History

of the

U. S. Food and Drug Administration

Interviewee:	Irving Weitzman
Interviewer:	Robert A. Tucker Ronald T. Ottes
Date:	December 10, 2002
Place:	Rockville, MD

INTRODUCTION

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

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

CASSETTE NUMBERS: 1 and 2

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

DATE: December 10, 2002 **PLACE:** Rockville, MD **LENGTH:** 90 minutes

INTERVIEWEE:

NAME: Irving Weitzman

ADDRESS: [redacted]

INTERVIEWER(S):

NAME: Robert A. Tucker and Ronald T. Ottes

ADDRESS: Food and Drug Administration
Rockville, MD 20857

FDA SERVICE DATES: **FROM:** August 3, 1961 **TO:** January 3, 2003

TITLE: Special Assistant to Director, Division of Field Investigations
(Last FDA Position)

INDEX

Tape	Page	Subject
!-B	18	GAO (General Accounting Office) report of FDA's handling of Consumer complaints.
	20	Tampering incidents
	21	Recalls-BonVivant
	22	Mushroom recalls
	24	Anti-Tampering Act
	25	Dr. Frank Young
	26	Restructuring of DEEO-formation of Division of Emergency and Investigational Operations (DEIO)
	28	Cyanide in Chilean grapes
	29	Office of Criminal Investigations (OCI)
	31	Food Borne Illnesses-FDA-CDC responsibilities
	32	Terrorism Bill
	33	Foreign inspections
2-A	34	Division of Field Investigations (DFI) minus Emergency Operations
	35	Inspector's Operation Manual (IOM)
	36	FDA Commissioners
	37	Associate Commissioners for Regulatory Affairs (ACRA's)
	40	Agency Emergency Operations
	42	Wrap-up and end of interview

RTO: This is another in a series of FDA oral history recordings. Today, we are interviewing Irving Weitzman, consumer safety officer in the Division of Field Investigations [DFI]. The interview is being conducted by Ronald Ottes and Robert Tucker at the Parklawn Building in Rockville [Maryland]. The date is December 10, 2002. The transcription of this recording, together with the tapes, will be placed in the National Library of Medicine and become a part of FDA's oral history record.

Irv, to start, we would like to have you give a brief biographical sketch of where you were born, raised, educated, and any relevant work experience prior to coming to FDA.

IW: Well, let's see. I was born in Brooklyn in 1939, went to school in New York City public schools. I went to a vocational high school, Food Trades Vocational High School, which doesn't exist anymore, where I was trained in cafeteria and catering as a cook. While going to school, I worked as a cook in a luncheonette in New York City.

While my mother wanted me to go to college, she allowed me to learn that cooking was hard work, and I then went to college. I got a degree in food science. I went, first, to the University of New York at Morrisville and got a two-year degree in food science, at which time, during the summer, I had to work in a cannery for the Great Atlantic and Pacific Tea Company, where we canned fresh products. Then transferred to the University of Georgia, where I got my bachelor's degree.

During that period of time, I also had to work in the industry, so I worked in a kosher slaughterhouse in New York, at that time, was owned by Swift & Company. I spent time on the kill floor and in the coolers, learning to break down sides of beef.

Then I went to graduate school at the University of Georgia, but I did not get my master's degree. I left before I finished my last required course, turned my research over to somebody else, and came to work for Food and Drug [Administration]. I had learned about Food and Drug, because I was going to school with somebody who was on educational leave from Food and Drug to get his master's degree.

RAT: You graduated in what year, then?

IW: I graduated with my B.S. in 1960 and I came to work for FDA in 1961, when I left the university. I started in the Buffalo District and worked in Buffalo from 1961 to 1968. When I worked in Buffalo, I moved into the Rayfield Building that was built in Buffalo for us, and as a sideline, was the acting district director in Buffalo the month before we closed the building. So I almost was the only person to open and close that building.

Anyway, I went to work for FDA in Buffalo, and I went through the normal training program that we had at that time, which was about eight or nine months long. I was assigned a mentor.

RTO: Who was the district director?

IW: It was a gentleman by the name of Allen Retzlaff, and the chief inspector was Bill Prillmeyer. My supervisor was a gentleman by the name of Mr. [Ted] Loveridge.

So I was assigned a mentor to work with, and I went out and worked with a number of people in the district. The day I started in FDA there, I also started with Tom Chin, who still works here for us, and a gentleman by the name of Richard Hunt, who has since retired from FDA. At the time I reported, there was a grand total of nineteen inspectors in the whole district. We covered all of New York state above just below the Albany County line and the western third of Pennsylvania.

RAT: Was most of your work there, food?

IW: Mostly food work. I did a little bit of drug work. I did a little bit of device work. Back then, though, the drug and device work was much simpler, because we didn't have the efficacy requirements at that time, covering safety for drugs. And devices, there were no device amendments. There was just very simple kind of inspection work.

RTO: Do you recall any significant work that you got involved in there?

IW: Yes. Well, back then, we were also doing the work for the Caustic Poisons Act. I remember doing some undercover work, recording a gentleman who was selling [Harry] Hoxey cancer cures and stuff. Also, I was supposed to do some undercover work on illegal sales of prescription drugs, and we did a lot of pesticide work. I remember the craziest assignment I ever had was to go get fresh manure from cows to see if there were

pesticides in the manure, to see if they were consuming pesticides in the pea silage they were being fed.

RTO: In that connection, did you get into livestock feed industry at all?

IW: Well, we did feed mill inspections, but up there, there was a big canning and dairy business. For example, one of the things was pea silage. Pea silage was very popular with the dairymen. They loved to get that stuff, ferment it and feed it to the cows. Somebody got the idea, "Well, maybe there's pesticides on the pea silage, so let's see what's coming," so I had to go into barns and wait for the stupid cows to pick their tails up, and then had to wait to make sure it wasn't urine coming out. They didn't want it to hit the ground first, so I had to catch it on the fly. And if you give it to an investigator today, they'd never do that.

RTO: Did they have any dairy farms there that they fed that pea silage?

IW: Yes. Quite a bit.

RTO: Did they collect milk from those cows to see whether there was any pesticides or penicillin?

IW: I didn't get any milk samples. I was assigned to get the other samples. But I'm sure that milk samples were collected.

I was involved in one injunction case. It was a very large cream pie manufacturer in Erie, Pennsylvania, as a result of my inspections later on after I'd worked my way up into micro work, that resulted in a TRO [temporary restraining order] shutting them down because of high micro counts.

Then I was involved with having to go back in after they supposedly cleaned up, to see if they were clean enough to start operations, and I was really surprised, because we went back in there expecting, after three weeks, that they had the place spotless. I asked that a line be pulled down, and found it dirty and stuff, and just told them they couldn't start up again.

RTO: Did you take swabs of their lines and equipment?

IW: During the original inspections, yes. One of their problems was, they were not designed for cleaning-in-place and they were cleaning-in-place, so the equipment allowed stuff to collect in different crevices, and I didn't have to take swabs. I just took some of that material, and the count was stupendously horrendous. So that was an interesting inspection.

I also did some inspections—while I was there, when they were working on the Hazardous Substance Labeling Act, and so we were doing some follow-up work on deaths and injuries reported under the Caustic Poisons Act, to gather data for Congress. I remember having to visit houses where children had died from burns to the throat from eating lye, and having to discuss with the parents where they kept the lye, and all this kind of thing. That was a very sad experience, because under the Caustic Poisons Act,

you had the very large skull and crossbones and "Poison" written on the label in red, and of the three or four of the ones that I did, the people kept the lye under the sink, right there where the children can get to it.

I had one lady say to me, "Why weren't there any warnings?" And I picked up the can that she still had under the sink and showed her the warnings They just never read it. That was an experience that sticks in your mind, but not a happy experience.

RAT: Did you get into any of the flammable product investigations?

IW: The flammable fabrics?

RAT: Yes.

IW: I didn't do too many of those. There were a few, but not too many. Usually some of the others got stuck with it.

RAT: X-33 or something like that. That was a product that was extremely volatile.

IW: Actually the fabrics, the children's wear at night, the nightwear and stuff that was flammable, violated that law. FDA did a lot of funny things. CPSC came off of us. The illegal distribution of drugs came off of us, from BMDD and stuff. Went through all that stuff.

RTO: Where did you go from Buffalo?

IW: I was transferred to Chicago as a GS-12 food specialist, not the ITS kind of person, but I was one of the first GS-12 food expert investigators. I was there for four years doing food work there. In Buffalo, of course, we traveled every other week, and during the spring when the milk flush came in, we traveled two weeks out and one week in, pulled a lot of sediments. But in Chicago, in the four years I was there, I think I went on a road trip once, because of all the work that was in the city of Chicago itself.

Curtis Candy Company, I was in there on some inspections because of reports from the military of salmonella contamination in candy they were getting from Curtis.

RTO: I missed your degree. Was it in microbiology?

IW: No. It was in food science. When I took the federal service entrance exams, because of the courses I had, I qualified as an investigator, an analyst, and a microbiologist, because my minor was in microbiology. My major professor in graduate school was the science advisor in the Atlanta District as microbiologist. So I had the background. In Chicago, I did those kinds of things, the more complex inspections.

RAT: Do you recall who the director was in Chicago at that time?

IW: I want to say Hart.

RAT: Sam Hart?

IW: Yes. He went over to the product safety group, but at the time, yes, he was the district director. A little later on, Mr. [Don] Healton was the regional director. In fact, I'll never forget, Mr. Healton once said to me, in Chicago, he says, "What do you think the regional director does?"

I said, "Walk around and drink coffee." [Laughs] Because that's the only time I ever saw him in the district. I did enjoy working for him here, though. He's a lot of fun.

So in Chicago, I did that kind of work. While I was in Chicago, I was sent to drug school at the University of Rhode Island, so I learned some pharmaceutical stuff. I remember that one of the most significant things I did in Chicago was actually drug work. Abbott had that problem with their large-volume parenterals with the faulty screw-on caps, that they couldn't get sterilized properly, and they had a total recall.

I had two tasks. One task was to stop the shipments that were being made—they were continuing to ship the large volume parenterals because they were a major producer in the United States, and there was a shortage problem. We permitted them to make individual shipments for those products that couldn't be replaced by another manufacturer. I was assigned the task of finding alternate supplies of product for hospitals when they wanted to get something from Abbott, and I took that job over, and within a month and a half, they made no more shipments, because I found supplies for everything elsewhere.

Then I was assigned a task going in with a team. We went in as a team inspection to review the revisions they had made to their process to sterilize the large volume

parenterals, not because I was a drug expert, but because I had the background and the knowledge in retorts. I knew how to sterilize things. So I went in with the team and contributed that part of the inspection.

RAT: Was this about the time when they made food sanitation inspections and sent a microbiologist out of the laboratory with the investigators?

IW: Yes. We were doing that, too, and in fact, I had to take one to Campbell's. He had a beard and a mustache and he refused to put on a snood, and I just turned around, took him back to the district office, and they never let him go out anymore again. In fact, they transferred him to headquarters. You might know who he was. Okay. I was the guy involved in that. He wouldn't put the snood on, and I said, "Sorry. You ain't making the inspection," and back we went.

But, yes, we were doing joint work. But we were doing that back in Buffalo, too. I worked with the district director in Minneapolis.

RTO: Feldman?

IW: Yes. I worked with John in Buffalo doing joint inspections, micro inspections. Enjoyed those.

RAT: Is there any other, besides this Abbott investigation, that you recall in Chicago?

IW: Oh, yes. Another legal case that I got involved with was, there was a flour distributor in Chicago that I was making an inspection of. They had their warehouse alongside the railroad tracks, and I got in there. The place was so rodent-infested that I watched them move a couple of pallet loads of flour and left a flour trail in it. I took a picture of the flour trail. And two hours later when I came back, I took another picture with all the rodent tracks in it.

I suggested, "You know, it would help if you closed the doors," because they kept the siding doors open, and when they went to close the door, one of these rolling doors, somebody had taken the track off where they rolled the door out. [Laughs] It just fell out onto the railroad tracks. We got an injunction against them.

RTO: Is this a flour processor or a warehouse?

IW: Just a warehouse, a major flour supply warehouse in the city. I got the city officials to come in with me and embargo everything. Then we got the TRO [temporary restraining order] and injunction against them, and then they had to find an entirely new site. There was no way that they could renovate the site they were on, and they were supposed to move everything. They weren't supposed to take any of the pallets or anything. They were supposed to move everything, bag by bag, and examine each bag. I was there for some of that. But they moved some of the pallets and they moved the mice into their nice new site that was rodent-proof, and then the rodents couldn't get out. But they didn't listen. So that was another one I was involved in. I was there for four years.

RTO: In Chicago.

IW: In Chicago, yes. An interesting thing that happened was, I was following up on a consumer complaint, going to talk to the complainant, a lady, in the Cabrini Green Housing Projects in Chicago. I drove in there in a government car, like we used to do. Didn't notice the police car following me in. When I parked to get out of the car, it pulled up alongside of me and a policeman rolled the window down, and I said, "Yes, sir?"

And he said, "This area is not safe. They shoot at us from the roofs. Do not get out of the car. Follow us out." And so I did.

Went back to my supervisor and told him, "You know, the police ordered me out of the site, and we'll have to call the lady to get the information." That was an interesting experience.

RTO: From Chicago, where did you next serve?

IW: Kansas City. I was transferred to Kansas City as a supervisory investigator, and I worked for—I've got to think of his name. Isn't it funny? He was a DIB, at that time it was Director of Investigations Branch, and I was no longer an inspector. I was an investigator now, a supervisory investigator. He retired out of Dallas as the director of investigations down there.

RTO: Ted Rotto.

IW: Yes. Ted Rotto. I worked for Ted Rotto. Pat Pozar and I reported to Chicago the same time. We worked side by side. Pat, of course, lost his life on a trip to Chile.

RAT: The Chilean grape investigation.

IW: Right. Chilean grapes.

There was a bunch of characters there, really a bunch of characters. I was a smoker back then, and I quit smoking with one of the other guys. We had a pact. He went back to smoking, and I was teasing him about smoking. When he got excited, he used to start stuttering, and he was fooling around one day, and he set fire to my beard, just fooling around with the cigarette lighter. He tried to tell me that he had set fire to my beard, but he started stuttering, and he couldn't tell me, and I didn't realize it till I smelled it. [Laughs] Then I put it out. By then, of course, half my beard was burned away, so I started shaving again.

But we were a very crazy crew. We thoroughly enjoyed ourselves.

RTO: I trust that you would wear a snood, as you called it, right?

IW: Yes. Well, back then, as a supervisor, I didn't go out very often, and I didn't have that beard very long before it was gone, because after he set fire to it, I just took it all off, and that was the end of it.

RAT: You were there during part of the expansion.

IW: Yes. I went down there for Project Hire. I was one of the so-called Project Hire supervisors, and it was a region then, regional office. Kansas City was a regional office, and [Lloyd] Claiborne was the regional director, and [Jim] Adamson was the district director.

They played a dirty trick on me when I got there. The first thing they did was they gave me a big stack of EIRs [establishment investigation reports] to review, and I went through them and reviewed them, and I set a bunch of them aside because they weren't very good reports. They didn't tell me anything. They assigned all those people to me. That was a really dirty trick. "You got a problem with these people? They're yours."

One of them, I remember, was a GS-11 investigator who'd gone out on a two-week road trip to western Nebraska, and I read through his reports, and I couldn't tell what he had inspected. If I didn't look for the data codes in the front, what products he supposedly listed, I wouldn't have known what he did. So I went back to him and I said, "You know, you need to redo these reports, because I can't figure out what you saw or anything else." I agreed, at that time, if you were a journeyman investigator, you could write an abbreviated report, but you had to tell something in the report. So I said, "Go into your notes and beef these reports up."

And he says, "I can't." He came back to me later on in the day, and he said, "I don't have anything in the notes."

I said, "Well, then take the trip over."

So he said, "I'll go out in a couple of weeks."

I said, "No, take the trip over. Plan to go out tomorrow and redo these inspections." I got a reputation right after that about the kind of work I would accept. [Laughs]

RTO: Sounds like there was some rather lax oversight before.

IW: Well, might have been. It was just simply—I think it was more a matter of there was too much going on at the time.

RAT: How many investigators did you have under you?

IW: It ranged from—I think the lowest I ever had was eleven, and I think there was actually a time when I had seventeen or eighteen people. It's quite a load of people.

RAT: Quite a staff to control.

IW: Yes. Very difficult. They had made that massive hiring and had all these people there, and they only had three supervisors, and so it was very difficult Roger Flesch was another of the supervisors. Let's see. Who else was there? Gene Sheveling. And who was the third one? He's the one who set fire to my beard, and you'd think I could remember his name. He was really a nice guy, too. Just can't think of his name. Sorry.

RTO: How long were you the super?

IW: I was there for five years, 1972 to 1977, and then I came in here to Compliance, on a hardship transfer, because my kids were so sick in Kansas City. They had constant strep infections. When I asked the doctor, "What can I do about it?" Because they were on antibiotics all the time. It was a losing battle. He said, "You've got to go someplace humid," and you guys brought me someplace humid all right. [Laughs]

RTO: How old were they then?

IW: Let's see. In '77, my oldest was nine, eight, and seven, were my children. That's the ages they were. They were just in school and constantly sick. So I came in here.

RAT: On a hardship transfer.

IW: On a hardship transfer, yes.

RAT: So you came in to headquarters Compliance.

IW: In to Compliance in EDRO. Right.

RTO: Who did you report to here as the manager?

IW: Bill Jackson was my supervisor. He used to get in trouble because he'd give me work, and I'd get it done in a couple of hours, and then I would wander around the halls. You remember? [Laughs]

RTO: Yes.

IW: And I did that for three years. I was a deputy FOI officer; I cleared compliance programs; I handled appeals from the field on turndowns from the centers. I remember authoring the instructions on hearings for device detentions that had just come into place, and we had to come up with the procedures, and so I put together the draft of the hearing requirements, how we would do it, made sure they got cleared and everything, brought them forward in the RPM [Regulatory Procedures Manual].

Then they advertised for an epidemiology person or a person to run the consumer complaint system as supervisor. I applied for that, and I got that job under Dick Swanson. That was in '81.

RTO: You came in, then, for consumer complaints, not as director of the branch.

IW: It wasn't a branch then; it was just a section in DFI *[Division of Field Investigations]. It was a section under the branch in DFI when I came in, and I was the section supervisor.

RTO: That was prior to the time when Swanson or yourself, either, were involved in emergency operations, is that correct?

IW: It was the predecessor for emergency operations. Remele Grove handled recalls. I handled complaints, and between the two of us and Dick Swanson, we were the group that was handling emergencies also. Even back then, we were answering the phone at night and stuff, but we were a section in DFI at the time. I was, and Remele, was, and we were a branch under DFI, and then we got pulled off of DFI and became the Division of Emergency & Epidemiological Operations, DEEO.

RTO: What was that year, do you recall?

IW: Well, in '81 I went in as the section. I think it was a couple of years after, probably '83, that that group finally broke off as a separate division.

RAT: So it was really because of your experience with microbiology, that they brought you in to head up that section on epidemiology.

IW: Right. And also because I had taken part in one of the epidemiology training courses that CDC [Centers for Disease Control and Prevention] put on for FDA, when I was still in Kansas City. In Kansas City I was also involved with that kind of work, supervising, that kind of stuff, so I had the experience.

[Begin Tape 1, Side B]

IW: Anyway, that's why I got that job, because of my experience and training in it, and my micro background and my food service background, because most of our complaints back then were in foods. Even today, the majority of complaints involve food, because people don't think that much about drug interaction and stuff like that.

RAT: The complaints would come in to you. You didn't have any authority over the field at all.

IW: No, other than an advisory capacity. We would get some complaints. We would serve as the complaint receivers for the headquarters area. They wouldn't call Baltimore District, and they wouldn't call the Washington, D.C., resident post. They would call us, and we would take them.

I was involved in setting up the computer program for the consumer complaint system and developing the complaint form that we were using. We were responding to a GAO [Government Accounting Office] report saying that FDA didn't pay any attention to consumer complaints and didn't make use of it, if you remember back then. So that was part of what I got involved with.

So I got into that and then I got involved with [Bill] Schwemer when we worked out the emergency procedures for the agency that went into the Regulatory Procedures Manual. That's when we started having not only the coordination role, but some directive role in emergencies, big problems.

RAT: Somewhere along the line, you began adding additional staff persons, is that correct?

IW: Yes. I started out with two persons. I had a technician and a CSO, and then I ended up getting—well, let's see, I had Marilyn Veek; and I had a PHS commissioned officer. I'm trying to think of his name. I see him in the hallways every so often.

RTO: Pete Cook?

IW: Not Pete Cook. Pete Cook I got later on from training, but this was Dr.—? He's upstairs in International Affairs, right now, I just can't think of his name, that's all.

RAT: We'll think of it later. Could it have been John Lucas?

IW: Yes, that's right. Then I had Janet Rowe, who's still with DFI; Pete Cook, who's still in emergencies; and after Tylenol, I got Dr. Fow, Mark Fow, who's still here.

RAT: Was the emergency operations under you?

IW: No. It was actually under Dick Swanson. The two of us, Remele Grove and I, worked together to handle those kinds of things. The division was a team. It truly was a team, and we all worked together to handle it, plus handling our regular things. Remele

handled recalls; I handled complaints. At the same time, together we handled the emergency operations. We maintained the red book, we started first the beeper system and finally got an answering service to answer the calls, instead of us getting them directly.

RAT: Somewhere along the line, I believe, you got into some tampering incidents.

IW: Yes, that was Tylenol. That was an interesting situation since at the time we first got into it, there was no anti-tampering act. Dick Swanson was in Illinois at the time, making a speech at a meeting there. He was in Du Paige County, and when the first victims started showing up in Du Paige County, he was out there, and alerted us to it.

We got into it simply because it was a regulated product, acetaminophen capsules. Technically, the only violation involved was adulterating some drugs after receipt in interstate commerce. That was the only charge that could be made from the federal standpoint. Of course, they brought some murder charges. That was the first tampering incident. That was a significant one.

Mr. [Paul] Hile was involved with coming up with the scheme of how to recall the product out of that metropolitan area and examining it all. He talked McNeil into looking at all the returns. We found additional product that had been tampered with, when it was pulled off the shelves and stuff.

RTO: Well, that was similar to a recall.

IW: Yes, we called it a recall. It was a recall, a withdrawal, although they ended up calling it a market withdrawal afterwards, because they said it wasn't the firm's fault.

RTO: Well, let's back up a little bit before we got to Tylenol, because under recalls, the agency has no authority, or had no authority, other than to recall, and there were degrees of the seriousness, and that would dictate the amount of follow-up you had to do, and the effectiveness changes.

IW: Yes. The three levels, Level One, Two and Three, which is still used today in the system. It's exactly the same thing. A Level One recall would involve the product that could cause death or permanent damage. A Level Two was, of course, reversible. A Level Three recall was a product that really wouldn't hurt anybody. It could be a labeling problem or it could be a filth problem that was not a danger to health.

RTO: Now, a Class One recall required 100 percent.

IW: A hundred percent review. I think it's still the same way today, with Class One, 100 percent effectiveness checks to make sure that all of it is off the market. Back before Tylenol, we were involved in tuna fish for botulism, and Bon Vivant soups. Bon Vivant soups, of course, was a recall that FDA actually had to take over because the company folded. That was also botulism. Those were all Class One recalls.

RTO: Do you recall what the problem was with Bon Vivant?

IW: Yes. It was underprocessing of the vichyssoise, and we found viable botulism in some cans of soup, not a lot.

RTO: Did that cause a death before it was pulled?

IW: I'm not sure. I know there was illness, but I'm not sure if there was death. I just don't remember anymore, to be honest.

RTO: Then we had mushrooms.

IW: Yes. That one was a result of a change in the process. They had come up with a new way to fill the cans. They used to hand-fill all the cans of mushrooms, and they came up with this new method where they used a machine to fill the cans and the sliced mushrooms and stuff, and the one thing they weren't controlling was how much mushrooms was going into the can, so if there was too much mushroom, there wasn't enough liquid to properly transmit the heat through the can, so you ended up with a botulism problem.

RTO: Was this kind of on a shaker thing?

IW: It was a tumbler. It would go through a kind of circular tumbler, and it would get filled up like that, and it would be shook at the same time, so that they got more into it.

The control mechanism that they weren't using was how much solid mushroom material was in it, the drained weight. At that time we had food standards for canned mushrooms, and had a minimum standard of fill, but there was no maximum, and the control mechanism to prevent the botulism would be the maximum drained weight.

RTO: This was mostly domestic mushrooms.

IW: Yes.

RTO: Did we have any problems with imported mushrooms?

IW: At that particular time, no, because at that time we weren't bringing a lot of mushrooms in. It wasn't until later on when we started bringing in Chinese mushrooms that we had the different kind of problem, which still exists today, of staph enterotoxin in the mushrooms, and that was because of the process that they use. They brine the mushrooms in a saturated brine solution to preserve them long enough to get them from where they're grown to the canneries, and sometimes they'd be in there for several days. Then they would wash the salt out, but that permitted the staph organism to grow and produce toxin, which is not destroyed by heat. So it was a different kind of problems with the mushrooms. But the original mushroom was the sliced mushrooms and most of it was going to pizza, especially in the No. 10 cans.

RTO: So it wasn't in a commercially—

IW: We didn't see it in the small cans. We saw it in the No. 10's. Again, this is a typical thing. The process is improved, and they don't think all the way through on the so-called improvement.

RAT: Wasn't there a number of different recalls, not just Tylenol?

IW: After the Tylenol thing, there was the extortions, which started in New Jersey, and that involved Kitchen Bouquet. Do you remember that one? The Kitchen Bouquet gravy mix, where the fellow put nicotine sulfite, I think it was, in the bottles, marked the bottoms of the bottles, put them in stores, and then sent a letter extorting money, and told us where we could find one of them. We found it. It was nicotine sulfite, like he said. That's when the FBI got involved.

That was before the Tampering Act. So, that's why the Tampering Act, when enacted, included extortion. It includes extortion, but in the Kitchen Bouquet case, the FBI was able to get involved in it under one of the other laws about extortion, because they were extorting money from a grocery chain.

RTO: Do you recall the year of enactment of the Anti-Tampering Act?

IW: No, I don't. For the longest time, I kept a copy of the act itself.

I remember working on that stuff, too. With the Tylenol, the original Tylenol one from Chicago, we went on twenty-four-hour duty.

RAT: One of the commissioners that seemed to have a very active interest in this whole area was Dr. Frank Young. Is that correct?

IW: Oh, yes. He spent a lot of time down here on the thirteenth floor, because we have been in that same space from the time I reported to that division in '81, until very recently, when we built a new emergency center for the agency on the twelfth floor. We were in that same space all that time. Dr. Young spent a tremendous amount of time down there with us during those emergencies. He's very, very active in the agency's emergency ops.

RAT: More so than any of the other commissioners?

IW: Absolutely. Much more so than any of the others. Very, very active. Of course, he went on to be the emergency coordinator of PHS [Public Health Service], but he was very, very active in it.

One of the other jobs that we had that I remember was the civil defense program. I was in the relocation cadre, at the alternate site. I didn't go to the mountains, but I did go to the mountain with Remele and Pete Cifala to restock and stuff. We would restock, if you want to call it that, bring the manuals up to date that were there, and that sort of thing.

RAT: Is that still active? I don't mean the site, but I mean the function part of it.

IW: I don't know. It was kind of tenuous a couple of years ago. There was still some activity, because I know that Gary Pierce used to go to meetings downtown at the Department of Energy, on strategic materials. At one time, I had a top-secret clearance, but they downgraded it to secret because of costs, and the only one who had the top-secret clearance in a division was the division chief, but that was fine.

RTO: What year was it that they pulled the recall function out and put it into Compliance?

*IW: I'm trying to think when that was. It was when they were reorganizing DFI, and they merged DEEO in with DFI and made it DEIO [Division of Emergency & Investigational Operations]. So, that would be, I don't know, seven or eight years ago.

RTO: Probably about '87, '88 something like that.

IW: Right. Somewhere in there. I took home all my SF-50s, so I can't go look at them anymore. I've got them at home, but I've kept every SF-50 that had ever been issued to me, so it shows my reassignments to all the different places.

But, yes, they merged us back into DFI and they took the recall operation and moved it over to OE [Office of Enforcement], where it's remained ever since. In effect, that hurt the response time from the agency on emergencies by physically separating us so far, because a lot of times, information that came to our attention, either came to our

attention because of a recall announcement or a recall was started because of something that came to us.

RTO: Where do you think the impetus for that change came from? Was it from the top level or mid level?

IW: I believe it was because in order to support the office structure that they needed over in OE to make it an office, they had to put some more people into it, so they moved a function that was related to Compliance over to them. But, in effect, it damaged the efficiency of the operations. That's my personal opinion.

RAT: What's your feeling about why, at some times, a recall pended for a whole week before the agency decided, "Hey, we need to do something about this"?

IW: Well, I think part of that was how slow it was for us getting information. They didn't have to tell us about a recall. They didn't have to tell us, period. They just didn't have to tell us. We still today, I think, discover recalls that took place two and three years ago. I think it's crazy that we publish them two or three years later, but I also think it's our fault when we used to sometimes take a month to make a decision on the class of recall. That's not very efficient, and it just confuses the public.

RTO: I remember Frank Young telling us that usually Friday afternoon—

IW: It was always three o'clock. Three o'clock. It had to be three o'clock. They wouldn't wait till four-thirty. They would wait till three o'clock, and then they would tell us, and then till it filtered down from the district to here and everything, was about four o'clock.

RAT: Now, the grape issue, that was one that was turned around pretty fast, wasn't it, decision-wise?

IW: Oh, yes.

RAT: Chilean grapes.

IW: That was the threat of cyanide in the grapes. That was, again, terrorism involving Chile. We started examining grapes in Philadelphia. Luckily, almost all the grapes came through Philadelphia. It was kind of that single port kind of thing, so we were examining the stuff and supposedly we found a few that contained cyanide. There was a lot of controversy about that, but the key was, there was a total embargo. If it didn't go through and get examined; it didn't come into the country. There was controversy over whether or not we really did find cyanide in them, but, hey, we said we did. That was it.

RAT: Well, that was one, I think, where Dr. Young was very much involved in that debate and reaction there.

IW: Yes. One of the other cyanide problems was out in Seattle, again, Tylenol, a lady trying to get rid of her husband, and to try and hide it, she put a few bottles of Tylenol back out on shelves. She's serving a life sentence, I guess. I know that she recently appealed.

RTO: The FBI would have been involved in that one.

IW: Yes. And as a result of those things, Congress passed the Anti-Tampering Act, and if you look at it, the Anti-Tampering Act covers everything that we had experience with, the extortion things, and for a while, there was a rash of innocuous tamperings, if you want to call it that. They included those in the bill, too. That was an all-encompassing law.

RAT: Did criminal investigators, the establishment of that unit, did that cadre have any impact on what DFI does?

IW: At that time, when they first were established, we were told that they would be involved in the tamperings, and we would refer, anytime we did some follow-up, anybody in the field who thought it was a tampering, we'd turn it over to them. Now, it's more selective. They still do some follow-up on tampering, but sometimes they just say "No, it's not significant enough. Let you do it."

I remember I got a complaint that involved tampering. I was the late-duty person, and this lady called in, a local call from here, about her husband, who had a Pepsi, and he

got sick after drinking it, and she kind of described the symptoms and everything. It made the back of my hair—I had a little more hair then—I wore it longer, not that I had more on top, but I wore it longer; anyway, it made the hair on the back of my neck stand up, because it sounded just like cyanide poisoning. I called it in to Baltimore right away. They did some follow-up work. The man was truly lucky. There was enough cyanide in that stuff to kill not just him, but a battalion of people, and it turned out she was trying to kill him, an economical divorce. He was a uniformed Secret Service officer for the White House, and she had done it. We had gotten started in it and everything, and I guess OCI [Office of Criminal Investigations] got involved with it, I'm not sure. But, strange.

RAT: Hasn't it kind of tapered off, though? We haven't had any recently.

IW: I'm not aware of any significant tamperings have recently happened. There's an occasional thing, you know, where somebody makes a threat in a store or something. For a while, AIDS, injecting blood into meat and stuff like that or into vegetables, or somebody would find some produce with some holes in them.

For a while there, everybody expected everything to be literally perfect. You picked up a peach and it had to look beautiful and stuff. Those days are starting to go away again. People are starting to realize that there is some natural variety or variation in products and stuff, so it doesn't seem to be so bad. At that time, there was terrible heightened sensitivity to the quality of product, so that's changed quite a bit. Now I think

they're more worried about, like with meat, they're worried about foodborne illness now, which is nothing new. It's just that we're noticing it now, literally.

RTO: Is the detection getting better?

IW: Yes, they are. Definitely. The methods of detection are getting better, and the physicians are no longer brushing this stuff off as innocuous. I remember in some of the early follow-up work that we were doing on listeria, we got some reports, and I asked the district to follow up on some reports of miscarriages caused by products. With one of them, we asked the physician if he would retest the mother, the blood, if he would draw samples so we could see if she had suffered from listeria. She had had a miscarriage. He refused to because he said she had enough trauma. She doesn't need to have this.

So, early on, doctors just didn't think that foodborne illness was very important. You had the shits, and that was it, it went away, or you threw up a lot, and it went away. Once they started discovering there were other problems associated with it, like the arthritis and that kind of thing, then they started to take it a little more seriously, and then, of course, CDC was doing much more. They were getting much more active in raising sensitivity, and then, of course, President [William Jefferson "Bill"] Clinton and his program of trying to improve the safety of food, and that has to be because of the lobbying, if you want to call it that, of CDC to try and fix that.

RAT: Is the FDA involved at all in these illnesses aboard these cruise ships, or is that primarily CDC?

IW: It's CDC, because they're all foreign flag, and under our agreement, if it's a foreign flag vessel, CDC does it. If it's American flag, we do it, and really, the only American flag cruise ships there are operate out in Hawaii. That's the only American flag cruise company that exists.

RTO: In the current climate of sensitivity to terrorism and so on, are there any initiatives under way to sharpen surveillance, foods, and so on?

IW: Well, certainly the terrorism bill. We hired 600 investigators to do import work, and Congress is asking us to quadruple our examinations of products coming in the country.

The law also, if CFSAN [Center for Food Safety & Nutrition] ever gets around to writing its regulations, has given us authority for detention of foods and drugs, not just medical devices and infant formula, has required registration of all manufacturers of foods, domestic and foreign, if they're going to sell to this country.

RTO: This is under the terrorism bill?

IW: Not the bill setting up the Department of Homeland Security.

RTO: The earlier one?

IW: It's the earlier one, yes. It has established that they have to give us notice ahead of time when a shipment is coming. They have to tell us who the manufacturer was, not just who's bringing it into the country. They have to tell us who the actual manufacturer is, and if they're not registered, it doesn't come into the country. Also giving us authority to, if we refuse the product, to mark the cases "Refused by FDA." All that has to fall into place.

We were given authority, not with this bill, but earlier, for civil penalties on foods, which we've never done, because we haven't issued the regulations yet, but we have done it on drugs. Those regulations are in place, so, yes, there's definitely increased sensitivity. In fact, Congress has told us, "We want you to do a lot more foreign inspections."

RAT: How many foreign inspections is FDA making now?

IW: We've been running around 1,200 a year. This past year, we didn't make as many, because for a while we shut down the inspection program because of the threats overseas. We've actually developed a procedure now. For example, we didn't make inspections in Israel for quite some time, and we've developed a procedure that we tested in Israel. We've made three inspection trips to Israel now in the past three or four months. Requires a lot of security. We work through the embassy, and the companies who are insisting on the inspections have to pay for the security, and it's twenty-four-hour security. We work with the embassy, too, and if the plant is located in a site that the embassy doesn't think is safe, we don't do it.

RTO: Then they can't ship.

IW: Right. They can't ship.

[Begin Tape 2, Side A]

IW: Again, there's been a significant change. Of course, we keep hearing over and over again about how vulnerable our agricultural production is in the United States. CFSAN came out with an advisory, if you want to call it that, because we don't have any authority to order plants to do security, other than advisory over how to look at security from their facilities, control who comes in and all that, like the drug firms have been doing for a long time. But we have drug firms that don't have very good security, either, any more than we have decent security in our own district offices.

RTO: Tell us a little bit about the change in DFI since they pulled the emergency operation.

IW: Basically what literally happened, when they merged the emergency operation into DFI, the investigations portion of the operation got slighted because of the emergency function, which was so big. Part of that merger was, again, to save bodies, so what happened was we focused a lot more on emergencies than on the investigational stuff. Once they pulled the emergencies back out of DFI, and I didn't go over with emergencies

at that time. Thankfully, I stayed with DFI. What happened was, we were able to focus back in on the things we had to do to support the investigators. Things that had to have been done all along during that period of time just got put to the side because of emergencies that kept coming up. I will say the field investigators were slighted. They were not getting the support in headquarters they needed to have.

By pulling emergencies back out, I know they really didn't want to do that, but by doing it, it enabled the Division of Field Investigations to focus on its customers again, and that is the investigators.

RTO: Did DFI get some positions when they pulled the emergency operations out?

IW: Yes, they got more positions. They got more positions simply because—well, we got a bunch of positions to start with before the terrorism thing. We got a few. Because they recognized we had fallen behind so much, we had so much to do and we were short-handed, and there were a number of retirements taking place. We were losing a lot of institutional knowledge. We just needed more people to do the job.

For example, during the period when we were merged, we were not able to keep the IOM [Inspector's Operations Manual] current. Remember, there was a commitment made that we would get away from the constant updates that we were doing, and we would quarterly update the IOM on to the web and we would publish it once a year. Well, those quarterly updates weren't taking place. The annual IOM was late in being issued. You know, this is a fact of life. This is what happened.

It looks like this year we're going to get the IOM done. We have made some quarterly updates, so it's falling back into place. We're starting to again support the operations of the investigators, and the investigators now have somebody at headquarters to stand up for them, if you want to say that. So, yes, it's made a difference pulling that back out.

RTO: You've served under a number of commissioners, I guess maybe more than one even in the era of your experience in emergency operations. Have you seen differences in top-level attention to this kind of activity in the agency. Dr. Young, of course, was strong.

IW: Right. But even before, for example, Dr. [James] Goddard, who was our first politically appointed commissioner, he wasn't in our faces much. He realized the importance of getting information in an emergency alerts.

RTO: His CDC experience probably fostered that.

IW: Right. There was one or two who were just—if we sent something up, okay, but they were standoffish. They never said, "Don't do it." It's just that some were much less involved in it. I think probably the one I would think the least of was [Herb] Ley. I think he was the least.

RTO: He had a lot of drug orientation in the agency.

Weitzman: Right. But even before, for example, Dr. [James] Goddard, who was our first appointed commissioner, he wasn't in our faces much. He realized the importance of getting information in an emergency alerts.

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Ottes: He had a lot of drug orientation in the agency.

Weitzman: Oh, yes. Oh, yes. But I think he was the least. And who was the one that went to Stanford [University]?

Tucker: [Donald] Kennedy. And then there was [Jere] Goyan.

Tucker: [Arthur] Hayes.

Weitzman: Yes. Hayes. Hayes was another one that wasn't right in there all the time. Most of them were appreciative of the work.

IW: Well, there was [Sam] Fine. He was ACRA.

RAT: He was associate commissioner.

IW: Before the merger. Right. Before they wiped out the EDRO. He was there. I remember when they wiped out EDRO. I keep drawing a mental blank on him—before John Taylor I. You know who I mean.

RAT: Yes.

IW: I draw a blank on him all the time. He was a very active ACRA. I thoroughly enjoyed working for Mr. Healton as the EDRO. I thought he was a great supervisor. He let you do your job. The next one was—

RAT: [Ronald] Chesemore.

IW: No. Before Chesemore, the ACRA. Chesemore followed Hile. What I didn't like about very active Mr. Hile was that at times he would change something without telling you, and then would say, "I never said that," when you were doing the other thing. I didn't care that he changed it, but at least that he be honest about changing it. Tell us. That was the one thing about him.

John Taylor I was a very, very strong individual. I knew him from Chicago. When I was in Chicago, he was the chief chemist, and I remember when he came into Chicago as the chief chemist. He made the chemists be professional and come in to work with ties and shirts. I thought there was going to be an absolute rebellion there. You know what? He turned that lab around. Then he went to CFSAN and did a great job in CFSAN following Mr. Taylor Quinn. Then he came up here, and he continued to carry it through.

Then Mr. Chesemore. Chesemore, I don't think he did us real good, to put it bluntly. I think he was too much of a politician, literally. He didn't fight for the field organization, literally. That was my opinion of him.

I didn't have any problem working for him and doing things for him, but I just felt that there were times when he should have stood up for us and he didn't. That's my personal opinion. I don't know if you agree with it or not, but that's the way I felt. This John Taylor—

RAT: Well, there was one in between there. Dennis Baker.

IW: Yes. Dennis. He was like an absentee landlord. We literally never saw him. That's the only thing I can say.

RAT: Then, of course, there's John Taylor II.

IW: Yes. John Taylor II, and at this point I'm out of the loop.

RTO: The emergency operations, that's now reporting directly to the commissioner?

IW: To the deputy commissioner. The deputy commissioner has taken the emergency operations, the terrorism people here, whatever office that is, and put them all together in one unit that he's in charge of. Right now we're still supporting the emergency operations office, but they're on detail to the deputy commissioner and eventually will be transferred to him.

RTO: On detail now.

IW: Yes. They haven't officially been transferred out.

RTO: So the agency really hasn't set up this unit that's going to do the emergency operations.

IW: Well, in effect, the agency did when it established our emergency command center down there. In effect, they said ORA [Office of Regulatory Affairs] is going to take the lead. It's going to work in ORA, because they've always had to assign somebody from each of the centers to serve as the coordinator with the emergency operations. In the new center, of course, they put in spaces, actually offices for them. There's computers and everything. Whenever they're needed, they're brought in. Just like they did for the Y2K operation. They had somebody from each center assigned to the Y2K center.

RTO: So there is now in that operation somebody from each center that's physically transferred there.

IW: When they need it then.

RTO: On a call basis.

IW: Yes. There's an office for them there, and when they're needed, they're identified to go over there.

RTO: They have identified some person now that they can liaison with.

IW: Right.

RTO: It's not a "Today it's Joe, tomorrow it's Pete."

IW: No. When there's something going on, yes. But we still have the call-down list for like when you're on the late duty and you get the call. The physician needs an IND [investigational new drug], you have a call-down list. You find the right physician to call, and call them to call back to the doctor for the IND, and that kind of thing. That continues the way it is. Which way it's going to go, I don't know. I have no idea what [Lester] Crawford has in mind for them. I don't know if he was establishing a little

empire to keep himself here or not when they named a new commissioner. I've always been blunt-spoken, haven't I? [Laughs]

RTO: Yes, you have.

IW: But I have to admit one thing. I thoroughly enjoyed all the years I worked for the agency. I never could have lasted as long as I did if I didn't enjoy the work.

RAT: You made it interesting.

IW: Oh, well, thank you. Yes, it was interesting. It was very interesting work.

RTO: Now as you entertain retirement, are you thinking about doing anything further in the field on the outside?

IW: Yes. Well, actually, I've been working on personal safety for the investigators, and I've been working on developing policy and procedures for personal safety for the investigators, not from the standpoint of the machinery, but so we don't end up having what we had in USDA over in California, with their people getting killed, and our people the same thing.

So I've been taking part in this verbal judo personal situational planning course, where I talk about policy and procedures. I've also been leading a little group to develop the policy and procedures, which I just sent our draft to Dr. [Steven] Solomon for him to

clear. I've been talking about this in the courses we've given thus far, the four of them—Baltimore, New York, Buffalo, Boston, and New Jersey. I was scheduled originally to contract to continue to do that for the remainder of the year, but as it turns out, I'm not going to be doing that. The management of DFI's going to do it. I've been contracted by Gary German to continue to serve on the Level 1 certification board. I played a part in developing that.

RTO: Do they have Schedule C credentials anymore?

IW: No. Those have all been wiped. These went away a long time ago, years and years and years ago. There was absolutely no reason, really, to have a special credential. You've got a bunch of people who do that kind of work now, they don't have any different credentials. So that's what I'm going to do.

I also have a hobby; I repair clocks. Turns out that the town right next to Lancaster, Pennsylvania, that is, Columbia, which is the home office of the American Horological Society, and they have a clockmaking school. So I think I'm going to take some clockmaking courses there.

RTO: Should be interesting.

IW: Right. And there certainly are a lot of clocks up there in that part of the country.

RTO: Well, Irv, you got anything else to say or to add?

IW: Well, the only thing I'll say is that if it hadn't been for the variety of work and some of the crazy things that we did, I don't think I would have lasted as long as I did. This is, I think, a very exciting agency to work for, wonderful, wonderful people to work with. There were very few people I didn't get along with. I got to meet a lot of counterparts in the state and local governments and in other agencies, really nice people. Thoroughly enjoyed it.

RAT: Well, we want to thank you very much, Irv.

RTO: We appreciate the interview.

[End of interview]