I don't think he died, but he was kind of a mess. And it was botulism [unclear] in that can. They apparently never found it in another can, which is unusual because they made the [unclear]. You usually don't do that.

Tucker: Was there ever any finding or theory as to the cause of it [unclear] or inadequate [unclear]?

Olson: I don't remember. Yes. Don't remember.

[unclear] after all of the stuff was recalled, and we were still interested in finding more. This is back in the early '70s, when the LACF [low-acid canned food] regulations hadn't even been published yet. The LACF regulations came out and probably were a result of that. There were no LACF regulations. And we had used . . .

TAPE 1, SIDE B

Tucker: [unclear] New York District.

Olson: Yes. In New York District, the way it was laid out in the, down in Bush Terminal, the front half of the seventh floor was kind of empty. The district was in the back half. The front half was empty. And it was a federal building. And I remember there was a lot of soup in there. This is where they stored all this soup for years and years. As a matter of fact, I don't want to say who, but I knew somebody who used to go up there, take some soup, and take it home and eat it, which we thought was insane, right out of the laboratory. So that was our big bot case.

And probably the most exciting thing I worked on was, it was a, it was -- I did a lot of different things in there, but [unclear] work. And we had a sample once of, it was broccoli, and it was under embargo in Florida for a pesticide called TOK, nitrofen. And the owner of the product shipped it anyway, under state embargo, and shipped it interstate, figuring that Florida didn't talk to FDA.

Well, Florida does talk to FDA. And, actually, the investigators . . . There were four truck shipments. I think they went to like maybe Savannah or something, or a southern city -- maybe it was Atlanta -- New York, and Buffalo. And the owner got word because he knew we were looking for the shipments. And he actually told the truck drivers to set the shipments on fire. He wanted to burn the evidence. And in one of the case, the investigator actually had to run into burning broccoli to get a sample because we were out to get this guy because of what he had done. And in New York, we had a couple of samples, and we actually simultaneously [unclear] and spec analysis at the same time. And I'd just never seen this before. It had a hundred times the power [unclear], and when you consider EPA [Environmental Protection Agency] does safety, their safety margin of zero, a hundred- to a thousand-fold, this is the highest I've ever seen it. So we did the analyses and then . . .

I'll never forget. This was going to be my first court case. We were going to court because these were all felony counts. This guy had to fight it because he was going to jail. So I was actually walking up front to get my tickets to fly down to West Palm Beach, Florida, where this came from. And as I was walking up there, Ted Hopes come walking down and says, "They caved in." I was very disappointed. I

had studied already. You have to review the methods and look at your worksheets, and it's a fair amount of work [unclear]. Then you listen to all the war stories people tell you about being up on the stand.

Another thing we did in New York . . .

Tucker: Did you ever, in your career later, ever get on the stand?

Olson: No, never did. But they shipped us to a court case going on in New York. It was about '70. I did hazardous substances work because the Consumer Product Safety Commission split off, oh, I guess '71, '72, somewhere around there. And I started in '69, so FDA did all that work. And it was probably about '70, I think, that we had a fireworks case that was going on in Jersey. And they were taking analysts over about five at a time because there was a lot of analytical stuff being raised about the analysis, and so we just sat in the court. It just gave us a sense of how courts work and everything.

[phone ringing]

Tucker: You said it was [inaudible]?

Olson: Yes, it was a fireworks case. This fellow was selling fireworks through the mail, and some kid bought this little kit, and rather than, why should I make a hundred small firecrackers, let me make one big one, which is, we would call a stick of dynamite, kind of blew his house up,

you know.

So anyway, this guy was under a court order, under an injunction, to not sell fireworks. So what this clown did was, he would take out two ads in, you know, like a comic book. One ad was for fireworks without fuses; the second ad was for fuses for fireworks. So now, back at home, some kid had gone out and bought it, set off basically a stick of dynamite, and the kid blew his leg off.

o now this guy was in for basically violating the injunction. And I don't know if this always happens, but he's before the judge who issued the injunction, so it was kind of interesting. You know, you always think of judges as being very impartial. This judge was pissed off. And you'd have this defense attorney who would stand up and he would go, "But, Your Honor, when you signed the injunction, you meant . . ." and he'd go, "Goddamn it! Don't tell me what I meant! I told you not to sell this stuff and you're selling it." He'd go, "But, Your Honor, you meant . . ." "Goddamn it, don't tell me what I meant!" This guy was something.

He had, it was interesting. The first time I've been in court, really, and there was a woman sitting there with, you know, I thought she was pregnant. Somebody told me, "No, no, she's not. He hired her." He hired some hooker off the street who had a thick old pillow under her tummy.

That was his pregnant wife, so it kind of gives you the idea that this is a bit of a show.

But anyway, we did win. We couldn't lose the case. I mean, this guy was sharp. As a matter of fact, the judge would even turn to the U.S. attorney and say, "Would you like to object?" He would jump up and go, "I object." He'd go, "Sustained." It was quite an experience.

Tucker: And where was that court?

Olson: This court was in Jersey.

Tucker: In New Jersey.

Olson: Yes, northern Jersey.

Tucker: Okay. And this was a circuit court?

Olson: Don't know. I'm not into the [unclear].

Tucker: Okay. It doesn't matter.

All right. Now, let's see. Anything else in New York [unclear] particular?

Olson: Oh, I mean, lots of things, but nothing [unclear] standout things.

Tucker: So then you left New York in approximately 1975. Is that correct?

Olson: Yes.

Tucker: Where did you go next?

Olson: I went to CPSC [Consumer Product Safety Commission]. Well, actually, the Bureau of Foods.

What had happened was, in '74, we were doing some small

survey. I think it was [unclear] esters. And we were looking for [unclear] esters in food products. And it was the first time I ever read a compliance program. There, she gave us the program. Up to that point, I didn't notice [unclear]. And when I read the program, I said to myself, "Gee, I wonder who writes these things."

Tucker: When you were at CFSAN [Center for Food Safety and Applied Nutrition], what division or . . .

Olson: Compliance Programs.

Tucker: Compliance.

Olson: Yes. I actually, I mean, I saw the program. I said, "I'd like to write these things." So I applied for a job writing them, and I got the job.

And it's funny, because one of the hooks I think that got me into CFSAN was, one, I had field experience, and even back then, the Compliance Program groups, they always wanted people with field experience to write these things. And, secondly, Ed Steele was down there. Ed was the Branch Chief. And Ed had come out of New York. Now, he had left New York I think in '68 to go to headquarters. But anyway, at least for him, he could go back and kind of check me out.

So I went in '75, writing compliance programs. That's back when Bob Angelotti was the Director of the Office of Compliance. Henry Roberts was Acting Center Director. My Division Director was Frank Thompson. The Division of

Regulatory Guidance was Taylor M. Quinn [unclear]. And then Ed Steele was the Branch Chief of Compliance Programs. And then they had just broken into sections, and Doug Tolen, I actually worked for Doug Tolen.

They wanted me to come in and evaluate compliance programs, but I kind of held them off for a little while. I was more interested in writing them. So I spent about a year or two writing compliance programs, another couple of years on the evaluation side. That was not terribly . . .

I loved the program work. It was fascinating. I worked very closely with the field. But we fought with EDRO [Executive Director for Regional Operations] all the time. But, again, it was a professional fight, if you know what I mean. The programs actually had a status. People read them; people cared what they said. That's back when the work plan was a big deal. It is again, but without the programs to support it. I mean, it was just an interesting time.

The unit I was in, we were kind of young Turks. We were all young, fresh out of the field, pretty sassy. This, foods back then, with people like Taylor Quinn, was a very powerful Center. Paul Hile was the Associate Commissioner, actually, Regulatory Affairs. And the EDRO, I guess [Don] Healton was the EDRO [Executive Director for Regional Operations].

Tucker: [unclear] first Paul. He was followed by Don Healton.

Olson: Right. And then Paul came back.

It was an interesting time. We actually, we started getting out to the field. We'd [unclear], visit field district and talk our programs and evaluations and what it is we're trying to do, and the field was actually pretty receptive to it. We'd publish evaluations. We tried to do them annually. We were very [unclear]. We had a hard time getting them out annually, but we did them. [unclear] was there now [unclear]. You just keep writing programs year after year.

We actually had an evaluation of process. We terminated some programs that weren't productive.

I guess just some examples. We had, back in the late '70s, the DALs were a big deal, Defect Action Level. I actually wrote my first [unclear] the DAL program.

Tucker: That was during the period of Measure-Act-Measure.

Olson: Yes, super-MAM. Measure-Act-Measure was Measure-Act-Measure, and then retail sampling surveys was another concept. We used Measure-Act-Measure. You'd measure the industry compliance. You took action, measured it again. And then [unclear] retail sampling [unclear], retail sampling survey programs, which looked at the quality

of the product, because, remember, Measure-Act-Measure was really inspectionally based. You go in, you can do an inspection, and you say they're doing good. The question is, is the product acceptable? The best you can say is it should be acceptable, so the retail sampling surveys -- huge amounts of data come out of that.

And the parallel to that was the Defect Action [unclear]. The theory was that you would set up defect -- you go out, you survey products [unclear] work, and you would look at the average. You look at fill flows and you would statistically set it at, if I remember right, it was the 95 percent level. So you would reject 5 percent of the product. And all it was, was the worst 5 percent; nothing absolute about it, just the worst 5 percent. You ran it for a couple of years, you reject the worst 5 percent, then you go out, in theory, you have nothing [unclear] anymore. Then you go out and there was a way to update DALs. And you kept moving that line downward and kept projecting the bottom end [unclear] wanted to stop.

The sampling that was done, the support was statistically designed. There was huge amounts of sampling. But then we reached a point where the Center had so much data, they didn't know what the hell to do with it. So the data was just sitting there, and the scientists were wringing their hands, and rather than deciding what levels

to go back and worry about, was it really three mandibles and two mandibles. It was awful. So eventually we did an evaluation. We told the program manager -- back then they had program managers. We told the program managers that they couldn't run any more DAL programs until they established a DAL.

Taylor Quinn was the . . . He -- Angelotti eventually left as his boss, the Compliance Director. He went to FSIS [Food Safety Inspection Service] about a year later. And then Taylor became the Office of Compliance Director, and Taylor basically was the man running the Center, and it was very good for the field. Taylor came out of the field. He was actually an investigator. He wanted compliance. He wanted to work with the field, and he kind of held the Center in rein. So they were marching forth, heading towards that goal to . . . He did not want, it really annoyed him when lots of data came into the Center and nothing was done with it, because he recognized the high cost of [unclear].

Tucker: As far as the industry is concerned, was there any reaction of the industry to this rather extensive sampling? That's what [unclear] many actions taken?

Olson: Yes. And then there was actually, I mean, there was a basis for this, for setting these levels. [unclear] almost [unclear]. Back in the '60s, even in the

early ‘70s, a lot of things were just numbers. I used to run, oversee, monitor the imports for country certification program, which was a program where we signed agreements with governments and they would attach certificates and import products coming in and [unclear] them. And back then, this concept of automatic retention was growing up. You know, these numbers, back then we had to have ten consecutive lots and 25 percent had to be not violative. They’re still using it today, and I remember the original. I had the original memo setting it up. Angelotti [unclear].

Tucker: In the earlier days -- and I don’t know whether [unclear] time you’re speaking of or not -- in earlier times, the agency was quite discreet and secretive about what their action levels were, and yet at a later time, it got changed. Did you see that change occur? Did [unclear]?

Olson: Yes.

Tucker: That was driven by what?

Olson: The FOI Act, the Freedom of Information Act. I think that was late ‘70s, early -- yes, that probably was about late ‘70s. The FOI Act really opened things up. It says you can’t keep secrets. It was almost immediately [unclear]. When we were writing compliance programs, there were certain things we didn’t have to give out. One was listing [unclear] because that would constitute

notification. Among other things, levels we were looking for, how we're sampling, the manuals, the [unclear] policy [unclear]. They all became public documents. And while it does create [unclear] angst amongst people, there's nothing they could do. And it really just happened overnight. At least in theory, it's a lot more open. I actually saw [unclear] to make it more open, to establish levels, you know, to try and do the right thing.

I'd have to be critical now and say I think we've taken twenty steps backwards. Now everything is case by case. Every, you know, case by case, basically. You've got nothing. So when people come and say, "What are your actual levels case-by-case?" that doesn't mean anything. So it was actually, I think, it's a step way, way back, kind of waiting for the world to kind of revolt against that.

Tucker: During this period, the agency were subjected to quite a bit of congressional oversight. Did that impact on any of the activities you were involved in?

Olson: No. I mean, it may have. Well, in Foods then, it didn't trickle down. I don't remember a lot of talk. And, again, we were the unit that, we had all the information on what was done for the field. Now, that may have happened out of EDRO, but we just, we weren't asked that. We weren't asked to support that thing. I mean, now the hearings [unclear] is astronomical, and these are people

who are going to hearings, and we just wouldn't hear about it. It just wasn't that amount of oversight, you know, going on at the level of oversight where they need all this intricate amount of data. Maybe it was just more [unclear], you know, where the Center Director could actually go up and just talk about the food program and the direction of the food program without having to go over how many [unclear] canned food manufacturers did you do in the last three months and [unclear].

Tucker: When you were there, there were various regulations developed. I think, did you mention the [unclear]?

Olson: No. That was written by Bob Spencer. He actually sat down and wrote. And Bob did this before I got, he did this probably about '73, '74. And, actually, he was the guy that sat down and wrote the regulation. And Doug was very good friends with Bob. He told me that she said it was the best [unclear]. Who would that have been? Who's the big GC down at EPA now?

Tucker: Richard Merrill [sp.]?

Olson: No. Peter Bryan [sp.]. He wrote the best regulation I've ever seen written.

Tucker: Richard Merrill [sp.] is at the University of Virginia.

Olson: Okay, yes. I was thinking of [unclear] school.

Tucker: Yes. [unclear]

Olson: Yes, but he said it was the best he'd ever seen written. [unclear] Bob promoted for doing that [unclear].

But the LACF was about the biggest one. It was a massive effort, too. They were all [unclear] because of the LACF process. They had registration, new registration. They did things under contract. It kind of turned into a bit of a mess, actually, just because there were too many steps to the process in FDA. And people wouldn't, people just kept reviewing things and re-reviewing things.

Tucker: Well, the process [unclear] established before the *Federal Register* announcement, pre-announcement. It was a very defined procedure that . . .

Olson: I'm thinking of the actual process when they send a file [unclear] to FDA, the review process was unbelievable. We had, there was one [unclear]. They had to file the process. We had to review it and figure out, are there any [unclear] in here, and we had that done under contract, the University of Michigan. So they had Food Technology review these things. If they saw questions, Bob [unclear] they sent them back to FDA, and we were supposed to go [unclear]. They had to answer these questions. What was happening was somebody down in Food Technology wouldn't send up the letters until he re-reviewed what the contractor had done and never got around to it. All of a sudden,

[unclear] we were sitting on top of 700 or 800 "deficiencies" from the contractor that no one had ever done anything with.

Tucker: Well, the agency got a lot of [unclear]. I didn't really hear about this. I don't know if it was publicized too much, the regulations of foods lag, but apparently it existed, as you're saying.

Olson: Yes.

Tucker: Why do you suppose that wasn't popularized as much as the drug lag?

Olson: Actually, this was [unclear]. I mean, these were, if you just think about it, these were processes that a contractor had identified as being problematic, could be problematic, and we were sitting [unclear]. What if the company -- and the company had already filed their process. So what if that company produced the product that may have produced botulism and had killed someone, and then come to find out that the companies don't know what they're supposed to do, and we had gotten back a review that says there was a problem with it and done nothing with it? It was actually the worst of all worlds. So I think what happened, it just got fixed as quickly as possible. This is not the kind, this is the kind of [unclear] it would be unbelievable, very [unclear].

That was about the biggest regulatory push I can

remember back then. You know, when you talk about super-MAM, the measure of retail sampling, what's interesting is those were actually driven out of the Office of Planning and Evaluation. Back then, OPE [Office of Planning and Evaluation] was a very strong unit. Jake Barkdoll headed it up. And they did all kinds of evaluations, and they were the ones that actually looked at the MAM, you know, the Measure-Act-Measure concept, things like that.

Nowadays, I don't, I know they still exist because I know people up there, but I'm not quite sure what they're doing. But in the '70s they were a very strong evaluation group [unclear].

Tucker: [unclear] was developing at one point a big plan to plan.

Olson: Yes.

Tucker: So it really got to be quite esoteric.

Olson: I was with Jake Barkdoll on a course somewhere, and he was remarking, somebody asked him how did he get the job as OPE director, and he says, "You're never going to believe this." He said, "I read about it in the newspaper, in the want ads." That's how he got the job [unclear]. He didn't know anybody, he wasn't the brother or husband of somebody. He saw an ad in the want ads and applied and got the job, which may be a first, actually, in the Civil Service, when you think about it.

Tucker: [unclear]

Olson: Yes, yes.

TAPE 2, SIDE A

Tucker: You were mentioning [unclear] the research centers were not supported.

Olson: Yes, but the centers wanted the research in the centers. They didn't see a need for field research centers, and the lab director didn't support it, so they never really had a base anywhere except in [unclear], and our job was to try and make them work, so we had all kinds of planning sessions.

Tucker: How many research centers were developed?

Olson: Seven.

Tucker: And these were strategically across the country?

Olson: Across the country. Most of them on the food area. Never had a drug research center, which was interesting. [unclear] The closest thing was the Sterility Research Group up at MCMI.

But that was interesting. Research was big in the '80s. That was a big function in DFS, reviewing programs was. But back then, the research program, we had [unclear] programs, long-range research, short-term research, all different kinds of research programs. And it was a real Achilles heel because it was a real point of contention with

the Centers. I've always said, at least in the '80s particularly, [unclear] compared to DFI. Why does DFS have so many problems with centers and DFI doesn't? And the answer lies in the fact that the centers don't see themselves as investigators. They've never seen that role, and so they're very happy to turn to DFI and say, "You be the investigator." They see themselves as scientists, and we're scientists, and that's where the basic rub comes in. They see no need, you know, they . . . I mean, they see a need for the field labs, and they want DFS to just simply be the people they can go bitch at when the labs don't do something, and then we can make the labs do it. That's what they really see our role as.

Tucker: Now, the charge to the research centers was generally, as you mentioned, that there were different kinds of programs, but what was the sort of the overall mission as related to the enforcement?

Olson: The overall mission was methods development, long-term methods development, new technologies for methodology, because they had the long-term commitment to hire full-time researchers who did nothing but research. So that was the resource to really get us into different areas.

They were encouraged to actually -- originally, they looked to actually place them in universities. The research centers originally, they looked for space in universities to

make them different. That was the original goal. After a series of changes in management and everything, that turned into a negative: Who do they think they are? They're no better than us. And then they, one of two of them had actually gone so far as to, I think Stroller [sp.] Research Group actually was in a university, and they had to pull them back because . . . And there was this conflicting thing. Well, we want to make them like everybody else, which is really an ORA, that's part of the cloth we wear.

Tucker: And as far as the staffing is concerned, were many of the researcher types kind of recruited from the ranks of the field?

Olson: Not really. And, to be honest, that's not what you wanted. You wanted fresh people coming in straight out of the universities. So it was always a mix. There'd be some people . . . And, to be honest with you, some field people really got into research science and did very well. They just flourished. Others got in there and really didn't flourish. And then we had outside people brought in by the research center directors, and some of them flourished, some of them really weren't that good. So it's a real mixed bag.

Now we're down to like three research centers. Their identities are questionable.

Tucker: Now, you mentioned originally there were seven. Where were those seven located?

Olson: Okay. Let's see, the seven research centers. The Spoke, which is the Seafood Processing Center in Seattle; the Total Diet Research Center in Kansas City; the Elemental Analysis Research Center in Cincinnati; Detroit had the [unclear] Pesticide Research Center; Minneapolis was the Sterly [sp.] Research Center, which became a research group; there was the Afilpot [sp.] Research Center in New Orleans.

Tucker: You have six.

Olson: Yes, I know. There's a seventh one. It eludes me at -- oh, the Animal, yes, the Animal Drug Research Center in Denver.

Tucker: Okay. Now, you just mentioned that currently there are three.

Olson: Yes. Denver still exists; Kansas City still exists.

Tucker: And the third one?

Olson: SPC, Seattle. Those are the only three that are left.

Tucker: What would you attribute that adjustment in size primarily?

Olson: Lab consolidation.

Tucker: The what?

Olson: Lab consolidation.

Tucker: I see, okay.

Olson: We shut down a lot of labs.

Tucker: Right. Well, that's another area that we want to explore. Were you pivotal in the lab consolidation initiative as well?

Olson: You know, I have to answer yes and no. I was not pivotal to designing what we did and see today. In fact, I wasn't here. I was pivotal in implementing it. I admit I'm the driver that terminated it. And that was not the first time we consolidated. I was pivotal with Arvin [sp.] in the '80s. We tried lab consolidation in the '80s, too. People may not remember that, but under Hile.

I actually was pivotal in CFSAN in the very early '80s in starting the micro consolidation which we wanted them to do. That had terminated with the infamous Feldman report. Poor John Feldman. John had this report, and he'd send it around and it talked about reducing the micro labs. And, again, that was, you know, someone's . . . I will admit, I'm the author of that report. And, again, it was done with what we knew at the time in the '80s. In the early '80s, micro programs were going down the tubes. Nothing. And John had gotten a report from CFSAN. I had [unclear] from CFSAN, but it turned into the Feldman report, which I never really argued with. Okay, John. But, actually, it was like about 1980, and I was, we were just doing work planning and everything, and what I was always worried about was, as hard

as it is, as EDRO back then trying to say, "Oh, we put the people where the work is." That really isn't true. We actually had to design programs because the people are there.

And the perfect example was Boston. Boston had one microbiologist, so every year we planned an FTE of micro work in Boston. And I asked a question one day. I said, "When that person leaves, we really wouldn't want to see it get backfilled, because it's crazy having one person. You can't have a one-man micro role. It just doesn't work. And the answer I basically knew was that, since we put the FTE to work there, they would backfill the position. So that kind of initiated a look-see in the micro area. And, again, it was never to reduce the amount of micro work. It was to just reduce the number of labs. So we have bigger programs, more robust programs.

It ended up in the Feldman report. Poor John took a beating over that but did well, became a DD after that. And the field just wasn't into any kind of consolidation.

Then in the mid-'80s, we went at it again, when Hile was here.

Interestingly, a little anecdotal story. When Hile was going to announce what labs were going to close, we walked into the -- he was supposed to announce it the following week. The Friday of the week before, I knew we were going

to probably shut three labs when Hile made the announcement we were shutting five labs. So the question is, what happened over that weekend? And I think a lot of it -- that was the weekend we were in here, we were working on [unclear].

In the '80s, we had just a terrible number of tamperings, and I used to work a lot on the weekends, you know, coming in, trying to handle the science. And that weekend, [unclear] Baltimore lab had people in the laboratory doing some work, and they had a question about an analysis. So [unclear] people would do, they clowned around and decided, let's call the Commissioner.

Well, they called the Commissioner's number, and guess what? He was there, Frank Young. So they asked him a [unclear] sort of question. Frank Young, being very charming -- you know, he was a charming individual, you know -- thank you very much -- and he called Hile, who was in Baltimore that day, who called up the field science. Naturally, I was here. And let's just say he was less than happy.

And I've always been convinced that that little antic cost us two laboratories. I'm really serious.

Tucker: Well, that's an unknown [unclear] the record.

Olson: Anyway, then we tried to close. Anyway, we were going to close five labs, and then all kinds of

congressional things happened. Then that got canned. Then we went from consolidation to -- oh, what's the word? We used this different word when we wanted to consolidate programs, not close labs. Specialization.

Tucker: Specialization.

Olson: And that [unclear] concept, okay, we'll keep the number of labs, but they just -- every lab wanted to do everything. We had seventeen pesticide labs out of twenty-one. So our question was, maybe we only need thirteen labs doing pesticides.

Meanwhile, let me tell you the four labs that didn't do pesticides. Two of them were trying to get into the pesticide program. That was always that dichotomy of you can get your regional directors, you know, then you've got headquarters, and no one truly wanted to oversee the show. So we tried specialization, and that, by then the laboratories had, I guess, felt they had won. They had won. We weren't going to shut them down. They wouldn't, they kind of brought the lab directors together, and I know in one region -- I won't name the region -- but, my God, they got together and their specialization was, well, I'll give you two samples of X and you'll give me three samples of Y.

Tucker: Time-wise, when was that occurring, the specialization?

Olson: Late '80s. But it never really went anywhere

because they were unwilling to . . . It's very difficult to just sit in headquarters and say, "Okay, New York, you'll only do this and that." It really gets into the programs, the size of the programs, the people: What kind of people are they, are they retrainable, where's your instrumentation at, are you old, are you new, are you in the middle of breaking out? I mean, there are so many variables that you really want the lab directors to buy into it because they can make the best decisions.

And then I left in '89, out of field science. And then in the early '90s, they, under Chesemore -- and I still think it was, I've always thought that a lot of it had to do with a lot of people not happy that the . . . If we had closed the [unclear] in the mid-'80s, I think that would have been it, but we closed nothing, and that really didn't sit well with people. So they went in the end of '94 and they made the decision, you know, we've got what we've got today.

Tucker: Probably there were a lot of personnel concerns about all of [unclear] being transferred or being taken away from work that they were comfortable with and so on.

Olson: Yes, very much.

Tucker: Were there resignations or earlier retirements, shall I say, because of some of that?

Olson: Well, yes. When we finally consolidated, yes. The basis for me to conclude we had to stop it was that, in the original study that was done, they had projected that we would retain 75 percent of the people and lose 25, and the reverse happened. We lost 75 percent of the people and retained 25 percent. And that's kind of staggering, it really is, to lose that, those number of people. And back then, the agency was, we were all taking cuts, so it kind of worked out very nicely.

Most of the cuts [unclear] were taken in laboratories. Like we moved, I don't know, Minneapolis to Atlanta. Just as an example, we moved Minneapolis to Atlanta, and Minneapolis had forty people, and at the same time we're taking cuts, and thirty of them retired, ten people went to Atlanta. We didn't hire thirty new people in Atlanta. So that's what kind of happened.

And I'm not saying that's bad. I mean, we didn't need that many hours. Who knows?

Tucker: There were probably -- and I think we touched on it earlier-- some members of Congress who went to bat to retain so many [unclear] location in their district.

Olson: Yes. I mean, that's a [unclear]. I don't even know -- as an agency, I don't even know how you deal with that. We want to close the facility because we don't need it, and he says, "No, don't close it because it's in my

district." Well, since everybody's facility is in everybody's, is in someone's district, you end up with nothing happens, status quo. So then what do you do? You just close the facility in the districts that have the newest congressmen because they're the least powerful? That's not the way to run the ship.

Tucker: Right.

Olson: So that's just an awful -- for them to step in and what happens as far as, just was silly. I mean, they're proud and their congressman is proud of it. I think he's crazy.

Tucker: Of course, there was a period when there was quite a growth in the numbers of new or updated laboratories.

Olson: That was recent.

Tucker: Yes, that's recent.

Olson: That was part of the price to all the . . . The thing that drove, well, the reason they gave that drove a lot of the -- and part of it is true, actually -- was the [unclear] buildings had all been built in the '50s and '60s, the labs, and by the 1990s they were getting old, so we were looking at replacing a huge number of labs, which they felt the money wasn't there to build all these new lab facilities. So we consolidated and built a new lab in New York; Atlanta's always been where it is; a new lab in

Arkansas; a new lab in L.A.; and Seattle had moved, had been updated in the ‘80s. Denver is older but ‘80s vintage. Kansas City is [unclear]. Detroit right now is new. Cincinnati has been there since the beginning but it has managed to keep that lab in really nice shape. [unclear] was an old lab but still, but still going through a lot of renovation. They actually had a hurricane down there in the mid-‘80s. It took the roof off, so they got all new equipment and everything, so they’re really [unclear]. And in the last month, [unclear], which is very old, and we’re looking to replace that.

Tucker: Now, the laboratory at Little Rock, what involvement did you have, did the Division of Science have with that lab? Was that sort of a separate entity from the other laboratories?

Olson: Yes. It was just, to put a lab there was a purely political decision. I wasn’t here. I’d heard the reason basically is that Kessler wanted to put something in Arkansas because Bill Clinton’s [unclear], Bill Clinton kept Kessler on as Commissioner. He wanted to give him something. So [unclear] said, “We’ll put a regional lab there.” It is a [unclear] lab.

I talked to, actually, Jim McGregor. He was, who was in NCTR [National Center for Toxicological Research]. I always ask Jim -- Jim was the head of the Washington office

here. And I asked him, did he think having NCTR where it is in Arkansas hurt its ability to [unclear] to recruit people, and so on? No reason to think we're not going to. We're getting people down there. It's just, to a city slicker like me, it's, you know, I just couldn't even handle [unclear]. But those people who grow up, you know, who like that -- it's not good or bad, just different, but you really don't get a . . .

Tucker: Now, you mentioned the National Center for Toxicological Research, which is the one we're talking about. What are some of the current missions and initiatives there?

Olson: You know, they're really there to do toxicology testing for the agency. Interesting fact about that is only about half of the Center is funded through FDA. The rest, they have to go out and peddle their wares. So they go out and sell themselves. So half the work they're doing is just for money. I have always thought they could do a lot fof FDA.

Back at CFSAN, when I was in there in the late '70s, GLPs had first hit -- [unclear] had a GLP inspection [unclear] flunked, and back then we were doing a lot of animal testing at CFSAN, and Ed Steele headed up a group to try and figure out, well, how are we going to fix it? And if you remember, at that time CFSAN got a new building, and

everybody kept saying, "We can't do animal testing at FDA. We can't do animal testing at FDA. We need a new building," which was the Beltsville facility. But I told them, I always used to say, "Why don't you just do out in NCTR? That's what it's there for." And the answer we'd get is, "Shhh. Don't say that."

I think it just would take, to get NCTR into the loop to do the tox testing would just take a very powerful Commissioner to say to the Center directors, you know, [unclear]. I think they're well equipped to do it. But without a strong Commissioner, the Center, they're not going to give up those programs.

Tucker: Well, as you've worked through quite a number of years for the agency, you've seen different management changes at the top. Are there any that you would comment on, as a scientist, as being particularly helpful in your field or maybe less so?

Olson: Yes. Without assigning management, you know, managers, I've seen some good ones and I've seen some absolutely horrible ones. I've seen people rise to a level that's just breathtaking. But I think there's kind of been an erosion of the concept of management over time, management and leadership. Leadership has almost fallen by the wayside. People, you see people who someone will say, "Oh, he'd be a good leader because they're good doers."

Doing something and leadership are two different things. And then there's an overall change in management styles.

When I started, it was very [unclear] I'll call it autocratic. And there were people who were very good. And the thing about autocrats is that they're very talented. It's a very efficient [unclear], it really is. And a lot of them, could they actually nurture people? Now it's more the [unclear] kumbayah. You know, kumbayah down the river. Let's all sing kumbayah. Is everybody happy? Is everybody [unclear]? And people [unclear] there's many idea out there. Some of these ideas are just blah, and no one [unclear]. So if you get a group of people together and you're trying to come up with a consensus opinion, you're going to have people there floating their opinion, and they're just blah. And [unclear] blah. The question is, do you let the wrong stuff affect the actual decision, and nowadays the answer is yes. It really is. That's always been a hard thing for me to accept.

Tucker: The agency has often been publicized [unclear] as a science-based agency, so based on what you just said, do you see that that is becoming less of a factor in the [unclear] of the agency than in past times?

Olson: Yes, yes, yes, because the real autocrats, the real autocrats actually listen to the science and did their best to [unclear]. Now, without that, without that real

leadership, on any given day, oh, you'll get a heavy-duty science-based decision followed by a heavy-duty political decision, followed by a heavy-duty personal decision, you know. They go [unclear]. It is hard for people to operate in that kind of environment. But you kind of have to put up with it. I think it [unclear]. They just kind of hunker down. It's not good to have everybody hunkering down.

Another big deal is the e-mail, this whole electronic e-mail system. I mean, one side is you can convey so much information, but the other side of it is just absolute overload, and you're creating a whole band of people in management positions who do nothing but file e-mail. There's no value added. I see it at all levels. And you [unclear] do that more so than in the days [unclear] because you just tend to not write that many memos. When you wrote a memo, it was something profound. Now, you should see the stuff that goes across in e-mails now. It's ludicrous. And it's going to affect things more and more, I think. Ten years from now, I can't imagine what it'll look like. But e-mail has actually affected the people working here [unclear]. That'll be their [unclear].

Tucker: [unclear] I came into FDA in 1962, and I used to sit at a typewriter once in a while [unclear] I was castigated for doing that and said, "Do you want to be reclassified as a GS-3?" Now it's interesting that at the

very top level, they have a keyboard for a computer, and that stigma doesn't cling to you if you use it.

Olson: But it's also created a, because it's so fast, everything is coming with zero turnaround. So, there's very little thinking going on to get something. If I don't respond to an e-mail in half an hour, what's wrong? I say, "I'm thinking about it." "What are you, nuts? Crazy?" But it really creates a whole, a whole thing of [unclear].

Tucker: Well, it's affected all of society in ways like that, so I guess one couldn't expect it would not invade government in administrative matters, scientific matters as well.

Olson: Yes. It really has. And I think it's, I mean, people are looking at the surface, but you've got to say to yourself, what is it really doing to the employees? [unclear]. What are they going to look like? What are they going to say? What do they think the values are? [unclear] simply push e-mails around [unclear]. People [unclear]. What you're really telling the staff is that [unclear] been cloned, so you've got to be careful, you know. [unclear].

Tucker: Well, you're going to be retiring in the next few days. Was there any particular thing that caused you to decide to retire at this time?

Olson: You know, it's funny. I remember people asking that because there are people who can retire, but I

[unclear]. And everybody does it differently. But what I found is you just, you begin to reach a point where, once you reach your retirable age, it's kind of a concept: Oh, I can retire. The infamous [unclear]. Oh, I can retire; oh, I can retire. Then if you go down, you begin to all of a sudden subtly say, "Hmm, maybe I should go next year." And then you begin -- and that's what I did. You pick a year. Then [unclear], you start thinking about dates in the year, and you pick a date. And then, as you approach it, if you're not ready, you'll find yourself pushing it back, and that's actually the way I -- I was actually thinking of January of 2005. So I said to myself, "Why would I retire in the dead of winter?"

Tucker: That's an important factor. [unclear] my associates who've retired and been extremely frustrated and unhappy because they were kind of [unclear] until . . .

Olson: Yes, exactly. So I said to myself, I can either push it back or forward, and I said I'd had enough, so I kind of, you know, I said, "Maybe I'll go in November of '04." And then [unclear] end of October; and then it was July. I think I was up to June. [unclear] take it easy now because he's going to retire tomorrow. So I kind of picked the summer and then the middle of summer.

Tucker: Do you envision continuing to be active in your field of science [unclear]?

Olson: Yes, for a while, for about . . . If I had to guess, maybe four years, do some consulting work. Following that, I'm an amateur archeologist, I'm also kind of [unclear] coin dealer, so I [unclear] selling coins. I'm a do-it-yourselfer [unclear] penultimate, work on old cars, you know, lots of things that you can do.

Tucker: I guess this kind of brings us to the end of our interview. I want to thank you very much for sharing your career experiences with us.

END OF INTERVIEW