History

of the

U. S. Food and Drug Administration

Interviewee: Edward Wojtowicz

Interviewer: Robert A. Tucker

Date: June 3, 1997

Place: Buffalo, New York

DEED OF GIFT

Agreement Pertaining to the Oral History Interview of

Edward Wojtowicz

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INTRODUCTION

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

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

CASSETTE NUMBER(S) 1

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

DATE: June 3, 1997 PLACE: Buffalo, N.Y. LENGTH: 55 minutes

INTERVIEWEE	INTERVIEWER
NAME: Edward Wojtowicz	NAME: Robert A. Tucker
ADDRESS: [redacted]	ADDRESS: 5600 Fishers Lane
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FDA SERVICE DATES: FROM: June, 1962 TO: September 3, 1997

TITLE: Analytical Chemist - Buffalo District
(Last FDA position)

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RT: Today, another of the series of FDA oral interviews for the history program is being conducted with Mr. Edward Wojtowicz, who retired on September 3, 1996 as an analytical chemist, Buffalo District. The interview is taking place at Mr. Wojtowicz's home in Lancaster, New York, and the date is June 3, 1997. Robert Tucker is here with Mr. Wojtowicz conducting the interview.

Ed, we usually like to begin these interviews with a brief autobiographical sketch as to where you were born, educated, and any experience in your field that you might have had prior to joining the Food and Drug Administration. So if you could kind of begin that way, we can proceed now.

EW: OK. I was born in 1939 in Buffalo, New York. I went through school in Depew, New York, high school, Depew High. I graduated from the University of Buffalo with a degree in chemistry in June of 1961. I had one terrific summer where I wasn't employed, played a lot of golf. In June of '62, the FDA hired me. I started working at what used to be the Old Post Office Building in downtown Buffalo. Right now it's home to the Erie County Community College.

We moved into our new building in 1963, I believe. That was the summer of '63. So I had a short tenure in the Post Office Building, which was somewhat interrupted, because I went into the service for six months in the active reserves in February of '63. When I had come back, we were into the new building, and part of my first test in the new building was putting together shelves for the solvent room, for the chemical room, kind of emptying all the boxes that were brought over from the old post office building.

RT: So when you joined the agency, Ed, did you come in as a chemist trainee or what was the job?

EW: Right. As a GS-5, making a total of I think it was $5,300 a year. It was amazing to make a hundred dollars a week back then and still have money left over at the next pay period, living home with mother and dad, no less. That was a nice way to do it.

RT: OK. Well, I noticed in the notice of your retirement that you were a part of the, I think they put it, the class of 1962. And I think it further related that you had participated in the early IDIP investigator chemist team effort. That was during the time of Commissioner James Goddard's tenure. So would you like to tell us a little bit about what that program was and your involvement in it?

EW: I think it was the first attempt at mixing together in the field--I'll actually say the manufacturing end of it--the chemist and the inspector. I know I participated in some training sessions where I gave instructions to the inspectors--they weren't investigators back then, they were inspectors--in some kinds of things like statistics, some analytical chemical procedures that we might see in a lab, things like that.

RT: Now, just for those that may be reviewing this record, as researchers in the future, the acronym IDIP stands for . . .

EW: Intensified Drug Inspection Program. You didn't think I'd know that. (Laughter)

RT: Now, you were working with investigators as a chemist, both disciplines going to plants, wasn't that the idea? And conducting very thorough and I suspect protracted-type inspections, not the previous in-and-out-type things. Is that correct that you spent some time there?

EW: Right. I think looking more toward the laboratory end of the manufacturers' operations, just making sure that, say, the methodology they were using was correct, that the recording of their data and results of their tests were done accurately.

RT: Now, at that period of time, who was the district director? Was that Allen Retzlaff?

EW: Either Mr. Retzlaff or Mr. Joiner, Curtis Joiner.

RT: Curtis Joiner. Yes, that's possible. And your chief chemist then, head of the staff that you were working with, do you recall who that might have been?

EW: Well, I know originally when I came in it was Granville Q. Lipscomb, Dr. Lipscomb, and then he was replaced by Felix Sabitino.

RT: Now, Dr. Lipscomb, of course, later was in headquarters.

EW: He went to Washington, right.

RT: And tragically was killed on the way home from the Dulles Airport after returning from a field trip for FDA.

Now, during those years as chemist, did you also get involved in some referee, perhaps AOAC (Association of Official Analytical Chemists) referee activities?

EW: Originally, I was sort of an analyst, a collaborative analyst, but then eventually I was able to do some research, and I was able to use some of the ideas I had to develop methods. So I developed a few methods that are in the *Book of Methods* now.

RT: Were you involved in analytical work with regard to pesticides? What was the kind of expertise that you worked in?

EW: Well, in the old days, you did a little bit of everything. Back then, our summers were mainly doing pesticide analytical work. So if you were part of the team . . . It was a team approach even back then, where you may be chopping up vegetables one day and then maybe filtering the next day or the next week, and then a week or so after that, you may be on the instruments themselves, you know, making the injections and doing the identification as to whether a pesticide was there or not.

RT: As I recall, you've spent about thirty-four years of your working career with FDA. Was all of that service at Buffalo, or did you work at other locations as well?

EW: No, I did everything at Buffalo District.

RT: I think the chemists were able, some of them, to serve longer at one place than some of the investigators staff. At least in earlier years they used to ship people around a lot, and that caused a lot of stress on the part of a lot of families.

EW: Right, that was before merit promotion. In those days, I guess basically you were told that your next paycheck was going to be in Cincinnati or St. Louis or whatever. You were somewhat obliged to be there.

RT: You would be there or not be with them anymore. That's what I've heard.

Well, during the course of your years, were there any particular regulatory problems or prosecutions that you were a part of?

EW: One of my first appearances in court was when we used to do BDAC work. BDAC was the Bureau of Dangerous Drugs and Narcotics. I believe that was the acronym.

RT: Bureau of Drug Abuse Control.

EW: Abuse, right. Exactly. I was able to go to Pittsburgh and testify against a doctor who was prescribing amphetamines above and beyond the doctor-patient relationship. I know we had vial after vial--two hundred, five hundred tablet vials in the laboratory, and we were building a case with the Justice Department against this doctor. Pittsburgh used to be in the Buffalo District many years ago, and what happened was that was subsequently given to Philadelphia, the entire state of Pennsylvania. So when I testified in Pittsburgh, that was when Buffalo District used go down to Pittsburgh.

(Interruption)

RT: You were mentioning how you were called as a witness in that particular legal matter, and as I understand, you've been an expert witness, scientific witness, in some other matters. Do any of those come to mind? Like the apple juice adulteration case that was tried up here in your district?

EW: Yes, I consider the Beech Nut case probably the highlight of my career. That involved a huge amount of money in terms of the juice that was produced and the fraud that was being perpetrated by this huge company, which everyone would assume would be on the up and up.

It basically started out, if you really want to get to the root of it, through a consumer complaint. A lady had tasted her child's apple juice prior to feeding it to her

baby, and it just didn't taste right to her. She made a complaint to the State of New York, who subsequently then they told FDA about it, and with investigations and sample collections, we did find that the juice was in fact adulterated.

RT: What was the adulterant, or how did it fail to meet the standard?

EW: Well, there really is no standard for apple juice. Up until that time, probably even now, there isn't what we would call a standard. There were some constants that were promulgated by a chemist named Allen Brause, Dr. Brause, and the original article by him and another person named Ratterman. They propounded certain constants like the ratio of fructose to glucose had to be greater than 1.6. Malic acid had to be in a certain range. There should be little, if any, citric acid present. Sorbic acid also is to be absent or at very small amounts.

RT: Now, this researcher, was he in FDA?

EW: No, he was in industry. He was working for a big food company in Ohio--Kroger. He had written an article that was published in the Journal of the AOAC (Journal of Association of Official Analytical Chemists), and it was sort of our bible if you will. We were working on using those numbers to guide us in any regulatory action we would take.

The juice that we had tested was being made by dilution of a concentrate which is perfectly legal as long as it's from apples. So the juice that was being diluted was made from a concentrate from a company called Food Complex in Brooklyn. Food Complex, all they were doing was just putting chemicals together, malic acid, fructose, invert sugar, which is 50 percent fructose, 50 percent glucose. So see there, if you did the analysis, you'd find a one-to-one ratio of fructose to glucose.

Well, browsing around we found that it should be no less than one point six to one, plus the malic acid that's present should be all levorotatory. In nature, only the L isomer, the levorotatory isomer of malic acid is produced. So if you were test the apple juice, you would find a one-to-one ratio of D, which is the dextrorotatory of the right hand isomer to the left hand isomer. So this means that possibly what they did use was just synthetic malic acid, which is why when it's produced, you get a fifty-fifty mixture of the D and the L isomer, where when nature makes malic acid, it's nothing but the L isomer.

RT: Of course, the substitution of these ingredients was a misbranding or adulteration. Was that prompted by cost factors? Were these added ingredients considerably less costly than to buy the real juice?

EW: Well, it was less costly to the company who was doing the dilution, who was making the apple juice, because the concentrate that Food Complex was selling was somewhere about a dollar or dollar and a half cheaper per gallon than bona fide apple concentrate.

RT: Now as far as the Beech Nut Company, were they also getting a rip off, so to speak, on that? In other words, were they also making an improper profit? Or was it the prime suppliers that were making the rip off?

EW: I think everybody. The Beech Nut Company was buying concentrate from Food Complex, the same company that was providing this small juice manufacturer in upper New York with his concentrate. So in tracing back . . .

There was a detective . . . Let me . . . Another aside, there was a detective hired by the Apple Process Institute--which is a group of apple juice producing

companies, legitimate companies, who were investigating Food Complex--and this detective found bags from malic acid, synthetic malic acid. He found bags from this invert sugar in the dumpster of Food Complex. What he did is he traced . . . He followed a truck that was hauling this concentrate, and where did they take it but to Beech Nut in Canajoharie, New York. So at the time, this technology for analysis of apple juice was somewhat new, and it was Beech Nut's contention in court that they were not apprised of this technology, that they didn't know how to test the concentrate to see if it was bona fide or not.

There was a person inside Beech Nut who sort of blew the whistle on Beech Nut, and he sent a letter to FDA. He called himself Johnny Appleseed, and he was actually a guy named (John) Lavery. I think that was his name. Anyway, he had quite a high position in their quality control department, and Beech Nut knew about these methods and, in fact, were, according to him, employing them, and they knew that the concentrate they were buying was not a good one. But because of the cost factor, say a dollar and a half less per gallon, when you multiple that by say millions of gallons that Beech Nut would purchase or would make from this concentrate, it turned out to be quite a profit.

RT: Now, of course, you were there as an expert witness from the analytical side. The investigative staff of FDA had also done some work similar to this detective's work. Is that correct?

EW: Oh, yes, they had done quite a bit of work, because they wound up tracing some of the shipments that Beech Nut was sending out. Beech Nut had tried to ship some of this stuff to I believe it was the Dominican Republic just to get it out of the country, and I think it was through the investigational branch, the Dominican Republic was notified of this shipment coming in, and they refused entry. So Beech Nut had to turn around

and bring that back. The investigators did a lot of sampling of the finished product; they did a lot of tracing as to where the product was going. I guess, Beech Nut was apprised that the State of New York was going to embargo a lot of their product. So what they did was they put it on trucks and shipped it out of state. I think they took it to New Jersey. But FDA was waiting in New Jersey for it, so they just couldn't hide this stuff.

RT: Now was that a rather long, in terms of time, case in developing and prosecuting, or did it move pretty quickly?

EW: Well, I think we were able to show that Beech Nut had been employing this concentrate, I think it was from about 1978 to about 1982 or '83. We got involved, and we told them to quit using it or we apprised them that it was nothing but a fraudulent mixture of chemicals. So that was '83. The case finally went to court . . . I testified in December of '87, so it took a while.

RT: What was the outcome, what happened as a result of this prosecution?

EW: Well, Beech Nut, the company itself, was then owned by Nestle, and what Nestle did was they paid I think it was like a $2 million fine or payment anyway to the United States Government, to FDA. They just pleaded nolo contendere, I believe.

RT: That was probably one of the larger fines ever paid by a food manufacturer, wasn't it?

EW: I think up until then, yes, I think it was. They paid . . . In addition to that, they paid like about $140,000 in investigational and analytical costs, too. What FDA was

trying to do was to go after the individuals involved, the head of the Canajoharie plant and I believe one of the vice presidents of the company, who had complete knowledge of this fraud that was going on. I believe that they were sentenced to . . . Originally they were sentenced to a year and a day in jail, to serve hard jail time, plus fines brought on appeal, and there was some question as to whether the venue where the case was tried was really the correct one. It all boiled down to, I believe, was just Nestle, a plea bargain type of thing, where the two individuals paid fines and performed community service for it. But the sting of the trial and the fines and all, it eventually, I believe, it just ended their careers.

RT: It was certainly quite an achievement enforcement-wise to have brought that all to fruition.

Well, that was a pretty good overview of the Beech Nut case. I think you may have worked in some other areas that were regulatory in nature. What were some of those, Ed?

EW: I did testify in Buffalo against, believe it or not, a body builder who was importing, if you will, anabolic steroids. He had a mailbox in Niagara Falls, New York. He was a Canadian citizen. What he was doing, he was coming across the border to pick up material at his mailbox here in the States. One time a shipment came in that was labeled pottery, and unfortunately the box developed a split, and the postal inspector or whoever at the post office was able to look inside the box because of the breakage in the inside of the box and noticed that it was kind of chock-full of little drug items. So it turned out that the drugs were anabolic steroids, which are sort of commonly used in saving you time and effort in terms of doing exercising to build up your muscle. The anabolic steroid will do that for you.

So what was done was that the box was sealed, and there was a phone number that they called, and they told the person there that the box was too big to put into his mailbox and someone would have to come and personally pick it up. So what this person did is he sent his girlfriend over to pick it up. And when she picked it up and took it out of the post office, I guess he was waiting for her in the car, and they arrested both of them for possession of these anabolic steroids. Basically a smuggling charge.

That turned out it went to court, and this person had just started in the body building field, and he was doing quite well. He had . . . Being a rookie, he had already won I think a couple of shows. So to him it was good money to be able to win these shows, and being a Canadian citizen . . . The outcome of the trial was that being a Canadian citizen, the judge said he was not allowed to come into the United States for a whole year. His punishment was a $250 fine, but the bigger punishment was that he was not allowed to come into the United States for a whole year. So this would deprive him of showing his physique at these different shows that were here in the States. That would probably mean quite a loss of income then.

It was interesting that the testimony involved methods, methods that were, say, in the USP, and how valid they were, they were clearly studied, and all that. The analytical part was quite solid. So it didn't take too long before the jury brought in a guilty verdict against him and his girlfriend.

RT: So it was primarily based on the evidence through the laboratory or the analytical work of the laboratory that clinched that case. Is that correct?

EW: Well, that and . . . I forget the person's name. Came in from Maryland. He was a criminal investigator, and he helped in establishing, to the jury's knowledge, increasing their knowledge in terms of how severe these anabolic steroids are. Because

he certainly couldn't use all of them that he had smuggled in. What he was probably doing was selling them.

RT: Was there any effort to trace to whom these were being sold, such as, you know, adolescents and so on?

EW: No, not from that case, because those samples were just impounded that day. They were seized. He didn't get possession of them.

Previous to this, he had come into the country . . . He landed I believe it was in Philadelphia, and he had quite a few anabolic steroids with him. But he had a prescription that a doctor had issued in Germany where he had gone to a show in Germany, and since he had the prescription covering these anabolic steroids, since they were legal in Germany, the authorities in Philadelphia just let him go. But it was interesting that he was having them mailed to him here in Niagara Falls, New York, and then picking them up by coming across the border from Niagara Falls, Ontario.

RT: Let's see. Did we say who that individual was and what that action, and how that action was identified, the importer, that is?

EW: It's a smuggling charge.

RT: Yes.

EW: It was a smuggling charge.

RT: And who was the individual that was . . . ?

EW: His name was Nimrod King.

RT: OK. That's what I wanted. I didn't think we'd really mentioned that.

EW: I didn't think you wanted me to.

RT: That's okay, because it's in the public record.

EW: That's part of the record, yes.

RT: Yes.

Okay, Ed, that was certainly a different turn in the work. Were there some other directions that your career took you?

EW: Well, from apple juice to anabolic steroids, olive oil was somewhat my next area of interest. I was sent to Winchester to be trained by a gentleman named Bob Reina in olive oil analysis, and I spent two weeks there. The training was very good, because we, in Buffalo at that time, were getting quite a few shipments of olive oil across the border, and without anyone in the laboratory capable of doing the analysis, most of those either were sent to Mr. Reina in Winchester or to possibly New York City for analysis. So after two weeks and some great training, I was the expert, so to speak, here in Buffalo. So they gave me quite a few samples to analyze.

Most of the time the oils were as labeled, as olive oil. But there was one importation that turned out to be mainly soybean oil, but it was labeled as extra virgin oil. So there are two tests that you do for olive oil: you do a methylation where you determine the methyl esters, and a second determination is one of looking for the amount and identification of sterols that are present.

Well, neither one of these tests confirmed olive oil as being present, but the company was quite adamant. They said that they had an analytical certificate from a laboratory in Italy that this was olive oil, and the sterol content and methyl esters were identified as those that you'd find in olive oil. So the company, the importer, was a company in Utica. They had their own lab do the analysis. They found a lab to do the analysis, and as it turned out the lab came to us to ask us what the method of analysis was for olive oil because they weren't familiar. So apprising them of what I did, the company performed the analysis, and they basically confirmed my analysis that the product was mostly soybean oil, not olive oil. So this was quite significant since it comprised almost $40,000 worth of oil. So that was another little aspect of my career with FDA.

RT: Now, as you worked in these various problems, analytical problems, did you work with counterparts in state laboratories or were the operations that we're talking about primarily federal actions?

EW: No, most of my work just about, just FDA regulatory actions.

We did . . . Well, in the case of some anabolic steroids, I did do some work for the New York State Police, and that . . . I never did testify in that. I just sort of did confirmatory testing.

I did do . . . Another aspect was consumer complaints.

RT: Well, with regard to consumer complaints, Ed, I think often one thinks of that being an area of the investigators' work. So perhaps you can enlighten us on the way that the chemist or the laboratory scientist becomes involved in consumer complaints.

EW: Well, I think the investigators . . .

(Interruption)

RT: All right, Ed. I think we're on again.

EW: Yes. The investigator currently picks up the sample, gets all the background information. I guess in the old days the investigator usually would handle the consumer complaint, and a lot of those would never make it into the laboratory. But I think FDA's feeling, anyway up until the time I worked there, was that the consumer complaint should go to the laboratory, and the analysts should take a look at it. So usually the complaint sample is picked up, and hopefully, say another sample from the same lot is also picked up, say at the convenience store or the supermarket or wherever the consumer bought their sample.

An interesting sample that I had was one of an orangeade drink. A lady complained that she had found some sewing needles in this bottle, a plastic bottle, a six-ounce, plastic-capped bottle of orangeade. And on getting a sample in the laboratory and comparing it to the follow-up sample that the investigator collected, I noticed that the consumer sample was much lighter in color, and on investigating the way that the sample was sealed, I found that I could take the sample seal off and put some paper clips into the bottle, recap it, and it would look as if no one had entered the sample at all. The sealing of the sample was very poor, because it looked as if no one had really tampered with it, and here we had a bottle that had not only needles in it, but some paper clips. So I suggested that the investigator go back to the complainant and inquire, because it was the complainant's son who brought the attention of his mother to the fact of these needles being in the orangeade.

Well, as it turned out, the investigator used his investigative techniques--I guess they give a course to the investigators on interrogation--and took the thirteen-year-old son aside, told him how severe the penalty might be if he didn't confess that he, in fact,

had opened the bottle, put the needles in just to scare his mother, and refilled what he had drunk out of the bottle with water. That's why the color was so light. And, in fact, that's what the case was. The son told our investigator that he had done this. But his mother had contacted the local police, who contacted the state police, who then contacted the FDA, and the matter sort of got out of hand, and he was sort of scared to admit that, in fact, he was the one who had tampered, if you will, with the product really just to scare his mother, and it had just gotten out of hand, and he . . . As I said, he was just afraid to admit that he was the culprit in this whole thing. So after a stern warning, I guess, from the police and from our investigator, the son promised not to do this again, not to scare his mother with this consumer complaint business.

Another sample that I worked on was a jar of instant coffee that had come into the laboratory, and underneath the paper seal, a teacher in the school had found a white powder inside of a plastic bag. Well, again this turned out to be nothing but flour, because I tested the product thinking that one of the students in the class had done this. I had done some testing to see if the flour was responsive to an iodine test, if it would turn blue, say, with the presence of iodine. I did some UV testing just to see if there were any drugs involved, because white powder one automatically thinks of cocaine or some sort of drug, maybe methamphetamine. Well, that turned out to go nowhere.

So what I had suggested is again that the investigator go back to the school and ask the teacher. And as it turned out, one of his students had done this as a prank, because his teacher had this bottle of instant coffee in his desk. So the student, again, to sort of scare the teacher, was able to take the paper lid off the top of the instant coffee, insert this plastic bag that had flour in it, and then reseal the sample and put it back into the teacher's desk.

But, again, the local police were involved, FDA was involved, and possibly a couple thousand dollars of investigative funding and analytical work, et cetera, you know, all this follow up to this consumer complaint that really didn't go anywhere.

RT: As you mentioned, these two were really instances of a deliberate or a prankish trick. Did you encounter in the consumer complaint area any problems that were not the result of the consumer end tampering? In other words, did you ever find evidence of problems in products that originated either in the manufacturer processing or distribution level?

EW: Very few times. Do you want to get . . . ? Do you want to get into this tragedy with the yogurt? Yes, we did . . . I did spend a weekend with three other analysts. We looked at over 3,000--I think it was 3,200--eight-ounce cartons of I think it was Kraft yogurt. We were looking for cyanide, because there was an individual who had consumed some yogurt, and it turned out that there was quite a bit of cyanide in the yogurt, the carton that this individual had eaten, and after spending a weekend looking at, like I said over 3,000 cartons trying to find cyanide, it turned out that the individual was a college student who had committed suicide. He was a chemistry student, and he had a part-time job in an analytical laboratory. The police, on searching his apartment, found a small jar of sodium cyanide, I believe it was.

And it turns out that his brother was also a college student, and since they were both of Oriental extraction, they think there's quite a bit of sibling rivalry among Orientals in terms of academic prowess. The brother had slightly better marks, and evidently, I think this person felt pressured by his parents to perform better than he was performing, even though he was carrying I think close to an "A" average. So I guess he just sort of felt up against it, and basically he just poisoned himself by taking this yogurt that he had laced with cyanide. But it turned out to be quite a bit of work for us, and once all the facts were in, it was a very questionable incident rather than something that should be considered a consumer complaint or tampering. There would likely be a larger amount of people affected than just this one individual.

RT: Well, Ed, during the rather extensive career you've had in the laboratory, would you go in a little bit to the differences in the actual work? At an earlier time, much of the work at the bench was I guess what you would call wet chemistry, and not so much of that is done now. Can you kind of speak to that, where the field has gone over the past thirty years or so that you've been working in it?

EW: Well, yes, instrumentation has greatly affected not only the speed, but the accuracy of results from the laboratory. As you said, when I first started, everything was, or a lot of the work was wet chemical. It was gravimetric analysis where you would weigh something say at the end, and the weight would determine potency or, say, whether it was within tolerances for pesticide or whatever. Titrations also were quite prevalent when I first started. But the swing has been to analytical procedures involving instrumentation, where the amount of sample that you use has gone, say, from gram amounts to milligram amounts.

Pesticides I remember . . . In the beginning, the tolerances were that if the peak didn't go off the scale, you didn't worry about it, so that we were basically looking like for DDT. So at seven parts per million, the peak was supposed to go off scale, and if it didn't go off scale, then the sample was in compliance. We didn't bother quantitating to actually come up with a definite number, even if it was, say, a half part per million where the tolerance was seven. So regulatory-wise, we have improved in terms of actually reporting how much we have now, rather than just saying, "OK. It's in compliance, because it isn't over the tolerance level."

RT: Well, that perhaps has also stimulated concern about the Delaney Amendment which prohibits any amount of a carcinogen in a food or drug product, and as instrumentation has become more sensitive, what wasn't detected at one time is now

detectable. Would you see that as another problem as far as that part of the law is concerned?

EW: Yes, I think that is. As you mentioned, we're down to a stage now where possibly you can even count molecules of, say, a pesticide with certainty that in fact this pesticide is present. So maybe when the Delaney Amendment was promulgated, the instrumentation wasn't as sensitive as it is now. So there has to be some sort of mitigation, I guess, involved in saying whether the product is violative or not, even though it has a pesticide or something in it that's not supposed to be there, where there is no tolerance for it.

RT: I believe the attorneys, the general counsel folks, had referred, and maybe the scientists too, to I think it's called the deminimus where you consider what the realistic adverse effects may be rather than just the presence of, in this case, a carcinogen. So that's one of the changes.

And, also, during the 1960s, Ed, I believe the agency's concept of laboratory work in the field was that each district should be sort of a full-service laboratory, whereas later as more attention was given to specialization of centralized lab functions, the full-service laboratory at every location has kind of been abandoned. The Centers for Excellence, isn't that what we kind of got pointing to? In that regard, do you have any thoughts about the advantages or disadvantages of this specialization in certain locations rather than having more full-service lab facilities in many places?

EW: Well, I think in the case of full service, I think a laboratory should have the capability of doing, say, all different kinds of analysis, even though it doesn't specialize. Let me go back. It should be capable of doing an analysis, even though it does specialize. Say, if a case came up, like a consumer complaint, where there might

be something of great importance, just a time lapse of, say, sending something to one of these centers may affect, say, somebody's life.

I know Buffalo District to me was sort of a boutique laboratory. We were almost capable of doing pretty much everything. We could do pesticide analysis. We did drug analysis. We had the capability. Everybody was trained in doing that. I always seemed to be getting the problems that, you know, all these consumer complaints were involved, the anabolic steroids. We were specialized in doing pesticide analysis, but we could also do different analyses based on, say, on need for that type of analysis, at that moment.

Centers for Excellence I think are great if you're doing surveys, where you go out and collect thousands of samples of, say, a particular type of drug or drugs, and the center is specialized in doing drug analysis. Buffalo District I know participated in surveys where fifteen hundred samples of apples, of pears were picked up, and we developed methods to look for pesticides on these crops. We were able to get the gamut of all pesticides that could be found on apples and pears. We did that over the course of . . . I think the year before I retired we had that survey, and we performed very well on that. Buffalo's always been a great center, if you will, for doing pesticide analysis, because we did have the knowledge. We had Ron Laski who was nationally recognized as a pesticide expert, and we had quite a crew of people who were trained to do the methods right from scratch, from doing the extractions to the final injection and quantitation of any particular pesticide that was present.

RT: Now, of course, along that same line, the agency currently has I think a 20-year laboratory restructuring plan which is impacting on some of the laboratories, including Buffalo. I think that plan calls for reduction of resources both in Buffalo and Chicago this year, with certain others to follow in various years through the year 2014. Do you have any reaction to that direction of the agency?

(Interruption)

EW: Well, I think the consolidation in someone's eyes was probably a great thing, but I think it's going to take a long time to get this thing to run smoothly. I think even now they're finding problems with the samples that Buffalo collects at the bridges, at the Peace Bridge or at the bridge at Lewiston which is next to Niagara Falls, in getting those samples to New York City and getting them analyzed. The whole idea was for New York to be one of these Centers of Excellence, but I don't think it's happening. I think the brokers are suffering, and I think, of course, directly then the consumer will suffer. Because Buffalo could do the analysis, even though it was a small laboratory. And I think the idea that samples could be transferred by plane or train or whatever and you get a turnaround time that would be acceptable in terms of consumer protection, I think it's going to take a long time for that thing to happen.

RT: Now one of the other changes that has occurred over the past number of years was, of course, the reconfiguration of the field generally. Originally, I think there were eighteen districts, and then they got down to regions, where a regional office managed or had oversight over several districts, and, of course, that's happened in the case of Buffalo in that there is more than one district under the Region II or Northeast Region, as it is called now, which is headquartered at New York City. Did this difference in management style create any particular problems in efficiency in coordination of chemistry and laboratory work, either between staff members of different districts or even within your own district, for example? Has that been a difficult thing to adjust to?

EW: No, I don't think so. I think we're sort of insulated from there. I know I never really got involved with that. My immediate contact was with either my supervisor or with a laboratory director. I think the next level of supervision above just the regular

bench chemist, I think, would probably be more involved in that. It just . . . It never bothered me. It never affected me.

RT: All right. Well, again, as you've just said, working at the field level, you may not have had as much contact with the commissioners or the top field managers. I just wondered if you recalled any particular period where we've had changes of top administrators. Changes of commissioners now are more frequent than in the past. Has that had an up or down effect as far as persons working at the bench are concerned? Are you kind of insulated from those kinds of things as well?

EW: I don't think . . . Myself, personally, I don't think I was really that affected by it. I was interested in knowing who our next commissioner was, if there was a new one coming in. We've had quite a few since I've been here. Dr. Kessler I think is probably the most dynamic of all the commissioners that I've worked under. He came to the field; we had a nice talk; he seemed very knowledgeable about what was going on. He seemed to want to get down to the--I hate to use the words "grass roots"--to the laboratory people, to the investigators, to talk one-on-one with them. He didn't seem to be reluctant in doing that. He may be reluctant in coming to Buffalo because of the weather, but other than that, I don't think . . .

RT: Well, as long as he doesn't come in the wintertime it wouldn't be bad.

EW: Right. I think he did come in June.

(Interruption)

RT: I think we have covered kind of a broad spectrum of work that you've done, and before we kind of close the interview, I'd like to ask you if you have some other thoughts about what you might like to add that we've either not well covered or possibly overlooked in the discussion today.

EW: Well, my main point will be one about this consolidation. I, myself, think that closing Buffalo District, closing Chicago, minimizing, say, Cincinnati's capabilities . . . I guess New Orleans is the next one to close. Winchester's duties will be minimized so that they'll just be doing device analysis. I think this is all against the whole idea of consumer protection.

It's probably, as I said, sort of like a pendulum. We swung one way, where the economies of getting rid of all these districts and all these people, forcing people to retire. I know the people who have retired after I left and when October came Buffalo District laboratory was closed, those people wish that they would still be working. We have lunches once a month, and we kind of go over all of this, and the point is that retirement was forced on them, that they didn't want this. People have left the agency; people have gone to other agencies. The economics of this whole matter may be one where the budget looks real good, but probably consumer protection will suffer as a result of it. Buffalo was always sort of a boutique laboratory, as I mentioned back. We could almost solve any problem, other than something that might be bacteriological or microbiological, because we don't have that capability. But it was a good pesticide laboratory.

We had an expert, Mr. Laski, who was forced to retire because of the closing. The capability of New York District is questionable in my regard, in terms of being able to handle the samples that Buffalo District could have analyzed if it were still open. Buffalo is a big port, probably . . . I think in our survey of trying to stay alive, we showed that it was the fourth largest port in the United States in terms of tonnage of

materials that crossed the border. So all these samples that are going to New York City, whether they are getting the same attention they would if Buffalo were still alive is questionable.

I don't know. I just feel that possibly down the road, we'll probably have another Project Hire. The FDA will be looking for more people to sort of fill the ranks of all of those of us who have left. But that's only something that time will tell. So if anything, that will be my prediction for the future. I know at the end of The McLaughlin Group they always ask for predictions. They never follow up to see if anybody was right. But if anybody in the future wants to follow up on this, why I predict that sooner or later, the FDA will be back at full force. In other words, fifteen, sixteen, seventeen district offices. We have maybe specialized laboratories, but at least laboratories that are capable of running the gamut, rather than, say just one specialty in terms of analytical capabilities. That's my prediction.

RT: I'll remember that. That's a prediction, and perhaps researchers who examine these interviews will be able to see if this prediction and others like it come to fruition.

We appreciate very much this opportunity to interview you, Ed. Thank you for it.