

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

**Interviewee:** Janice F. Oliver

**Interviewer:** Suzanne W. Junod, Ph.D.  
Robert A. Tucker

**Date:** July 28, 2009

**Place:** Rockville, MD

## INTRODUCTION

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

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GENERAL TOPIC OF INTERVIEW: History of the Food and Drug Administration

DATE: July 28, 2009

PLACE: Rockville, MD

LENGTH: 90 Minutes

INTERVIEWEE:

INTERVIEWER(S):

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FDA SERVICE DATES:

FROM: May 28, 1968

TO: August 1, 2009

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Interview with Janice Oliver

July 28, 2009

TAPE 1, SIDE A

RT: This is another in the series of FDA oral history interviews. Today, July 28<sup>th</sup>, we're interviewing Janice Oliver, Deputy Director for Operations, Center for Food Safety and Nutrition. The interview is taking place in the Parklawn Building in Rockville. Participating in the interview is Dr. Suzanne Junod and Robert Tucker of the FDA History Office.

As we begin, Janice, would you give us a brief overview of your personal and educational background, and we can then move into your FDA career, hopefully tracing it from when you began through your increasing areas of responsibility up to the present time.

With that introduction, we'll let you start.

JO: Okay. I was born and raised in Wilkes-Barre, Pennsylvania. I attended Wilkes College there, which later became Wilkes University. I majored in biology, minored in chemistry.

I was interviewed by an FDA investigator when I was a senior in college. He was interviewing for new employees for FDA's Philadelphia District. I thought FDA would be an interesting place to work as an investigator. I thought I would work for FDA for

five and here I am 41-plus years later. I was hired and started in Philadelphia as an investigator.

RT: What year was that, Janice?

JO: May of 1968.

I grew up in a family with four brothers and never thought to ask how many women investigators were working for FDA at that time. Two other women from Wilkes College, who were friends of mine, and I started in Philadelphia only to find out there were few women investigators at that time. The investigation field wasn't thought to be for women and some didn't think that we'd make it. However, most everyone was great and very helpful. It was a great place to work.

There were eight newly hired investigators in Philadelphia at the time I started. We all became good friends. I'm the only one that stayed longer than five years in FDA.

SJ: Did you know Imogene Gollinger? Was she one of the group of new hires?

JO: Imogene was from New York.

SJ: That's what I thought. She was in a different position, and I didn't know if you actually knew her.

JO: Yes, I did know her but not well. She was in New York.

RT: I was just going to ask, was that the first hiring of women for investigational work?

JO: There were maybe three or four other women in the country before that. In 1968-1970, Philadelphia had more female investigators than any other district. In addition, several female investigators transferred later to Philadelphia District as specialists.

Being an FDA investigator was a great career. We all started out in training. At that time, all investigators started out in food work. You basically did warehouse investigations, and a lot of work on the docks so that you learned how to document evidence, how to collect samples and build a case. We inspected many warehouses and food processors as well as import work, and had a lot of fun. I got my car stuck in a snowstorm, and police cars helped shove me out of the way, and then they got stuck. I can still see the three police cars as they pushed me on my way and they waited for a tow truck.

RT: I'm trying to recall -- was that in the era of Project Hire?

JO: No. It was pre-Project Hire. Project Hire came in 1972.

When I got hired, there was no Consumer Product Safety Commission. FDA did all the hazardous substances work including investigations into injuries from paint, and injuries from fireworks. One of my most memorable investigations was when half a dozen children in Chester, Pennsylvania, were injured from fireworks, which some



teenagers had bought. The teenagers left the fireworks under a tree, and these little kids lit it and got badly burnt and ended up at the Boston Burn Center. It was really a tragedy. I can see those little kids and I can remember it as if it's today, and that was in 1970.

SJ: When they hired you, did they make it clear the kinds of work you'd be doing?

JO: They said you had to be able to lift 45 pounds, that you'd be doing inspections, you'd be at the dock doing samples, you'd be inspecting warehouses. They said you'd be doing investigations, consumer complaints and all.

SJ: So you weren't terribly surprised at the work.

JO: No. But it was a lot more varied than I thought, a lot more fun. It was a job you continued to learn new things every day. You learned how to conduct investigations. We learned about fireworks, toys, injuries from toys, paint production, chemicals, food processing, investigations into foodborne illnesses, etc. We met people in all walks of life and types of homes.

I remember I did an investigation into a lead poisoning. A little boy had gotten severe lead poisoning, and they thought at first maybe it was his father who had poisoned him, but it wasn't. It was from storing grape juice and apple juice in pottery that ended up being contaminated with high levels of lead. And it was good pottery.

You know how there are certain things that you remember? I remember -- this might not be what you want to talk about. Oh, it is? Okay.

I remember another investigation where the rodenticide manufacturer actually impregnated little cookies with rodenticide, and several kids ate it. It was with thallium, and they lost their hair and became very sick, the poison in little vanilla cookies, and then . . .

SJ: Why did he do that?

JO: Because he thought it would attract rodents. I mean, he just had no idea.

A lot of regulations have really changed in the past 40 years. And a lot of the local ordinances have changed.

SJ: When was that roughly that they . . .

JO: That was in the 1969-1970.

SJ: It's really late for that.

JO: Yes. Then the mother wrapped the rest of the cookies up in foil, put them on top of the refrigerator because she didn't realize their contaminated condition. She put them there, and another child ate them. It was really, really sad.

There's been lots and lots of changes in FDA since 1968. We had no device regulations. They came later. Good manufacturing practice regulations for foods changed in the 1980s, but we had no low-acid canned-food regulations, and I clearly

remember cases of illness from mushrooms. Philadelphia was, I call it the mushroom capital of the world because you had so many mushroom canneries around the Kennett Square area. As a backup to concerns of botulism in mushrooms, we worked long hours, till two o'clock, three o'clock in the morning, many of us in the office, getting things ready, getting the assignments. People worked days, nights, and weekends going out after those cans and inspecting them.

Then there was the Bon Vivant vichyssoise soup problem, where you had the two people in New Jersey who became very ill eating cans of vichyssoise. They developed botulism and had paralysis. After that, when the low-acid canned-food regulations were developed, there were no botulism outbreaks for 30 years related to commercial canning. All the ones that we had seen were really related to home canning.

There were a lot of changes, a lot of work. And people were very, very dedicated, and they still are.

One thing I'd say throughout my entire career. The folks in FDA are dedicated to the mission and will do whatever it takes to, for food safety, for product safety, whatever it is, working days, nights, weekends, or whatever.

RT: That's true. I worked in a state health department prior to my FDA career and used to work with FDA personnel. They had a lot of canning in the Midwest, which is where I was located. And those FDAers would go out at midnight or two o'clock in the morning to see if operations were being conducted less carefully than day-shift hours, like watering of tomato juice and so on. I had a great admiration for that very element you're speaking of, much dedication and commitment on the part of FDA's field staff.

JO: Right. And the investigators go out and went out at two o'clock in the morning, when the plants were beginning to open, or at three o'clock, so that they see how the cleanup was done and how the start was done and that's done throughout the agency's history. I think people don't appreciate all the work that a lot of FDAers do. But it's, you know, they're dedicated people.

As an investigator, I was able to go to the University of Wisconsin, to a course for three weeks in microbiology. You could learn all you wanted. The professors were there, etc., and then there were FDA investigators and others who taught you.

I went to Basic Drug School in Rhode Island for three or four weeks, and became a drug inspector in Philadelphia. Philadelphia was a great, great district for drug inspections. So I inspected these firms.

There were many drug specialists in Philadelphia District in 1968-69, an era when the investigators had to transfer to get a GS-12; there were probably half a dozen investigators who had just transferred into Philadelphia from other districts in the country to become drug specialists; it was great to have them there, to learn from them, and to go out on inspections with them.

I went to Advanced Drug School to learn physiology and pharmacology at the University of Pittsburgh. We had a lot of opportunities to take epidemiology courses, which I was able to do. You had opportunities to learn on your own, too.

I remember one of the supervisors that I had said if you start as an investigator and you spend at least 15 minutes extra per day reading on related science or investigational techniques, you will do well. People took that to heart and did that extra

reading so that they learned more about things for the future. There are a lot of good people, good, dedicated people in FDA inspecting food, drug, device, and cosmetic establishments.

RT: It was probably also during that time when transfers were mandatory for promotions that gave broad experience milling in the north and northwest and the pharmaceutical industry and so on, so that a well-rounded career person really got a broad exposure to a lot of different industries.

JO: Right. I think, in my mind, that the agency has lost something by individuals not being able to get transfers and that broad experience from different locations.

When I was in Philadelphia first, I did not think that going to another district would give you that much, because when you don't have the experience, you can be blind to new possibilities. Having been in Boston, Baltimore, New York, and Orlando, I learned a lot and learned that I had been narrow-minded not to see the benefits of experience in different districts.

Industry is a bit different. The people in the areas are still Americans, but slightly different, and you learn a little more about those industries and about how things can be done differently, so you can take the better and gain additional insights. So, I think in the long run, by not moving around, one is disadvantaged.

And there's reasons for not making the changes and not risking the economics of moving around since you also have two-income families nowadays. You didn't have that as much before because many who got transferred at that time had wives who did not

work a lot outside the home. It's become basically two-income families, harder to have those transfers happen and for people to do that. But you lose something by not doing it. It is that broader experience. You get a wealth of knowledge from other locations. You get a lot of experience if you're willing to listen.

RT: Well, at one time I think, in the administrative level of FDA, sometimes inspectors were told, "Your next check will be in Seattle," or wherever, and that put a lot of pressure on families.

JO: Yes, it did.

RT: When I was in Indiana, one young FDA inspector left the agency because he was sent out on a two-week road trip about the time his wife was due to have their first child. The district director was a bachelor and didn't have too much empathy for those things. That was bad for the morale of a lot of younger inspectors.

JO: Right. Well, I think today FDA management is much more family-friendly. The agency is certainly much more family-friendly. And now you have some work-at-home privileges. Investigators can't investigate from home but they could write reports and prepare for inspections. I think that's very helpful for the family and the individual and the agency. In some instances one could get a lot more done at home than in the office by being in a quiet area and concentrating.

But in terms of men and women, it's really interesting. Now, if you look across the country at the ORA organization, it's probably half women. I don't know the exact statistics, but there certainly are a large proportion of women investigators and managers. I was the first female supervisory investigator. I had transferred from Philadelphia to Boston District as a GS-12 and had applied for a supervisory job. I was selected as supervisory investigator three weeks after I got to Boston; then I was fortunate enough to become a Deputy Director for the Investigations Branch. Later, I applied for the Director of Investigation job in Baltimore District and got that, so I was the first female supervisory Director, Investigations Branch.

RT: How long were you with FDA before you reached that level?

JO: I was with FDA eight years before I became a supervisory investigator; I became the Director, Investigations Branch, in 1979, so that was 11 years later. Some said, "Well, you got it because you're a woman," or maybe you got it because whatever. But when you're the first one, that's what people may say.

But I worked with a great group of people in Baltimore District. All the supervisors there were men. It was an interesting experience. I learned a lot from all of them and truly enjoyed working with them.

SJ: Do you have any memorable supervisors that influenced you when you were . . .

JO: Oh, yes. Bob Bartz. When I first joined FDAS, Bob Bartz was my supervisor.

He was a wonderful person. He taught. We went on road trips with supervisors then. He was a great investigator himself. He was very calm. He used to always tell me how I wasn't politically sensitive and I needed to be more politically sensitive to my supervisors, because I spoke my mind a little too much. He was right. He was a wonderful supervisor and person.

Joe Phillips was another of my supervisors in Philadelphia District. He mainly was a drug specialist. He grew up in Philadelphia District and he really taught me how to do drug investigations as well as how to be a better trainer and coworker. He also was a great person, great family man, and also told me how I needed to be more politically sensitive and watch what I was saying. He was also right.

I was the Federal Women's Program coordinator in Philadelphia District. There weren't very many women in the agency, and so we had a lot of meetings to promote awareness and fairness. I worked with others on EEO issues. That really exposed me to personnel procedures that I wouldn't have had otherwise, which really came in handy later on in my career. I met a lot of different people through that, and valued their friendship.

RT: Well, probably some at least reasonable degree of assertiveness was an asset. We've interviewed other women who have achieved high positions in the agency who have along the line been criticized or commented on by somebody that they were very zealous. But that served them and the agency well. You need to be a little bit assertive, women probably more than men at that time.



JO: Yes. Well, they were right. There were some things I was saying that could have been said a little differently. I was lucky to have supervisors who coached me how I could have said things differently, how I could have done things differently, and did it in a very nice way. They were very good. Joe just died a couple of years ago. And I knew his family well.

I knew Bob Bartz's family and knew the kids and I knew Bob. Bob Bartz built his own boat from scratch and later went to New Orleans. He later got cancer and died. But he was a great, great person.

Philadelphia was a lot of fun.

FDA is like a family; each district is especially like a family. We had Christmas parties. We had all kinds of office celebrations, like after the mushroom crisis or after something like that, we would always do some type of a celebration to wind down. So people would have a lot of fun together and remember those times. It helped to get through the long hours that there was much camaraderie such as Christmas parties where everyone brought their families. We were always doing the Mummer strut, as that was in Philadelphia.

But it was a great time, too, because it got you to socialize with a lot of people.

Jim Nakada always had a Christmas party. He was the Director, Investigations, and every year he would have a Christmas party that he and his wife cooked everything for. It was wonderful. It was like an open-house buffet for the whole Investigations Branch.

SJ: Now, I have this theory -- and it just is theory; I'm still having to collect evidence, or counter-evidence, for that matter -- but I have this idea that when women came into FDA, that in some respects the nature of the work changed. And part of that was CPSC (Consumer Product Safety Commission) work. Ellen Morrison talked about being employed in a bra factory because it was ruled a device, things like that. To what extent do you think women were either influenced by changes in the agency, mandated missions, because, etc., and to what extent do you think they transformed the kind of work that the agency took on?

JO: Let me go through a couple of things.

One, when I came into the agency, there were just a few women, and the work had not changed at that time. We did a lot of heavy lifting. I was very strong at that time -- not now, but I'll tell you, I could cart those bags, throw those hundred-pound bags over my shoulders, do all that kind of stuff, because we did. Some women didn't want to do that and didn't. But I grew up with four brothers, so I was probably kind of a tomboy and used to doing that kind of stuff anyhow.

But I think that the Consumer Product Safety issues that the agency split off to the Consumer Product Safety Commission brought some of the investigators, some of the people with FDA went there. And I would say that more of the heavy lifting and all stayed with FDA than left.

But afterwards, we had the blood bank regulations, and for some reason more women performed more blood bank inspections.

The device industry came into vogue about 10-20 years into my career. I would say more devices were being used in medical treatments and then we had the device regulations. So that gave FDA another specialty area. Then Radiation Safety transferred into FDA. All of that came from HHS. And in 1969, the Public Health Service transferred from HHS (then HEW) the shellfish, food service, and milk state cooperative programs to FDA.

When I transferred to Boston, I went on this huge ocean liner under construction, a liquid natural gas ship, that FDA actually inspected. It was the middle of winter. Wind was blowing, and I'm walking on this little plank behind Walter McPartland, the Interstate Transportation Specialist, as he's showing me what he inspects.

I don't think the women changed the work. I think work changed with the times. I think that sometimes there were different ways of doing things so that a lot of things like HACCP (Hazard Analysis of Critical Control Points), there was a lot more record inspections that came along later. Drug inspections, drug GMP's, some of that changed.

SJ: And did you see -- I wouldn't say disproportionate, but did you see a number of women moving into those less-visible jobs? Or was it just a general move?

JO: There was a general movement of more women into the agency. I did not see women just taking less-visible jobs. Change takes time. I think in the blood bank area, for whatever reason, you had more women investigators than men. There were probably just as many women in the foods area as in other areas. ORA has changed -- now there are a significant proportion of women in the workforce.

SJ: Right.

When you did blood banking, was that one of the first biologics activities that the agency undertook?

JO: Yes. Originally blood banks were inspected by the Center for Biologics, and then the field began doing inspections of blood banks, so that when I was doing the blood bank inspections, we were generally and initially doing them with some from the Center from Biologics; then we were able to do them on our own.

Interesting, those who came from the Center for Biologics to do inspections and audits on biologics were all women. So there could have been a disproportionate number of women versus men in that area.

RT: When Biologics came in, weren't the people who had come with that group somewhat more education oriented than enforcement?

JO: Oh, they were, yes. They were very education and science oriented. They were very much, as they called it, science oriented as opposed to enforcement oriented. They did inspections a little differently than the traditional FDA way. Biologics took a long time to become mainstream within FDA.

SJ: Did that have something to do with the creation of the Team Biologics?

JO: Team Biologics helped that become much more mainstream in FDA, but that happened after many years.

SJ: I was told at one point that the only time they had ever seen Mary Pendergast extremely, more than extremely upset had to do with biologics, because she said it was about time that they learned what FDA did in inspections and went about conforming and bringing enforcement actions and things like that.

JO: The Center for Biologics had a primary focus on vaccines, the development of the vaccines, how they were manufactured, etc. You had some of the same firms manufacturing drugs, and yet the investigators would inspect the rest of the firms for the drugs but not be allowed to inspect the biologics section. The biologics part of that firm would be inspected by the Center, folks from the Center for Biologics as opposed to the field. At that time, the field wasn't necessarily even notified that the Center was going to be in the firm; it took a while to merge biologics inspections into the agency and get the field properly trained. FDA investigators in the field are trained properly . . .

SJ: Are trained, yes.

JO: Yes, to do that.

SJ: Team Biologics was more of a transition or a bridge.

JO: Right, but it's still there, yes, it's still there.

But the blood bank inspections, too, initially were all as a team. They were alone by Biologics, then there was a team with Biologics and the field, then the inspections were done by the field themselves.

The AIDS epidemic really put a focus on blood bank investigations: more training and more frequent inspection.

#### TAPE 1, SIDE B

JO: 9/11 also had a significant impact on FDA and CFSAN. Bob Brackett came on board in CFSAN during Joe Levitt's tenure as Center Director. We were looking at the idea of whether any of the terrorist organizations could affect the food supply. We looked at what was happening around the world, and at organizations of Osama bin Laden and others to see if any of their training have related to food materials, or foods per se. Bob Brackett became the lead with a focus on foods.

At that time, we took on and did an analysis of the food supply, working with the military and the methods they had to see where the vulnerabilities were, and created a staff which Dr. Brackett headed up at that time which really looked at counterterrorism, the vulnerabilities of the food supply, and developed methods to analyze for the various agents in foods.

Then the anthrax incident happened, which created much concern about "white powders." Well, in the food supply, flour, sugar, powdered sugar -- there are lots of

things that look like white powder. In many different places at the time, you had state labs and various labs analyzing all kinds of powders to see if it was anthrax because of the anthrax situation and white powder. A lot was done by the CDC. But then you needed the ability of the foods labs because the foods labs are familiar with food matrices and how to analyze foods.

For a while there was quite a bit of effort diverted from the regular traditional food safety into reviewing what might be done, making sure that there was preparedness in the country for the food supply, establishing systems of communication, etc.

Then the Bioterrorism Act was passed. Before that, food manufacturers did not have to register with FDA. They may have registered to be licensed in a state, but not with FDA. That was the first time food facilities had to register with us, provide us the names of responsible individuals, provide us how to contact responsible individuals if there was some type of an emergency.

It was also the first time where we required prior notice from folks who were importing into this country.

SJ: It required a lot of computer expertise that was a long time coming.

JO: Right.

SJ: A painful process with a lot of wasted resources but a lot of misbegotten effort, at least early on.

JO: Right. Well, in the registration system, too, we're still trying to fix some of the problems, issues that were found out later that we could use now for food safety. Also, FDA had to work more closely with Customs and Border Patrol. All of that effort took away from traditional and food safety regulations, which we were prepared to do for the Food Safety Initiative, like the egg rule. Without additional resources, it was hard to do the other food safety work that had been planned.

RT: This prior notice was to Customs or to both?

JO: It ends up being both.

ORA has a Prior Notice Center. That is the one that gets notified. But it's also using the Customs infrastructure.

SJ: So all the computer systems had to be compatible.

JO: Right.

SJ: And that was -- I lived through that. That was very painful.

JO: Yes, it was. But it did happen. But there's a lot that happened. Around the same time, you know, the Department of Homeland Security got established in there, and Customs transferred. So Customs, at the same time, was trying to be incorporated into



that broader organization as we were trying to work with Customs. There was a lot going on in the country as a follow-up to 9/11 as to where our vulnerabilities might be, and how to guard against attack.

SJ: Some of it, I understand, has to do with immigration as well, because there was particular concerns that these industries were more vulnerable to terrorists because traditionally we allowed so much immigrant labor, and so, with all the immigrants coming into the country . . .

JO: I wouldn't say that was the primary issue.

SJ: But that was Homeland Security, one of Homeland Security . . . We weren't, obviously, as concerned about that as Homeland Security was.

JO: Yes, yes. I mean, but there were a lot of different issues that came about as a result of 9/11 as to where should FDA focus, where Customs and Homeland Security should focus, etc.

SJ: Talk about David Acheson and his place and role when he came in.

JO: David Acheson came into the Center from FSIS (Food Safety and Inspection Service), USDA. He was a physician there. He hired into the Center as a Senior Medical Officer; we needed more attention to the medical outbreaks and illnesses happening in

microbiological and nutrition areas. We had some medical officers, but we felt we really needed more and needed a leader.

He had an expertise in *E. coli*, having done research himself studying *E. coli*. Obviously, *E. coli* 0157:H7 was a huge issue, first in USDA with the Jack-in-the-Box outbreak, and then FDA had the juice outbreak where children were getting sick with HUS (hemolytic-uremic syndrome), etc.

He later became the director of our Food Safety Initiative staff, after Bob Brackett, and the Center lead for counterterrorism following 9/11. Bob Brackett became Center Director, David Acheson became the Director of the counterterrorism staff.

David also was a natural spokesperson, a natural for the television. I always said to him he could do nationwide news because he just was an excellent spokesperson, could take the information and put it out so people could understand it. He looked well on the television, had a presence about him, was credible, had the medical credentials, and was an excellent spokesperson for the Center for outbreaks.

I led a lot of the outbreaks investigations before as a senior management official. I transferred them to David once he was in that role. He became the lead for follow-up on outbreaks as well as our spokesperson for the press.

The bioterrorism section in the Center also reported to David. He worked with the other agencies, states, the White House, and with the industry in setting up a method of communication so that if there was some type of an emergency, that communication would be set up. He was very instrumental in developing a better communication process for emergencies with industry and other agencies.

Then he was asked by Dr. (Andrew) Von Eschenbach (FDA Commissioner) to be a senior food official for the agency. He led the development of the Food Protection Plan and led coordination across the agency for outbreaks, and continued being the spokesperson for major outbreaks.

RT: You, of course, took the position of Deputy Director for Operations. Would you care to cover some of the activities which that entailed?

JO: Yes. I was Deputy Director for Systems and Support first. Then I was Deputy Director, just the single Deputy Director under Joe Levitt for the whole Center. When Mike Landa came to CFSAN, we split up the deputy position again. He was Deputy Director for Regulatory Affairs, and I was Deputy Director for Operations.

I'd say that in the time in the Center since I was Deputy Director, the two things that were the biggest that I really had a lead on, besides day-to-day operations, were the Food Safety Initiative, which I led, and really helped draft the whole initiative, the budget for the initiative, the Food Safety Initiative Report, the founding of [foodsafety.gov](http://foodsafety.gov), the founding of the Food Safety Partnership, and doing that.

And then, in 9/11, post that time, I had initially developed the focus on counterterrorism for the Center, where we were going in the BT [bioterrorism]. This became more important and needed an office focus. I basically did a lot of the day-to-day management in the Center. I generally managed what was happening in the offices, the development of regulations and that type of thing.

RT: You were in direct communication with field operations as well. Is that correct?

JO: Yes, yes, yes. I worked with field operations as well.

The Office in the Center that works with the field operations is, was our Division of Regulatory Guidance before the reorganization, then our Office of Compliance, then it was our Office of Field Programs. Now it's back to being our Office of Compliance. That office is the one which traditionally works with the field. They work with the Field Food Committee. I was very active with the Field Food Committee up until the past few years.

Fifty percent of the field resources are in foods. And so a large portion of our resources and what needs to be done has to be done through the field and with the field.

RT: You were working with ORA?

JO: Right.

RT: Closely, I guess.

JO: Right, right. CFSAN needs to work closely with ORA. We need to work more closely together and to have more of a single program. But I think a lot of that has, you know, happened and it's a good working relationship. Now I think with the global food supply, we need to work better and differently. I think as time goes on, technology

changes and the world changes. There have to be different working relationships, and I think we're at a point of doing that again.

SJ: Are there particular training -- I mean, how best do you pursue, just based on your many, many years of working in both fields, is it education, is it cross-training?

JO: Pursue what, working together with ORA?

SJ: Yes, enhancing the cooperation between the sectors.

JO: My personal opinion now, after many years, is that there has to be more collocation, that ORA is an organization here, CFSAN is an organization here; having two stovepipes doesn't quite do it. There has to be more of a working together, that the managers have to participate in each other's management. You need a foods program management as opposed to a Center for Food Safety and as opposed to ORA.

I think because of changes, the globalization, the science, the things that happened with melamine, new technologies, the new emerging pathogens that you have -- I think because of all of that, there has to be a closer working relationship between the two. In these past few years, I've gotten to the point of saying there has to be -- at first I thought maybe liaisons. First I thought, well, working together more, we have communicated more, we have periodic meetings. I met weekly with the deputy for several years. That in itself doesn't do it. There's just too much going on in the world and too many things changing to have that knowledge, so I think there has to be a bridge somehow where

we're both collocated, where some of us are collocated beyond the liaison, not where the field . . . Maybe some of us in the field, maybe more exchanges, maybe some, more fields going into a laboratory or field methodologies and back and forth. I don't think it can work as efficiently otherwise.

RT: At the chief executive level of the agency, the Commissioner's Office, you've probably seen changes there that are dramatic over the rather long tenure of your career. Are there any commissioners who come to mind that were particularly interested in food vis-a-vis all the other responsibilities?

JO: Well, in the foods area, Dr. (Frank) Young was interested, Dr. (David) Kessler was certainly interested, came around and started the Food Safety Initiative, and then Mike Friedman was acting, certainly interested in food safety. And the last commissioners, Dr. (Lester) Crawford and Dr. (Mark) McClellan, Dr. McClellan was there in a lot of the counterterrorism, the bioterrorism, those issues. Dr. Von Eschenbach was clearly interested in foods and concerned about the decline in foods budget and trying to bring it up. He brought Dr. Acheson on in the Office of the Commissioner. Drs. (Joshua) Sharfstein and (Margaret) Hamburg are clearly more in the forefront with foods than anyone else was in the beginning of this tenure. Foods has the interest of the White House at this time, too.

Most commissioners coming into FDA have medical backgrounds. They're a physician, and I think their initial focus is usually in the drugs area because that's where they've come from and are most familiar. But foods has had a part to play, I think, with

all of them. I don't think there's been as much focus on the resources or as much of a realization of the need for resources and how things have changed up until the past five to 10 years.

SJ: There's been a lot of talk of a single food agency, and now Mike Taylor has returned to FDA. Tell us a little about your observations on the debate and the likelihood -- talk to us about a single foods agency.

JO: Single foods at the agency has been back and forth on the agenda for years. I'd say that I first noticed it maybe 15 years ago, and obviously, with the Food Safety Initiative, and at the time of the Food Safety Initiative, there was a lot of talk about a single food safety issue, and some -- a single food safety agency.

Some people looking at the resources that FSIS had and that they have a huge amount of resources, they have 20 percent of the regulatory, you know, of the industry to regulate and 80 percent of the resources. That's where it was back then. It's probably closer to 75/25 now. But that brought a lot of the concern on, and obviously there's a lot of outbreaks, a lot of illnesses associated with FDA-related products, still outbreaks and illnesses associated with USDA-related products and all.

But, so, a question. I don't think you can put FSIS and FDA together, just like that, without statutory changes and other changes. I think to spend all of the time and money to put the two agencies together wouldn't solve the problem, that FDA needs resources and needs some changes in the statutes, and I think that's where the focus should be. You will find different people with different ideas.

I don't hear as much talk about it has to be a single food safety agency now as I hear more people acknowledging that FDA needs resources and FDA needs more statutory authority.

SJ: It's cooperation.

JO: Yes, and you need cooperation at all levels and you need the changes in legislation.

There is cooperation between the two agencies. There's also competition in the way the laws are set up, there are some things that are not black and white. If you look at the open-faced sandwiches, the closed-faced sandwiches, the pizzas without the pepperoni, I think some of the things have become kind of silly. So when the laws first were enacted, you didn't have those changes, but the changes in what people eat, the changes in the global marketplace, have made some differences, so it's not an easy fix.

SJ: Now, did you think the example of Homeland Security has played any role shifting people's concerns about combining agencies?

JO: I think that Homeland Security was an influence; anytime you try to combine large agencies together, it's difficult to meld them efficiently. Some people I have heard say that after Homeland Security, maybe we ought to look and focus on things differently, because, I mean, anytime you do any type of reorganization, there always has to be some type of a matrix to have the new organization function efficiently.



SJ: There are surely cultural issues.

JO: Right, yes.

SJ: Institutional.

JO: Yes. There's always that, because look at when the Public Health Service came into the agency. Look at when Rad Health came into the agency. Look at when Biologics came into the agency. They were small compared to FDA and FSIS. Look how long took for these programs to function as part of FDA. Change is not easily accepted by everybody.

RT: I guess that's true of individuals and true of organizations.

JO: Right, right.

RT: Was there anything else you'd like to share with us about your experiences?

JO: The only thing I'd like to say is I've had a wonderful career at FDA. FDA is a great place to work, and the people in FDA are very dedicated, very mission oriented all across, I don't care what position you're in at the agency. You may find one person here or there who is an exception, but as a whole, I don't think you'd find more dedicated

people in any agency, both field or headquarters. In both the field and headquarters, everybody needs to realize how great everybody is in all the other places. FDA is a great place to work; the differences are really minor compared to the focus on the mission.

SJ: Obviously, as we're going through this transcript and as you're going through it, we always have the opportunity to bring up other things, make corrections, add things.

JO: Okay. So I could add things on something if I wanted to add.

SJ: Exactly. So when we both go away, we both may figure out things that we should have included.

JO: Yes. I thought about seafood HACCP and juice HACCP.

SJ: Well, HACCP (Hazard Analysis of Critical Control Points) in general.

JO: Yes.

SJ: Would you like to talk about that?

JO: Yes.

I mean, FDA was the first to promulgate HACCP regulations for seafood. It changed the culture, because it was the culture of preventive controls on top of a base of

good manufacturing practices. And there wasn't so much change in outbreaks. If you look at juice HACCP, there were a number of outbreaks that were affected by juice; following juice HACCP, the outbreaks decreased significantly.

As science has advanced and as time has gone on, science has led to changes. There have been pathogens that have evolved that weren't there before, and I think we'll have to keep changing as an agency and keep alert, be observant, and make sure we know what's coming up.

SJ: With the science.

JO: Yes. The science has to be central. The science really has to be central.

Then the DHEA (Dietary Supplement Health and Education Act) came along.

SJ: Do you think there were allegations at the time that one of the reasons we got DSHEA was because the Kessler administration, which was fairly new at that point, was more concerned about NLEA (Nutrition Labeling and Education Act).

JO: No, I would not say that. I would say DSHEA came into being because FDA took some regulatory actions based on food additives and food additive charges. There was a concern by some that the food additive standard should not be used for dietary supplements, and that's when dietary supplements were advancing. There were definitions of dietary supplements that came into being, and there was a groundswell of

people who, for whatever reason, thought FDA was trying to take vitamins off the market. We were not.

SJ: Which has a long history.

JO: Right. And so there was such a huge groundswell of letters written to congressmen that really influenced the path of DSHEA.

DSHEA had some very good points such as GMPs.

SJ: The disclaimer was unique for FDA. It was more of a European approach.

JO: Right.

SJ: This product has not been evaluated by the FDA.

JO: Right.

SJ: What affect do you think that's had on the consumer?

JO: I don't know that it's had much effect. The only reason I say that is because look at the market for dietary supplements, how it's grown. It's a huge, huge, huge market! It's grown by leaps and bounds.

SJ: People have said that FDA threw up its regulatory hands in DSHEA.

JO: I don't think the agency threw up its hands.

SJ: It's one of the few pieces of legislation that have prevented us, I mean, the Proxmire amendment being the first, to prevent us from taking on a new area of regulation.

JO: Well, what it didn't do is it didn't have a pre-market approval process for dietary supplements like they have for drugs, and that's, I think, what people are talking about. But I wouldn't say the agency threw up its hands.

SJ: What effect do you think L-tryptophan, the dietary supplement L-tryptophan had?

JO: I don't think it really had that much. I think L-tryptophan was an issue. It's something the agency followed up on; it was a significant issue. I don't think it really shaped the legislation. I mean, it may have been a part of their thinking, but I wouldn't have called it the shaping of the legislation.

TAPE 2, SIDE A

JO: Okay. I was saying that when the AIDS epidemic came, you had, obviously, a

concentration on doing blood bank investigations, and they were done so much more frequently that you had a lot more blood bank investigations being done by the field. And you had a lot of regulatory actions being taken then, too. You had the American Red Cross action that got taken in that period of time, too.

RT: Between the two segments that then combined, the FDA field and the Biologics, there was a period of adjustment, as you've been describing, for the Biologics folks to look at their role, not so much as consultants, but like FDA as reviewers of facts and so on. FDA traditionally, I think, did not regard field people as advisors. They would just find the errors, and the industry was to take the initiative on the correction rather than looking for a federal correction recommendation.

JO: Right. The field was thought of as the enforcers, the regulators; they would do inspections and take actions. When I started in the field, they really kept track of how many regulatory actions you did, whether inspections resulted in prosecutions, injunctions, how many seizures you did; that was a significant part of what we did. Education was not much of what we did.

Education became more of a part when Biologics and the other Public Health Service programs came into the agency. I think we're going back now into more of the enforcement mode. I see that turning at the present time, in the past three to six months. I think you need enforcement as well as education. I mean, you need the regulation, the enforcement, and the education just to keep people honest and to keep people focused on what they need to be focused on.

SJ: (Dr. Alexander) Schmidt's famous quote that we're an educational agency, but we put slow learners in jail.

JO: Right.

So, it's a different time.

Boston district had more device work than in Philadelphia, and less drug work.

But there was still quite a bit of food work, and I supervised the shellfish program and the food service program and the interstate milk shippers' program, which was all a little different for me, but I learned a lot about cooperative programs. Those programs had never quite mainstreamed. They're different; they're federal-state cooperative programs. The agency benefits a lot from the states' cooperation in all of those programs. There's no way we could do all of what's done by the states in those areas.

I think when I was in Philadelphia, I learned the need for state cooperation and the need for working with the states, and ended up being in the Central Atlantic State Association of Food and Drug Officials; when in Baltimore District, I ended up being president of that association.

Working with the states and working with the local governments was, then and now, the only way FDA can assure food safety; it has to be an extremely cooperative effort. I think the agency is moving more towards that now.

Ten years ago, I held the first 50-state meeting on the Food Safety Initiative and on building an integrated food safety system. Much to my disappointment, the time wasn't right to move forward with that.

Now, there was another 50-state meeting this past year that David Acheson led. And there are a number of workgroups that are doing a number of things.

But since that meeting 10 years ago, there have been many cooperative federal/state advancements such as eLexnet. There's a federal-state IT infrastructure that isn't used as much as it could be used, but you have a lot of state data in there.

But I'm just meandering on, but when I think of when I started, we had the teletype: click-click-click-click-click-click-click, waiting for the teletype with its multiple copies. We individually typed our reports, gave them to secretaries, had multiple copies made, you know, five, 10 copies. Look at now. Look at the huge difference in technology, that you have your computers, you can make any changes you want, you can say that you can copy, recopy, and do that, but it's a huge difference. You waited for the teletype to come in to tell you about something from across the country. You're there two or three o'clock in the morning pulling them off individually, trying to line them up. Now all you do is put them in a chart and put them in a table and send them off, and it's there seconds later all across the country.

SJ: Has e-mail and electronic technology made up for some of the fact that we don't transfer people?

JO: No. I think that e-mail and computer technology have saved a considerable amount of time drafting reports and collating data.

I think that the e-mail has a huge value and a huge downside. The huge value in the e-mail is that you can get all this information to you. The agency doesn't have quite



the infrastructure yet to analyze the data and to put it in places or to use the webs like the Yahoos, like the Googles, you know. Put something on Google and I can find it in a second, but I can't even do that in a report that we have. So a lot of the IT things that are being done now are necessary for us to take advantage a little more of that, and for us to get the recalls and such things. They're just starting with Food Shield and some of those things now to better utilize that technology.

But I think, I don't know how it is in the field, but in the Center, we've come kind of to the point where there's just so much e-mail sometimes, especially in the times of an emergency, that it's hard to keep up. You need information people to be analyzing the data.

I think we as an agency, just in this past year, at least in Foods, are beginning to see all the information that's out there in the world of the Internet and the world of the Web, that we can be using and analyzing so that we can be more targeting where the problems are. We can be more targeting the labeling problems and issues as opposed to having an investigator travel down the street for everything. There's a lot of data that is just beginning to be used. CFSAN was setting up groups for data analysis. ORA is beginning to do the same -- we have to make sure that we're coupling and that we're using the synergy of both as opposed to duplication of effort.

But the technology has made so many things so much easier, but it's also made our job harder in that, look at all the imports. When I came in, there were hardly any imports. You went down to the dock. You could look at all the invoices that came in, you could look at what was coming in, you could actually look at each of those manifests. Now there are millions and millions of them.

So the agency started a system that's a pilot in California and a couple other districts. They're doing the PREDICT system. It'll be across the country so you can put certain, particular information in there and do a risk analysis as the products are coming in. We have millions and millions and millions. Just the airplanes coming over. The shift in technology and how we get across the country has changed since I started.

SJ: Is a lot of that statistically based so we're having more statisticians on this risk analysis, or is this the kind of thing that, you know, experienced people in the agency can work with without hiring new staff?

JO: No. You need both. The agency is really looking, I mean, in Foods, we're looking at it, and looking at the statisticians for the risk. We've done a number of contracts, looking at risk. There's just so much that has to be done to the data to really focus us.

If you look at China in the past year and the melamine situation there, the situation with the heparin -- and we had melamine twice, melamine I and melamine II, one for the pets, where you had the pets dying, and the other where you had the infants very sick and dying in China. Luckily, none of the latter got to the United States. But it really brought to light the fact that one ingredient in one country could affect what's going on around the world; so that our food supply is a global food supply, whereas when I started, the food supply was primarily the food supply in the United States. But now it's a totally global food supply, and people expect the fresh produce, fresh fruits and

vegetables, fresh fish, every day of the year. They're not looking at the different times.  
So it's really a change.

SJ: Can we take a break?

RT: Continuing now.

Shall we talk a little bit about tampering episodes that you dealt with?

JO: Right.

In the 1980s, there were two Tylenol tampering incidents, both of which were obviously very visible because of the illnesses and because of the product that was involved.

The first Tylenol tampering incident began in the West, and there were significant illnesses. Then when people went and found another container on the shelf which actually had something that could kill an individual, it created a whole stir throughout the country.

Johnson & Johnson and McNeill did a tremendous job at that time by deciding to go out front and recall all the product they had, withdraw it from the market. They did significant press and outreach strategy.

But that really was the start of the Anti-Tampering Act. And after that there were a number of copycat tamperings, because people began taking capsules apart and putting things in them; it was happening all around the country.

In isolated incidents here, you'd get called up in the district office on a Friday afternoon, saying someone called up, they got sick from taking some type of capsules, or they'd go back on the shelf, there were more capsules on the shelf, and so FDA was running around all over the country.

Initially, we put press out to tell people about the tampering and all, and gradually we realized the press was actually feeding other people, who went out and did more tampering.

But that precipitated an anti-tampering act. That precipitated the seals on the container tops so you can't get into any of your over-the-counter drugs now. I mean, everybody is complaining about not being able to get into them. But they're tamper-evident. They're not tamper-proof. People wanted tamper-proof. There was a number of years when there were tampering incidents, one after the other, and you would see them in the papers.

But that also was the beginning at FDA of having our Office of Criminal Investigations, and Terry Vermillion came in as the head of that unit. They hired a number of people, and the people they hired were basically from law-enforcement backgrounds, preferably federal law enforcement, so they knew the legal structure, knew working with the marshals, and took over doing what the field investigator had done before.

Gradually tampering has decreased. They have not ended. Every once in a while you'll still find that type of problem. But that was the beginning of another new act for FDA to review.

During the second Tylenol tampering, I was on detail at the headquarters and ended up actually being the coordinator for the second tampering. We were working with Commissioner Frank Young, working with Johnson & Johnson, all over the country just trying to find out what was happening and to assure the American people what we were doing, because people then were very afraid to take almost anything because of what was happening.

RT: I thought it was significant, too, that the Office of Criminal Investigation identified their field personnel as agents rather than investigators.

JO: Right, right.

RT: Which was kind of a demarcation between the two.

JO: Right. They came from the FBI, from Secret Service, from other federal agencies and that type of law enforcement, and that's what they were out to do. They were out to do the criminal, and so that's what their focus is on, on criminal.

RT: They, of course, had authorization to carry firearms.

JO: Yes, right. They've been invaluable to the agency. They have really served a different purpose in a different part of the agency, so that's another one of those changes that happened while I was coming along in the agency.

SJ: But one of the things they claim helps cut the tampering cases down as well, especially the copycats that you're talking about, the razor blades in candy, that kind of thing, it was just, they knew how to deliver a lie-detector test.

JO: Yes.

SJ: They got so many confessions and the law was so tough, in terms of mandatory jail sentences and such, that they really eliminated. Those stood out without even anything complicated.

JO: Yes. Before OCI came in, some FDA people went to a federal investigatory, federal agent school, like the Quantico type school or whatever, and you did, a number of us had courses on how to interview people, how to tell the body language, how to tell if they were lying or doing that type of thing, short of just the lie-detector test. But OCI staff are specifically trained in asking those types of questions and knowing that body language, and being able to pursue further. They had a different expertise. They made a difference, I think, in the tampering and in the change and in the prosecutions and all that they did. So I think that was a good thing for the agency.

You were mentioning before the NLEA. That was another act that came into being as I was coming along in the agency. We've had a lot of changes and a lot of good changes.

The Nutrition Labeling and Education Act, the secretary at that time was talking about the Tower of Babel, that all of the labels that were out there were the Tower of Babel. It was at a time when there were a lot of claims, a lot of low-fat, a lot of lose-weight-fast products, a lot of this that were -- not that there aren't any now, but I think it was different at that time. At that time, we didn't do much testing for percent of fat or the amount of sodium. FDA came out with the Nutrition Facts panel for the first time, which gives you your number of servings, your calories, the number of calories, the amount of protein, carbohydrates, fats, and there's been some minor changes in between. Your vitamins are generally minor, but they're on the bottom, so that a person can actually look at it, if they're on a low-sodium diet. You can also tell the number of calories. I think for a while there was a lot more looking at the label than there is now, and probably we need some more re-education and possible label change on it. Initially, NLEA changed the amount of and type of claims put on the label.

But now I think, with the many diets now being promoted, there are bad diets and a lot more claims that are being put on labels. Some people are saying the nutritional-facts panel obviously didn't work for obesity. What else can we do? How can you do the different things? Changing behavior is not easy. If it were so easy, we would have done it a long time ago, or someone else would have done it too.

SJ: Wasn't FDA fairly ambivalent, prior to NLEA, about any kind of claims on food labels, any kind of health claims? We recently acted against Cheerios that used statistics in such a way that we thought they were making a drug claim. Because, as I understand it, there was a huge -- the Department had to play a major role in structuring the

legislation so that FDA could find it palatable to do these certain studies. There's a whole history of the evolution of the food label, which is one thing.

JO: Right.

SJ: But I think actually bringing it to fruition had some political elements.

JO: Anytime you have an act, a change in the Food, Drug and Cosmetic Act, whether or not it'll get passed or it'll be a variation, when you looked at the Dietary Supplement Health and Education Act, when you look at the Nutrition Labeling Act, look at the Anti-Tampering Act, you'll see that there's a political realm to it, there's an agency realm to it, there's a science. But anytime you have legislation passed by Congress, there's a whole process; that's how you get to a law.

The secretary of HHS was a very strong advocate for labeling changes, calling it the Tower of Babel and saying that something had to be done for the label. We worked with the secretary, the Center for Foods, in focusing on that. Anytime you have an act, you always have the involvement of the Department, the Hill, and the agency.

SJ: Yes. It was (Louis) Sullivan who was the secretary . . .

JO: Right, yes. He was very much talking about that Tower of Babel. There were many complaints from industries, from consumers, and consumer groups about not being able to tell whether something was truly about low fat, low sodium, and low in calories.



What did it mean? We had no definition, so we couldn't tell them what it meant. We were not out there enforcing. What we were doing is spending our resources on more significant violations of the Act, on health hazards, whatever, because resources have always been an issue.

RT: The obesity problem is ubiquitous, I believe, in the population perhaps, from children in the school lunch program on through the rest of life. If you stop and observe people, you'll see a lot of people who are overweight. In a buffet that I sometimes go to, I see those type of people returning two or three times to the food trays. How you educate someone who really enjoys eating is really difficult, maybe an insurmountable task as far as that part of the problem is concerned, except for school lunches, if you can regulate that. But individual choice of diet is difficult to influence.

JO: Mm-hmm. Well, just look at cigarettes; I mean, just look at cigarettes where you knew there was a significant risk with tobacco. But if you just look at that, where you use it was a significant negative health outcome. Granted, there was an addiction associated with it. To change people's behavior is very difficult. A lot of behaviors are learned throughout life.

FDA got involved with education, and in the Food Safety Initiative in '97-98, one of the things we did was to try to look at food safety from the standpoint of safe food practices and what you eat for adults. What we learned was you had to start with the kids for food safety education.

We also learned that schools stopped doing classes they used to have for food preparation. They were all gone. So the only place we could find to get food safety education in was with the science classes.

So we formed an agreement with the Science Teachers Association, the National Science Teachers Association, 10 years ago, and we now train science teachers throughout the country, got curriculum there on food safety, on foodborne microorganisms, on the knowledge about listeria, about soft cheeses, about pregnant women avoiding them. We've had a lot more luck doing it that way than in some other way because lots of things have changed in the country.

You know, when a lot of people walked to school before, they don't walk to school anymore. I mean, now they're saying you need to put grocery stores in the local area so they have to walk. They're not going to walk, even if it's around the block. You've got to put the schools closer now so that kids have to walk to schools and get the exercise.

So there's lots of societal changes that encourage obesity.

CFSAN did some programs with the Department in inner city for teens and discovered you had to begin preteen. I mean, that's really what it ended up saying: too late; you need to begin earlier than that. If you get young kids, you get them to do something with their parents because then they convince their parents, and the parents get embarrassed, and so they'll change some of their behaviors. But it's very interesting in looking at changing behaviors because . . .

CFSSAN had a task force working group, when Joe Levitt was the Center director, to deal with obesity. There was a report on what could be done, and we worked with Keystone. Combating obesity is something that has to be done government-wide.

SJ: Was that a little later because I know that Alan Rulis worked on that -- a huge report that basically came to the conclusion that calories still count?

JO: Oh, yes. Calories count, yes, right.

SJ: It was a scientific equation, so to speak.

JO: Right. It's still the calories in that food or meal, you know, the number of calories that you take in.

But it's also on the burning of the calories so that the exercise makes a difference in the calories that you need.

SJ: Speaking of Center directors or whatever, can you talk a little bit about the Center directors that you've worked with? I assume you weren't there when Sandy Miller was there.

JO: Sandy Miller was there when I came into the Center on a detail from the field. If I hadn't gone to the Center on a detail from the field, I would have never gone to the Center to work.

It's probably not the best thing to say, but the centers and the field aren't quite in sync, and when I was in the field, the field felt like the centers were telling them what to do, and they knew what to do.

When I went to the Center for Foods on detail, I realized how smart the people were that were in the Center, how much they knew that I really didn't know, and how much science was behind things that were important for the field to know. I later applied to the Center and became the Director of the Division of Regulatory Guidance.

Under Sandy Miller, the structure of the Center was such that you had an Office of Food Technology, an Office of Toxicology, an Office of Microbiology, that your major sciences were offices. Then you had your Office of Compliance that really did the letters, and did all of that type of thing.

When I came into the Center in 1989, Dr. Fred Shank was the Center Director. There still was the Office of Compliance, and each of the main sciences had an office.

In 1992, the Center was reorganized when Dr. Shank was still there. Mary Jo Veverka was in the Office of the Commissioner and was very instrumental in the reorganization. The Office of Compliance abolished food additives, which was in Office of Compliance at that time, became its own office, and offices were offices by product category. You had an Office of Seafoods; an Office of Nutrition, where dietary supplements was; an Office of Cosmetics and Colors; and an Office of Land Foods and Beverages. Science was in each of those offices.

But the breadth of the Center in terms of science was not sufficient to have each office, product office, have enough science in that office, so you had to work across offices. The structure was built assuming there would be growth in the Centers and you

would get more people to staff it up; that's never happened. And so the Center was never really able to fully utilize that structure and have the resources to benefit from that structure.

After Fred Shank, Joe Levitt became the Center Director, and that was right at the time when the Food Safety Initiative was starting. He stayed as Center Director for five or six years when the Food Safety Initiative was building. Then there was a cut in resources again, a cutback in resources, and the Center had buyouts. We needed to come down in dollars or wouldn't have sufficient resources to pay the salaries of people in the next year. So Joe left and Bob Brackett came on/ He was only there for a few years, but he was there during the time that resources went down, down, down. We had buyouts during his time period.

RT: Well, if we have covered what we intended to today, we might close. We can later supplement the record if something else comes to our minds.

We want to thank you very much, Janice, for this interview, and we wish you much happiness in your retirement years.

JO: Thank you.

END OF INTERVIEW