History

of the

U. S. Food and Drug Administration

Interviewee: Richard J. Ronk

Interviewer: Robert A. Tucker
Ronald T. Ottes

Date: May 10, 1995

Place: Rockville, MD

DEED OF GIFT

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Richard J. Ronk

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

CASSETTE NUMBER(S) 1,2,3

GENERAL TOPIC OF INTERVIEW: History of the Food & Drug Adm.

DATE: May 10, 1995 PLACE: Rockville, MD LENGTH: 160 min.

INTERVIEWEE	INTERVIEWER
NAME: Richard J. Ronk	NAME: Robert A. Tucker Ronald T. Ottes
ADDRESS [redacted]	ADDRESS: U.S. Food & Drug Adm. Rockville, MD 20857

FDA SERVICE DATES: FROM: 1961 TO: 1994

TITLE: Deputy Director, Center for Food Safety & Applied Nutrition
(Last FDA position)

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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.

RT: This is another of the interviews in the FDA oral history program. This morning, May 10, 1995, the interview is being held with Richard J. Ronk, retired deputy director, Center for Foods, Food and Drug Administration. The interview is being held in the Parklawn Building, Rockville, Maryland, and present in addition to Mr. Ronk is Ronald Ottes and Robert Tucker.

Richard, as we begin these interviews, we usually like to start with a brief resume of your personal life, where you were born, educated, and any positions you might have had prior to coming to the Food and Drug Administration, and then we can go on with your career track in the agency.

RR: Well, thank you for having me today. I appreciate the chance to do this, record some things that might have happened in my career. I was born in Omaha, Nebraska, in 1933, and went to school there, man and boy. I once thought that if I'd have paid five dollars a month into a retirement plan at Creighton University, I could have retired from Creighton University before I got out, because I went to St. Peters Grade School there, and then I went to Creighton Prep to high school, then I went to Creighton University as undergraduate, and then I went to Creighton University as a graduate student.

After I graduated from . . . I was raised by an aunt and uncle. My mother and father both died by the time I was nine years old, so I was on my way to Boys Town when my uncle decided that he would take me in and raise me as his own. So I was raised by an uncle, who was quite an inspiration to me in my life. He took on this new family when he was fifty-five years old. So I think back on that as a signal event in my life. He also saw that I got a good education. I went to Creighton Prep, a Catholic boys school, before he died.

After high school, I was employed by the post office. I was the first non-veteran hired by the Omaha post office after the Second World War. I was more than eleven years younger than the next youngest guy at the post office. I was kind of the kid on the job there. I worked for the post office nine years, six months, and

five days before I came to the Food and Drug Administration. I quit the post office on a Saturday and came to work on the next Monday at the Food and Drug Administration. I had no break in service, which ended up being the golden years; all of those years counted toward my retirement from the government. I ended up with forty-two years service, with nine years, almost ten years of that being at the post office.

The post office at that time also gave you the opportunity to get an education. I went to school in the daytime and worked at the post office full time at night. Looking back on it, it seems like it would have been quite a chore, sixteen-hour days, but it wasn't. It was a pleasure. I enjoyed it, and always enjoyed my work at the post office.

At the time I left the post office, I was offered the opportunity to stay there as a postal inspector. But I had trained to be a chemist by that time and wanted to pursue, of course, chemistry at the Food and Drug Administration. I was recruited by Mr. Allison, chief chemist in Kansas City, who was the prime recruiter of Food and Drug people at that time. This was in 1961, and there was quite an expansion of the Food and Drug Administration at that time. I was hired by the Kansas City District, and started my career there as a chemist, and stayed there for seven years.

RO: What grade, Dick?

RR: I started as a GS-7. And the big reason why I came to the Food and Drug Administration was because a classmate of mine who had gone there and had been successful--Mary Jane Dolan, who had a very successful career with the Food and Drug Administration, although she died quite young . . . She died when she was forty years old, having served as supervisory chemist, Denver; deputy director, New York; director, Division of Program Operations, Bureau of Compliance.

Mary Jane was an outstanding student at Creighton, where I was marginal. (Laughter) Mary Jane always said that the reason she got the job at Food and Drug

was because her references were mixed with those of my wife, who also was a fine student at Creighton, whose name was also Mary Dolan. Al Russel, an inspector who investigated references for us at that time, said he did in fact mix the references between Mary Jane and my wife. There were also other Creighton students at that time who came to the Food and Drug Administration because of Mary Dolan. That would be Paul Smith, who's still in the Chicago District office, and Gerry Roach, who retired as a chief chemist in Buffalo. (Gerry Roach was my best friend in college and still is one of my best friends in life.)

I came to Food and Drug; worked in Kansas City; stayed in Kansas City as a chemist. I had some interesting cases there. The work of a chemist was very interesting and varied. After seven years or so there, I went to headquarters. Tony Celeste was working in the guideline section for Taylor Quinn at that time, and Tony said there was an opening there, that I ought to apply for that, and I did. So I went to work in headquarters in the old Bureau of Compliance in the guidelines section working for Taylor Quinn, who was the section chief at that time.

RO: What were some of the major industries or activities in Kansas City?

RR: Well, Kansas City had . . . At that time, as you know, their inventory was very much agricultural. Kansas City itself was a big food warehouse, if you will, and they did an awful lot of food work. They did an awful lot of undercover . . .

RO: OTC (over the counter)?

RR: . . . OTC work at that time, amphetamines and that sort of thing. Al Barnard, who was the director, was quite involved in that. At that time, Mr. Allison, who was the chief chemist there, was very much involved in my career, and felt that I could provide a lot of guidance to the younger chemists. I was a little bit older then than the new chemists. Almost immediately, I became a trainer working for Hyman P.

(Tiny) Silverberg and trained some of these new chemists, like Corbin Miles, Ken Hartman, Paul Smith, and Mike Rogers, and many other people that made careers in the Food and Drug Administration. I enjoyed that our inventory was spread over Kansas, Missouri, Iowa, and Nebraska.

RO: What year was it that you came to Kansas City?

RR: I came in August of 1961. Roger Barnes was hired just a month before I was, and Roger was a superb chemist. I recall Mr. Allison taking personal charge of our training. (FDA was still in the courthouse.) We were asked to come to his house every Friday night for instructions in food and drug law. Roger Barnes and I used to go and sit in his family room while our wives would be upstairs with Mrs. Allison, and we'd have cookies and Kool-Aid and hear Hy Eiduson's audio tapes about FDA law.

I recall Mr. Allison said, "Now, Dick, you've been with Food and Drug ten years. How much sick leave do you have?" I said, "Well, I have seven hours, Andy." (Laughter) And he says, "Well, seven hours isn't much." I said, "Yes, but, you know, you could be sick and tired of work and things like that. I was kind of sick and tired of most of them." So it was that kind of session. Roger and I enjoyed that.

But I think, one of the things, we did get a great appreciation for the Food and Drug Administration from Mr. Allison. We learned from Mr. Allison a great deal about FDA, and he kind of instilled in us the spirit of the FDA at the time. There was a great camaraderie at FDA at that time. There was a great deal of social interaction in the district office between people, between the inspectors and the chemists. We had a lot of parties, and we'd go to the ball games together. So we kind of sought out each other's company. Everybody was from someplace else, and we were all young. They were great times and lifelong friendships were made.

Corbin Miles came at that time, and we lived near each other at a place we called "Tobacco Road" near the Bendix Plant in Kansas City. We both had young

children there, and it was quite nice. We rode in the same car pool in the mornings. Ken Hartman was there at that time. (He became the quality assurance director for Frito Lay and left the Food and Drug Administration after he was there about eight or nine years.) But we had an interesting car pool, and we made friends together.

RT: Who was the director of the district at that time?

RR: Al Barnard. After I had moved to Prairie Village I actually rode in his car pool. Before I came to headquarters, Al Barnard and I were riding home one night. Barnard by that time had decided that he would become the deputy director of the Bureau of Drug Abuse Control (BDAC), and Barnard had told me . . . I had told Barnard that it seemed like all the problems had been solved, and that, you know, that there wasn't as many violations and all that sort of thing. He said, "Well, the problems have not been solved. Look at these food additives if you think the problems have been solved." So Mr. Barnard kind of had a premonition that I would spend ten years of my life essentially running the food additive program for the Food and Drug Administration after 1971. After I came to headquarters, it was some time after that.

RO: Andy was still there when you left.

RR: Andy was still there . . . Andy had retired. Don Healton had come. Mary Ann Donovan and I were looking at our personnel records one afternoon, which we weren't supposed to do, and we found that one of the reasons that Mr. Healton came there was to try and organize the supervision of the district better. I was an acting supervisor at that time, and so was she, as well as a number of other people. He was sent there to try and get the acting supervisors back on the bench and get actual supervisors in in their places, which he did. He brought in John Taylor from Detroit and Tony Celeste from New York, and Garland Reed from Cincinnati to be the

assistant chief chemist right about that time. So Garland then was my direct supervisor in my lab, and I went back to the bench.

One of the operating theories was that I would not be able to do the work, that I would not be able to perform as a GS-11 chemist as I had spent my early days supervising. And it was hard! I had been away from the bench for so long, it was difficult to perform as a senior chemist on the bench. I needed extra time. What I did was get my samples, get everything organized, go home with the car pool, and then Barnes and I would come back to work. And Barnes would sit down and say, "Now this is the way I think you ought to attack this sample." So Roger then essentially took over the training of me as a senior chemist, and nobody was ever the wiser. (Laughter) I think Healton was astounded. I know John Taylor was astounded that I was able to do that.

I enjoyed the bench. I think it was a tremendous amount of fun. There's just no way at that time to match that particular job, because you had variety everyday. You had a variety of samples: you'd have drug samples, filth samples, have check samples, and you could have the OTC samples with a lot of court work involved with that, and imports.

At that time, the lady chemists were not allowed to do prophylactics (condoms) for defects. It was seen as something that was not proper for ladies at that time. There was a young chemist from Kansas State. Shirley Schaeffer was her name. And Shirley broke that up one day. The procedure was carried out inside a cardboard screen. The apparatus was called Hercules, and it would deliver three hundred milliliters of water to each prophylactic. Then the prophylactic would be rolled on a towel to see whether or not it leaked. If you found three in the first fifty, you could reject the lot, or if you didn't find any, you could stop. If you found one, then you had to go on to examine 385 before you could stop the analysis. The majority of the products examined were defective.

We actually prosecuted the Dean Rubber Company of North Kansas City, Missouri, for having defective prophylactics. These were not considered safe and

effective "drugs" as birth control devices. They were considered drugs for the prevention of sexually transmitted diseases. They have never been judged to be effective for birth control. So we had a nice trial on that. As part of the trial, the powers that be in headquarters (Josh Randolph) decided that it would be a good idea to have Dr. Masters of the famous Masters & Johnson sexology team as a witness, and one of the things that we had to do was prove that the tests that we were doing were not inappropriate to the task. The defense was an all-out challenge to the way we conducted these tests.

So what we did was, we had Jean Peterson, who was a microbiologist with Food and Drug, actually show that the syphilis spirochete was small enough to pass through a leaking prophylactic. So we actually did that with petri dishes so that we could say, "Yes, these leaking holes could be a problem if the person had syphilis. Even a large molecule like that would be capable of going through a small hole in a latex prophylactic."

Dr. Masters was going to testify to the stresses of intercourse, that in fact the act of intercourse was so rigorous and would in fact stress the prophylactic to "work" this molecule through if in fact the person had this disease. The counsel for Dean was Justice Whittaker's daughter (the Supreme Court Justice's daughter--he was a Kansas City person), and she had lived in Kansas City. After Masters testified, she got up and said, "Dr. Masters, you have people come in to your office and have intercourse in front of you?" And he said, "Yes." And she said, "And these are married people, and single people, and all kinds of people?" He says, "Yes, that's right." She looked with disdain at Dr. Masters and said, "I have no further questions." (Laughter)

Joe Teasdale, who was the assistant U.S. attorney handling the case (who later became the governor of Missouri), thought he had lost the case on that basis. He got us back in the witness room and said, "Whose idea was this?" So, of course, he blamed the district for Dr. Masters, and whose idea was this witness.

We tested the rubbers in the court. We went to great lengths to show that we had confidence in our tests. We actually had an inspector collect a condom that day in Kansas City and bring it in. The only trouble was that he went and collected a Schmid prophylactic, which was the only gum rubber prophylactic sold in the United States at that time. The Trojan condom was not the same, as it was latex rubber. So I had to explain the difference between latex rubber and gum rubber and all that sort of thing.

Then I performed the test in the courtroom. We knew from experiments in the laboratory that prophylactics will hold almost an indefinite amount of liquid. In fact, they look like giant "geese" when you fill them up with water. I would keep putting water into the prophylactic, and Mr. Teasdale would say, "How many times the water test is that, Mr. Ronk?" And after we got to three liters, I said, "Three liters, that's ten times the prophylactic test." The judge intervened at that time and said, "I hope you realize that that's a nice table I've got out there, and I don't want water all over this place. And I hope you've got some plan about how you're going to get this out of here." Which we did not.

Bob Smith and Weatherwax had already testified. Weatherwax from Los Angeles had already testified, so they were sitting in the courtroom. So Smith had the idea that when I finished, he would just come up and take the table, the Hercules, and everything, and he and Weatherwax just walked out of the courtroom with the table, and we didn't get water all over the place at that time.

We won the case. The case demonstrates how difficult it can be to show responsibilities. We were trying to show that Wilbur Dean was in fact responsible for the violations, that he was in fact the plant manager, even though his father was the person who was technically the head of the company. His father was eighty-five years old. We knew that they would never convict an eight-five-year-old man of criminal violations. This case was a fourth offense of the Food, Drug, and Cosmetic Act. We knew they would not convict him. We knew that the witnesses would not testify, because they had quite a few criminal violations of other kinds of

things, theft from interstate commerce and all sorts of things on their records, which we would introduce if in fact they testified. So they had to avoid testifying. So it was very difficult.

Don Price, who left Food and Drug also and became the quality assurance manager of the Lilly Company in Indianapolis, was the lead inspector on that and did an excellent job in pinning down the responsibility of Wilbur Dean for these violations. The outcome was, however, that he was not convicted personally. The firm was fined $45,000 for the violation, but we couldn't convict Wilbur for the violations. U.S. Attorney Teasdale did a great summary to the jury, essentially saying, "We had a good time here at the trial. There were a lot of things that were funny that went on, but this is a serious violation of the Food, Drug, and Cosmetic Act. Now, you're either going to enforce the Food, Drug, and Cosmetic Act or you're not. It's really up to you." And he won the case I think really on the basis of his summary.

That case probably was two months work on my part. So that was the kind of thing that we did in Kansas City. We had a lot of OTC work. For instance, we prosecuted one case in Cedar Rapids, Iowa, where a person was in fact shipping amphetamine tablets. He was making twenty-five milligram amphetamine tablets, sending them to doctors in Iowa, who then sold them through the mail to people.

Al Russel and Harold Leap essentially handled this case. It was a sting operation, more or less. They went up and said, "Well, why don't you make these for us and send them to us and that sort of things. One of these days we'll maybe even get into the legitimate drug business and maybe you'll be another Ewing Koffman, and we'll get into the legitimate drug business. Why don't you send them to us at the Right Way Drug Company, 1009 Cherry Street, Kansas City, Missouri. He was so focused he didn't realize he sent them right to the district office. We would get these twenty-gallon drums of twenty-five milligram amphetamine tablets there.

Mr. Allison wouldn't let us weigh these drums and calculate the number of tablets, but we had to count each one of these tablets individually. (Laughter)

There were literally thousands. So we would spend all day and well into the night counting every tablet that was in one of these drums hoping you didn't lose count, and you really felt bad when you lost count and had to start over again. (Laughter) Two people did it so there was no check analysis.

One of the things that bothered me then and also bothered Mr. Allison was that it seemed that the drug work was so interesting that it overshadowed everything else we did.

RT: Well, was the Total Diet Study done in Kansas City?

RR: No, eventually yes. We did radioactivity samples in everything but milk at that time. So that was seen as a very important program. Jerry Klem won a cash award of, I think, about two thousand dollars at that time, which was quite a lot of money, for developing new techniques for how to handle samples for radioactivity analyses.

There were a lot of people that were very good at methods development in Kansas City. We had one superb chemist, Floyd Yarnell, who was very much involved. Harry Conroy, when he was still there as supervisory chemist, Harry was a superb chemist, a wonderful person, and a wonderful manager. Harry Conroy was one of the nicest people that I ever met in my life. I think he just died recently. I think Ted Benjamin is still alive. He was chief inspector. Ted's living in California.

We had a lot of radiation work at that time, and samples from all over the country were done on a production-line basis eventually in Kansas City. We developed new counting techniques; we developed new ashing techniques; we developed new digestion techniques for foods in general. So there were a lot of papers that were published in the AOAC at that time. This experience was important for the Total Diet Study that came along later.

Ken Hartman was very much involved with the Total Diet Study. Ron Haig was sent from Detroit to take over the program. The administration didn't feel we had a good pesticide senior chemist at that time. Weatherwax in Los Angeles was

considered to be the premiere pesticide guy at that time, and Haig in Detroit was considered to be very good at it also. So Haig came to Kansas City to take over the pesticide program and to provide training and advice to the chief chemists on those operations.

Hartman developed a number of new techniques using the Dohrman gas chromatograph, which was a chlorine detecting apparatus, essentially, to do identification work. So FDA was always sure of the compounds that were coming off of the columns. This was all original work. FDA was at that time developing pesticide methods that became the standard of the world. Laura Giufrida here in headquarters and Jerry Burke in headquarters. Laura Giufrida is considered to be the developer of the electron capture detection system.

We were very careful in reporting results, because if we got a peak, we didn't decide that it necessarily was a pesticide. We had to be sure that it was chlorinated; we had to be sure that we had other kinds of identification beyond just the fact that we got a peak on a gas chromatograph at a particular time that matched a standard. Of course, that turned out to be a good idea, because with many of these peaks, that have exact retention time at a pesticide peak, have exactly the shapes and other things that you'd expect, turned out not to be chlorinated and not a pesticide. The famous Aldrin peak from corn comes to mind.

The beginnings of the Total Diet Study were there. We, at that time, did all of the sample preparation in Kansas City. We had a contract for those items that we wanted to have cooked done at a convent up at Leavenworth, Kansas. They did that for years. There were a lot more market baskets at that time. And there was a lot of discussion about the appropriateness of what we were doing.

John Wessel from Baltimore was asked and I think did an excellent job in validating the scientific appropriateness of the Total Diet Study at that time. John essentially had a career in pesticide work after that for the agency.

That was the kind of work the lab did in Kansas City. To go back again, Mr. Barnard was very interested in OTC work, and there was an awful lot of that done

in Kansas City. FDA lost a lot of people to the Bureau of Drug Abuse Control when it was formed. Jerry Nelson, who was an excellent supervisory chemist there, became one of the chief chemists of the Drug Enforcement Administration (DEA). Romano from New York was one of the chief chemists. Willie Kaiser then left Kansas City and went to work for Romano in Miami. Claude Roe went to work for DEA at the same time for Bob Seger in San Francisco. So we lost a number of good chemists at that time to what became DEA.

RO: What year was it that you came into guidelines at headquarters?

RR: I came into guidelines in June of 1968. I came in right at the time that one of the Kennedys was killed--Robert Kennedy was assassinated. I came back while that was happening and reported to headquarters at that time. Taylor Quinn, who was my supervisor, was gone. He was working on a "fish bill" as usual, and Tony Celeste was in the process of leaving to go to Chicago to be chief chemist at that time. Larry Stern and Ray Hamilton were in there at that time, and I became kind of Ray Hamilton's roommate there, and Hamilton kind of took over the task of indoctrinating me into the headquarters system at that time. I also worked on food compliance tasks for John Lupien.

One of my tasks that was given to me by Mr. Fine at that time was to develop the compliance policy guidance system, which I did, and I think it's still operative in the agency. But I did that along with Tenny Neprud, Walt Moses, Harold O'Keefe, and Howard Pippin.

(Interruption)

RR: Ted Byers decided that I would kind of head this project up. From an administrative standpoint, Walt and Harold were both GS-16s. I had some experience in cataloging things and had an interest in it, in fact. So he assigned two

very senior people, Harold O'Keefe and Walter Moses, who was stepping down as the food case branch chief, and Harold O'Keefe, who was leaving the job of drug case branch chief. They each had two assistants that worked on these early guidance documents.

The whole idea at that time was to somehow have this compliance policy guidance system essentially capture both the FLAGS (Field Legal Action Guidance System) that were the legal action guidelines at that time and also any of the precedent material that was handled by Mrs. Pendleton at that time with a card file. It was and is very difficult to capture the precedents of the agency. At that time also there were better and more systematic files. Mrs. Massey was the guardian of these files, as all of us recall. She was certain no one made off with them and would essentially be sure that she got them back. She would send out runners to your office to come and take all the files off your desk and bring them back to records. But everybody always sent a copy of everything that they wrote to CA26 (Mrs. Massey) wp that the administrative file was complete. After the move to Rockville from Crystal City, it fell apart.

I asked about that system, and Gerry Meyers told me that we had about 500,000 letters that hadn't been filed at that time (1985). So that was the impact of Mrs. Massey leaving. I think right to this day that we've never regained control of the files and that there is no existing precedent system that can in fact capture all of these things that are done of a precedent-setting basis. The agency has decided, for better or worse, that regulatory precedents don't matter as they once had. So there was a system of internal and formal advisory opinions. Paul Hile, when he was associate commissioner, put out a notice that essentially erased all the precedents and established that in the future the only advisory opinions that would have the force and effect of law would, in fact, be those that were formal advisory opinions signed by the associate commissioner for compliance and published in the Federal Register.

There is no reason to answer the mail anymore. The agency, if it has a formal guidance, it is the compliance policy guidance system. But it doesn't begin to cover the precedents that have been established in the agency by the various centers.

RO: Those 3 X 5 cards were pretty much the Bible in the field.

RR: It was more than a card. Mrs. Pendelton also maintained a precedent library. We would get after Larry Stern because Stern thought that anything he wrote was precedent, and he would throw away the more appropriate other letters that were in the precedent file. He was a great generator of correspondence. Stern and a number of people came from another unit that was disbanded prior to the Bureau of Compliance days. There was essentially an industry letter-writing unit at the Tempos on the Mall that had a number of people in that that . . . Carl Sharp, Don Kilbern, Milton Gates, Dick Nacewicz. There were a number of people that were working in compliance in various areas at that time that had started their careers there and brought to headquarters as GS-9s, essentially to answer correspondence.

RT: Well, now, 1968. Was Rayfield still head of BRC?

RR: Rayfield was still head of that. No, he was not. DFO (Division of Field Operations?) had gone. In fact, while I was still in Kansas City, DFO was over, and we picked up some people from DFO camp. Harris Kenyon was running the field with Roy Keeny and Paul Hile, and that was it.

RT: That was a liaison office. BRC became two bureaus: the Bureau of Compliance, Al Barnard, and Voluntary Compliance, General Fred Delmore.

RR: That was it. There was no structure to that at that time. And for a short while, I worked in the Division of Regulatory Guidance. As you recall, all of the

district directors reported directly to Dr. Goddard. So that was . . . But when Rayfield was still here, around that time in '68--before 1970--there became two bureaus, the Bureau of Voluntary Compliance and essentially a Division of Regulatory Guidance that was in this bureau. So the agency was very much in flux in terms of that compliance organization from 1968 until 1970, until Dr. Edwards arrived and the agency moved from Crystal City.

RO: Where was Fred Garfield then?

RR: Fred Garfield was at DEA (Drug Enforcement Agency). He went over and took Barnard's place, as you recall.

RO: And then Barnard came back to head up BRC (Bureau of Regulatory Compliance?).

RR: Barnard came back to head up BRC for a short time, yes. And he was the head of BRC when I came in. And General Delmore was the head of the other group, Bureau of Voluntary Compliance. The letter writers all went into Voluntary Compliance, and then they came into Division of Regulatory Guidance.

RT: There was a cadre, as you have mentioned, of several people that were kind of letter writers, and it seems to me that maybe some of those persons were Morris Yakowitz and Abe Lederer. Are those the kind of people you were trying to remember?

RR: The person I'm trying to remember became essentially the chief food and drug officer of the Bureau of Drugs and, in fact, handled the investigative team that went to Chicago on the Searle investigation. Carl . . .

RO: Sharp.

RR: Carl Sharp. Carl Sharp came from that group, and then there was a guy that did interrogatories that we used to call Captain Destructo. He was from Boston originally. He was a very bright guy and handled case work in drugs.

At that time, they kept very close track of the precedent material. Mrs. Pendleton would essentially take the subject matter of every letter that was sent out from the compliance units and catalog it, and that's how she made her cards. After she left there was nobody to take that over. And Bureau of Foods and the Center for Food Safety after that essentially kept their own precedent files. They had two rooms filled with letters by subject matter, so they could still go back and look at letters that went back to the Harvey days.

There were things that were important about that at the time. For instance, I looked for several years one time before I found the prior sanction for caffeine, for instance. The prior sanction for caffeine is an interesting letter. It was from Jack Harvey to the head of Coca-Cola, Paul Austin, and the date of it was September of 1958, several weeks before the effective date of the Food Additive Amendments. I understand that it was the price of the passage of the Food Additive Amendments. It essentially said that the Coca-Cola formula and all its ingredients, even though they were secret, would in fact fit squarely in this new category of prior sanction materials. They had all been judged safe in their prior sanction, even though the Food and Drug Administration was not aware of what they were. (Laughter)

So it was important to have those. In fact, when we did the GRAS (Generally Recognized as Safe) review, we went back and tried to find all the prior sanctions. Because anybody that had a letter from the Food and Drug Administration that said it agreed it was safe under the old food standards was in fact a prior sanction ingredient.

A good example of that would be brominated flour. The only approval for bromination in flour was part of the original standards. It appears nowhere else.

But it is still used in the United States only on the basis that it was prior sanctioned as part of the food standards. So caffeine certainly was one of those ingredients. That's the whole story of Coke and caffeine, which is well-documented elsewhere.

But the files were important, and I think Mrs. Massey should be remembered well. As long as she was here, you could go get an AF (Administrative Files) jacket and find the history of anything in the AF jacket.

Ken Kirk, who was the associate commissioner for regulations at that time, insisted that all of this precedent information be on the left-hand side of any jacket that he looked at. Then he would look at your initials and decide whether or not he knew you or not. If he didn't know you, then he would check everything you did until he got some confidence in what it was that you did.

John Lupien, who was here at that time, and handled a lot of casework at that time, kind of broke me in on the casework side while I was working in the guidelines section. I provided him with laboratory advice, essentially, on cases. He and Dick Nacewicz and Milton Gates did all the casework at that time on the food side.

We seized Kaffa Coffee, and we were in the process of seizing Pringles. Kaffa Coffee, as you recall, was advertised as a product that didn't have any coffee acids, since they were all neutralized. You had sodium salts of the coffee acids. As soon as you drank it, you had acid salts of the coffee acids. So we saw that as a scam, and we seized the product in Buffalo. Pitt Smith was pleased to seize it.

The Pringles was another matter. We decided that Pringles was not a potato chip in our wisdom. There was no standard for potato chips, but Pringles was not a piece of sliced potato deep fat fried, but was shredded potato material formed so each one was identical and put into a package. I kind of tore my drawers with Kirk on that, because one of my problems in my whole life is to see the humorous side of things, and I had worked on that seizure.

So when the company came in to see Mr. Kirk, John Lupien and I went up, and Mr. Kirk said, "Well, I understand that you have been working on this. Do you have any other reasons why you might say this is not a potato chip?" And I said,

"Well, there's clearly one." I said, "It doesn't have the mouth feel of a potato chip; it doesn't taste like a potato chip; it doesn't appear to be a potato chip; and the other thing that you can do with a Pringles that you could never do with a potato chip is it's so strong, you can get a whole bowl of dip on it." (Laughter) I couldn't resist it.

And we didn't seize them. What happened then is we came out with a common or usual name. That was one of the very few common or usual names in regulations that still exists is one for potato chips, and it would include Pringles in that category.

But I enjoyed that kind of work. There was a lot of challenge to casework, and there was a lot of fun in that.

RO: What grade did you come in as?

RR: I came in as a GS-12. I got to be an eleven in the district and came in as a twelve. At the post office, I didn't make enough money to live on, I thought. I made five thousand dollars a year, and I came to FDA at $6,345, and it seemed a fortune. And, in fact, I never had any financial troubles my whole life after that. Food and Drug always paid well enough to survive. If you lived modestly.

That was not true of headquarters before I came, and Les Ramsey would always talk about how hard it was to live in Washington during the fifties, because one really didn't make enough money. Although I often wondered about it. Ramsey ended up owning a good portion of Fairfax County before it was over. He was on the board of all the banks out here. He bought a farm when he was a GS-9, and he kept the farm until the seventies, and essentially then took advantage of the subdivision of that farm along Lawyer's Road over there in Vienna.

RO: About all it had on it was scrub pine. At Christmas time, he'd let you go over there and cut those scrub pines.

RR: Yes. We'd cut those scrub pines for Christmas trees. Ramsey, of course, was another person that was a tremendous figure in the Bureau of Science.

But one of the things I also did at that time. Kirk did finally get some confidence in me, and I was sent up to see Kirk and (Reo) Duggan one time. They said they'd read in the newspaper that a group of Indians had been poisoned by mercury in fish caught from Canadian lakes. So this would have been in 1968 or 1969. So it was really one of my first encounters with the Bureau of Science.

So they thought they might want a guideline for mercury in fish. Duggan sent me over to the Bureau of Science, and I said, "Well, what do you want?" "Well, go over there and find out what they think would be an appropriate level of mercury in fish." I said, "Who do I go and see?" "Well, you'll see the toxicologist." So OK. So I went over there. I always thought Duggan didn't like me for some reason. So I go over there, and I went to see Garth Fitzhugh, who has just recently died in his nineties. Garth was there . . . Dr. Lehman was the director; Burt Vos was the deputy director; and Lehman was in charge of the laboratories.

I went in to see Dr. Fitzhugh, and he says, "What do you want?" I said, "Well . . ." I gave him the newspaper clippings, which he looked at, and I said, "Mr. Duggan thinks we need a guideline for mercury in fish." "He does?" I said, "Yes." "Come back tomorrow." So I went back, and he had a little piece of paper, and it said, "Reo, .05 parts per million seems OK. Garth." And he gave it to me, and so I went back to Mr. Duggan. I said, "Is this all there is to setting a guideline?" He says, "What more do you want?" (Laughter)

After the mercury business became popular in the seventies, that .05 parts per million went to all kinds of international committees, and everything, and it stayed .05 parts per million. It actually was what was considered to be the sensitivity of the mercury in pink wheat method at that particular time. It had no other basis in fact than that. Although scientists worldwide had all kinds of basis in fact about why that should be the number evermore until the court case down in Florida raised it to 0.10.

So I got the FDA award of merit for that. Not for that, but for the mercury in fish program later on. But I often had second thoughts about the scientific appropriateness of the number that was decided upon.

RT: In today's climate, do you think that that tolerance would have been established?

RR: Yes.

RT: The same way?

RR: You could have had somebody sit down and do an awful lot of research on that. Essentially what was being established was being established in the way that it always was. Guidelines and numbers like that really started with arsenic in beer in England with the Royal Commission that Calvin, Lord Calvin, chaired, and they decided that they would establish a level of arsenic in beer based on the sensitivity of the analytical method. If you decided that no level was safe, and you couldn't establish a safe level, then the appropriate way to do it, realizing that the world would still go around, was to set it at the level of analytical sensitivity.

In fact, that stayed that way until Dr. Kennedy was here, and we were talking about dioxins, and I recall Taylor Quinn told him exactly how we established a number of tolerances by analytical sensitivity. They were guidelines mostly; they were not tolerances. He said, "Well, I think we ought to do risk assessments. I want a risk assessment on that."

Joe Rodericks, who was working with Food and Drug and was the associate director of the Division of Toxicology at the time, although he was a chemist, had been looking into that for some time. Both he and Dr. Angelotti, who was in charge of compliance, were somewhat taken aback by the lack of scientific elegance in the

way that these things were done. I think they probably were right. We should have used the scientific method to establish more of the tolerances and guidelines.

And so Joe started to work on doing risk assessments, cancer risk assessments at that time. Saccharin was current at that time, and so FDA started doing risk assessments pretty much on using techniques that Rodericks decided on. Leo Friedman, who was the director of the Division of Toxicology at that time, had been consulting with Mantel Bryan at George Washington University. Mantel, who was a professor at George Washington University, and Dr. Friedman and others would sit and try to figure out how one would go away from traditional toxicology and try to establish these endpoints that then would have a biological reality.

So right at that time there were advisory committees on safety assessment to the Food and Drug Administration. They established essentially guidelines about how to do cancer testing, guidelines on how to do reproductive toxicology, and all those sorts of things, which were published in the *Journal of Toxicology and Applied Pharmacology* by the FDA advisory committees. One around 1972 had established that we should do in utero testing of animals for cancer risk assessments. Harvey Mandell was on that committee and also one of the Nobel laureates who was president of Roosevelt University was also an advisor to the center at that time--to the Center for Drugs also. But we had high-powered advice on how to do this. But the one that really tried to put it into a procedure about how you actually did this was Joe Rodericks, and he published extensively on that.

RO: That was later though, wasn't it?

RR: That was 1972. When Kennedy said this in 1977 or so, we were able then to build on the risk assessments. So we quit doing the analytical method about 1977. But up until that time, you know, 0.3 p.p.m. (parts per million) of chlorinated pesticides, and when we did all the action levels, those action levels were all

analytical sensitivity. But that technique was one that carried over from those early days in England and was done in the old Bureau of Science.

The guidelines, the action levels, as you know, came from John Zaic's little black book in New York. Zaic essentially kept that at his desk. They then became the FLAGS, the legal action guidelines, which were secret, which were kept in your desk, and they were never revealed to anyone, until we gave away the filth guidelines years later.

One of the things that happened at that time, I was the head of the Compliance and Guidelines Research Branch in the Bureau of Foods, and so we released those guidelines. Someone from *The Denver Post* came to see me about that, and it also turned out to be a "stringer" for *The National Enquirer*. So people were astounded that filth was allowed in food. Depending on how you wanted to say it, you know, if you tell someone that you allow one rodent pellet per pint of wheat, that's a bushel of rodent pellets in a sixty thousand bushel car. That's a lot of rodent . . . (Laughter)

If you say that you allow so many thrips on a certain section of a microscopic plate that you're going to look at, it doesn't sound so bad. But if you say you allow three thousand thrips per ounce of asparagus, you have a little problem explaining the realities of that. *The National Enquirer* said, "FDA Research Chief Says No Twenty-Four Hour Flu."

We had talked about the significance of filth with salmonella and other sorts of things. That if you add rodent pellet to salmonella and then you put it in your mayonnaise, you could have significant outbreaks of food poisoning. So that's what the reporter then got interested in. So he checked with Dr. Bryan at CDC. So on the front part in big headlines, "FDA Research Chief Says No Twenty-Four Hour Flu." I said one of the things that people think is twenty-four hour flu is really a case of salmonella poisoning and whatever.

Virgil Wodika was the director of the center at that time, and he said, "I thought I was the research chief here." I said, "Yes, you are." What happened though is my mother-in-law, who one of her favorite diseases was twenty-four hour flu, so my mother-in-law saw *The National Enquirer* in the Red Owl grocery store in Worthington, and bought one. She saw that it was me that was quoted and took the paper back to the grocery store and got her money back. She says, "That's just my son-in-law, and he doesn't know what the hell he's talking about." (Laughter)

But the guidelines and the action levels certainly served a purpose, and I was always proud of the work that I did there.

After cyclamates came along in 1968, it turned out that Ben Oser, in his laboratories in New York, did a study with cyclamate and saccharin and found that they caused cancer of the kidneys and reported that to Abbott. Kasperson was the vice president in charge of Abbott Laboratories at that time. Kasperson and the other people at Abbott came to FDA headquarters at the time that Dr. Ley was commissioner. Abbott's side of the story was told to me during a meeting with Abbott Laboratories and Dr. Schmidt much later on. So what I'm telling you now is what Abbott Laboratories' Kasperson told Dr. Schmidt of their side of the story on cyclamates.

Kirk was in charge of the agency that Friday, and they decided that they didn't want to bring this up to Kirk. I think with good reason, because Kirk would have by Monday decided that cyclamates was gone. So they decided they would go see the surgeon general of the United States, Jesse Steinfeld.

RO: Excuse me, Dick. When you say "they," who . . . ?

RR: Abbott. I'm telling you Abbott's side of the story, which I took notes on at a meeting with Dr. Schmidt. So they went and saw Steinfeld. Steinfeld then went to the Food and Nutrition Board of the National Academy of Science who was

holding meeting. They took the data to the Food and Nutrition Board of the National Academy of Science, who decided it was a carcinogen, and then the department took it over. Steinfeld essentially took over that problem at the time. Food and Drug was not involved until four or five days later, when Dr. Ley and Mr. Goodrich went to see the secretary about it. By that time the secretary and other people had decided that they were going to allow cyclamate as a drug. They were going to allow it to stay on the market as a drug.

One of the outcomes of that was that when Dr. Edwards became commissioner of Food and Drug . . . Virgil Wodika and Dr. Simmons both told me this, who were privy to that through administration. The administration was changing at that time. They decided that anyone that had anything to do with cyclamates at Food and Drug was out. So they got rid of Summerson, Ken Kirk, Rankin, Goodrich, Arnold Lehman, and they tried to get rid of Blumenthal. They tried to send Blumenthal to EPA, but it didn't work. So even though the agency was not involved, they paid a heavy price for the cyclamate decision.

Dr. Schmidt, to his credit, overheard this story, because Abbott was repetitioning for cyclamates at that time, and Dr. Schmidt told them, "Well, that's an interesting story, but let me tell you another one."

(Interruption)

RR: Dr. Schmidt told the Abbott people, "I hope you don't ever think that while I'm commissioner of Food and Drug that you're ever going to go around the agency like you did that time. And you can be assured that I personally will be involved in this to be sure that before we would ever consider cyclamate on the market again, that we have all the scientific information that would be required of a food additive before we ever even thought about putting that product back on the market.

What was obvious was that whatever reasons were surrounding that controversy at that time that a lot of the reason that Abbott then persisted in trying

to remarket that product, spent a lot of money in trying to remarket that product, is because they thought some great injustice had been done to them at that time. And Kasperson really believed that until his dying day. I think . . . I never could see why they felt that. Food and Drug really didn't do anything at that time. In fact, Food and Drug did *not* have anything to do with saccharin until we decided to ban it in 1977.

What Dr. Edwards did when he came to the agency, one of the things that he did was to immediately send saccharin to the National Academy where it stayed for seven years, because it was obvious that one of two materials was a carcinogen. It could have been saccharin or it could have been cyclamate. I guess the decision was that it was cyclamate, because they had fed so much more of the cyclamate. Cyclamate was only twenty times sweeter than sugar, so they fed a lot more cyclamate than they did of saccharin, which is three hundred times sweeter than sugar. As we're all well aware that the carcinogen turned out to be saccharin at that particular time.

What Abbott could never understand again though, once you took cyclamate off the GRAS list that it couldn't come back again into the food supply unless it met the requirements of a food additive. There were a lot of other effects that it had. Cyclahexalamine conversion and other sorts of effects that it had that had to be resolved, which we have never resolved to this day, although there has been a lot of time and trouble spent on that.

Saccharin, of course, turned out to be a carcinogen three times before the agency would ban it. Impurities were seen as a cause of it as well as other reasons of why not to do it. But once the academy finally gave us a report, which was seven years later, then the agency did decide that saccharin was in fact a carcinogen, and because of that attempted to ban saccharin.

The sweeteners probably are the only food additives that have the financial clout to make it worth while to spend the kind of money that they spend on those

kind of materials. Aspartame, when it was first approved, I think the first year that aspartame was on the market, they did $500 million worth of business in the additive itself. The other additives aren't worth that much. They may have functional effects that are that important, but you can only charge a few cents a pound for them.

RT: The "Sweet 'N Low" product, isn't that saccharin?

RR: Yes.

RT: So an accommodation was worked out for the warning on the packets rather than a ban. Is that correct?

RR: The law is still in effect. The only reason saccharin isn't banned by the Food and Drug Administration to this day is that Congress repasses this law every once in a while which does that. Would they have done that if aspartame was on the market at that time? I would doubt it. I think saccharin would have gone the way of all flesh.

After I left the guidelines section, then one of the things I did was took over the Division of Food and Color Additives. In fact, we're talking about those things. So I did that for ten years.

RO: And in about 1970?

RR: That was 1970, late '70, '71. I didn't want to go over there. Tom Brown had come out here, and Angelotti had become director of the Office of Compliance. The pesticide part of the regulations division there that did food additives and pesticides, Frank McFarland was the director, and after him . . . Oh, gosh. Black guy from Detroit, still here, runs Industry Services.

RO: Nat Geary.

RR: Nat Geary. See, you don't have alzheimer's. Nat Geary had taken over that. Voluntary compliance was gone. We'd had a big reorganization and gone our separate ways down to wherever we went. I ended up at Foods. Quinn and Blumenthal sat down with me at the time. I didn't want to go over and take over this division. Nat had left. Angelotti wanted me to go over there, so he gave me until Monday to let him know. I said, "I have no interest in these damn food additives. I don't want to go over there." And Quinn says, "Go over there, and it will be OK." And Blumenthal said, "Yes, and I'll help you with it." Of course, Blumenthal was running toxicology and was a superb guy. So I said, "OK. I'll do it." I went back to see Angelotti, and Angelotti said, "Well, you really didn't have a choice." He said, "I already gave you a temporary promotion." So that's how I got my fifteen. So I advanced fairly rapidly in headquarters. I came in as a twelve, and got a thirteen a year later, and a fourteen a year after that, and the year after that I got a fifteen.

I went down the coffee room when I got the fourteen, I remember, and Nacewicz was down there. He said, "I understand you got a fourteen." I said, "Yes, I did." "Well," he said, "you don't seem very happy about it." I said, "Yes, but it's kind of delayed." He said, "Well, how long was it?" I said, "Well, it was two weeks late." I said, you know, "I'd been a thirteen a year, so it was two weeks late." (Laughter)

One of the big jobs that had to be done there was the GRAS review. Because of the cyclamate incident, President Nixon had decided that we would review the Generally Recognized as Safe list, and that was part of his address to Congress; that was part of his State of the Union address.

So we got a lot of contract money. It was a very small unit. There were only five people in the food additive side. Lou Buckley, Allan Spiher, both very

experienced Food and Drug people, and Paul's deputy . . . What was his name? Well, he was doing plastics . . .

RO: Bill Randolph.

RR: Yes. He was doing plastics, and he left right about that time because he didn't get to be the director, so he was upset and left. But Lou Buckley was Mr. Food Additives as far as I knew. Spiher was also very good, too. And they had started in that unit when Tillie Checchi ran it in the commissioner's office. That unit started out in the commissioner's office with Tillie Checchi essentially implementing the new statute. They always got somebody to implement a new statute. They had Bill Cook essentially implement the pesticide statute when it came along, and then they had Tillie Checchi on the food additive amendment. Fred Cassidy and Einar Wulfsberg were also involved in that.

They had all kinds of theories about how you regulate it. One of the theories that Spiher had was that this GRAS list really should be done away with. You wanted really to move these GRAS additives into food additives status, and then have them have the same tests as essentially were being performed on the new food additives.

Food additives after they passed this amendment were not controversial. If you went back and looked at 1966 *Food Technology Journal*, for instance, they had a big article on food additives, with industry people and government people both saying, "It's amazing how uncontroversial this has been." And then cyclamates came along right after that. So for ten years there really was no controversy about regulating food additives at all. Cyclamates came along and put the whole thing into question, which somewhat, still today, prompts people to have grave reluctance about these food additives that they didn't seem to have at that time. But certainly

Cyclamates and the Chemical Feast, Turner's book, and all those things put great pressure on the food additive system.

So we evaluated the safety of all of these ingredients. Everything on the GRAS list, everything that was prior sanction. Many of them were retested. All of them had reproductive studies done at FDA's cost, and that went on until about 1978 until . . . I remember I had a meeting with Mr. Hile and Dr. Novitch. The question that we were still at it ten years later, and there were only about thirty-five that we couldn't deal with and I think they still haven't dealt with them. They're just tough. Like cellulose. Cellulose has dioxin in it. So what are you going to do. You end up with problems that couldn't be solved on about thirty-five of these additives. Sulfites happened to be one of them.

But Paul Hile and I decided that we would just, with Dr. Novitch saying, "Well, I'm not going to give you any more money." So Mr. Hile said, "Well, why don't we just declare a victory? Why don't we just say it's over?" So we did it. It was done. So we just announced it was done, and that was the end of that. So even though we had not done thirty-five of them and haven't to this day.

So it was a big project. We spent probably $100 million on that project to do that one way or another. Out of that came a number of other big programs. The Bio Monitoring Program grew out of that. Dr. Schmidt, when he was here, was asked one time at an appropriations hearing, "Ask for everything you need." Both the Republicans and the Democrats. Mr. Kennedy and whoever the Republican was at that time said, "Just come up here and ask for whatever you need. We don't care what the department thinks. Just tell us what you need." So we were sitting there writing down what we needed. I said, "Well, we've got this bio monitoring thing. Why don't we ask for about 150 positions there? Oh, why not? So we got essentially the laboratory part of that done.

I spent a good many years in that. Of course, it grew, and everything seems to expand to take in whatever resources you'll put into it. Where five or six guys

used to do it, now there's seventy or eighty people that do it now. But everything became a lot more complicated.

One of the things that complicated matters on the regulation side at that time was Peter Hutt's insistence on preambles. And one of the loathes that people didn't really think about is the preamble that we write is a scientific paper. It could be published in any journal. It's a complete analysis of the facts about any particular problem with references and everything else. That is a tremendous job. Just think, if you had to say, "OK. You're going to do a Ph.D. dissertation on a problem." Because each one of these things was a problem. Each one of these had new science in it. "And we want you to put together a paper that describes that." And that's what we had to do. I mean, that's essentially what we have to do now. So it takes a lot more time.

Goodrich has never agreed with that. Never felt that that was necessary to do that. That all you had to do was have the basic facts about why we regulate it, and that many of these things, the standard of law, you couldn't articulate it in words anyway. It was reasonable certainty of no harm, and what does reasonable constitute? You could write that down. That is essentially what would be in the preamble. You wouldn't have to have all these other sorts of things in there.

But the legal community liked the Hutt preamble so well that it became the standard for the rest of the government. So now everybody does that that way. But FDA certainly set the standard for doing that, so it takes a lot of people. It takes people of better quality than I was. So we essentially had to go out and hire them. Not a lot of people that write regulations have Ph.D.s, in effect, are in fact scientists in their own right.

I, myself, when Paul, my son, who is now graduating from high school, was being born, I essentially was drafting in the waiting room for Paul to arrive, and I wrote the first part of the preamble to the saccharin ban and started out with Sir Percival Potts in 18--, cancer of the scrotum. Chimney sweeps essentially started this

whole business of cancer assessment, and that's the way the regulation starts out to this day.

One of the things I got was a call from Parklawn. (Laughter) "You refer to Sir Percival Potts. Where is the reference?" I said, "Well, there are only two books in existence that describe this study, and one's in the Library of Congress." We had to go over and photocopy in the rare books section of the Library of Congress the reference to Sir Percival Potts and the cancer of the scrotum. But that's the amount of detail that we go into on these.

RT: Do you see that as ever reversing, particularly now with the current administration's concern about reducing regulation effort? Do you think that aspect of regulation writing will ever revert to a simpler process?

RR: It isn't the problem of writing the regulations. It's the requirements themselves. I'm going to be inducted as a fellow of the Society of Toxicology in Aspen, Colorado, in July, and I have to give a speech, and it's going to be on these changes. It's going to be, I think, about, how you could always ask a question that can't be answered; there's no great skill in that. And one of the things is that the adverse consequences to scientists is never in saying yes. The adverse consequences are in saying yes. There are no adverse consequences to saying no.

When Metzenbaum was over there on the Hill, Gary Flamm and I went over to explain to him why the agency continued to stand behind aspartame. He said, "Mr. Ronk, you've worked for the government for thirty years. Why aren't you on the side of the consumer?" I said, "Well, I'm on the side of the law, and the law requires that Food and Drug, if it becomes convinced that something has reasonable certainty of no harm, we have to regulate it. I mean, that's what we're supposed to do. That's what I see as my job in upholding the constitution, that I took an oath that I would do when I came in here." If the answer is supposed to be yes, we're supposed to recommend that. But all the adverse consequences are to that.

When Dr. Schmidt was here, we had a big meeting about aspartame, and a lot of people had kind of turned their back on it in the center. Allen Forbes and Al Kolby had decided maybe we hadn't done enough to regulate aspartame. So the scientists were all sitting along the wall, and Sam Fine was really in charge of the meeting, whether or not we're going to go forward with the regulation.

I essentially told Dr. Schmidt that, "You know, if we turn this down on the basis that we've followed all of the requirements to regulate this material, we've answered all our questions, if we now say that there are other questions that need to be answered, that we didn't answer all these questions internally, we're essentially sending the message to all of these scientists that are sitting along the wall don't you ever prove anything again." So Dr. Schmidt said, "Sam, what do you think?", and Sam says approve it. Dr. Schmidt says, "Well, even though I'm kind of like the guy in the Dickens novel, I have kind of a little piece of cheese or something in my stomach kind of giving me a little heartburn over this, but I think we will go forward with this." So we did.

But that's the problem. Right now we can't approve any sanitizers. The law says you have to approve additives at the level that's not necessary. Well, that's never going to be a level that satisfies the microbiologist. He wants to be sure he kills all the bugs. So he's going to want to have a good, strong solution. Whereas the toxicologist worrying about oxidation products, he says, you know, "If I had put this into the wash of the cold water of the chicken processing plant, and there's chicken feces and everything else in that cooling water, what are the reaction products with ozone in the cooling water?" You can't answer that question. You could spend your life on the chemistry of what that might be. You can't answer that question. So if you ask that question, you will never get the answer to it, and you'll never get out of the woods.

Guys like Blumenthal, and Vos, and Fitzhugh, and Gary Flamm, and people like that understood that, and they never told people what to think, but they would go over every evaluation with somebody, and they would ask them, you know, "Where

does this question lead? I mean, what's the purpose for this question? Where does it lead?" Right now in the agency because of the Congressman Dingell business and all sorts of things, the scientific managers are almost seen as doing things that are criminal if they ask questions about the evaluations that have come in from the scientists.

A real explosive situation, and it will have to be resolved. But I think it can only be resolved by scientific managers who see their job as problem solving. Here's the reality of the situation; here's the problems that need to be solved. Are these things going to resolve in something that is a biological reality again? Is the risk that we're talking about a real biological reality or is it totally theoretical? Those things really need to be addressed in all of the centers.

RO: Is that some of the problems with color additives that seem to be dragging on?

RR: Color additives were kind of interesting. Color additives, of course, was a safety-in-use law, and people never realized that as new tests came along that once you say, "OK. I'm going to have a safety-in-use law, and I want you to . . . And I'm going to provisionally list that, and you keep asking any questions that you need to have answered . . ." Well, as new technologies came along, reproductive tests came along, well, we'd better have those, too, now. And we have a new protocol for doing cancer assessments in utero. Well, you better do those studies now, too. So the target for colors changes constantly while they are on the market. It wasn't like something that was off the market would essentially reach a threshold. I'm a gate keeper, so I have to decide enough is enough today. I'm going to let it pass over the gate.

The colors were safe in their time by the technology of the day many, many times. FDA would see Red No. 2 as still probably as safe as any of the others. It really got banned on a political basis. What happened was the study that was in progress collapsed. FDA decided it collapsed itself. It was doing the study. So since

we said, "Well, there are no studies ongoing to demonstrate the safety of this provision of this color." And so the choice was the commissioner had to ban it because there were no ongoing studies to demonstrate that. So essentially it bought time on the market by doing studies. So it was inherently set up to never end because you would continually have new studies that had to be done as the technology changed.

The colors are interesting, because we essentially banned them all, didn't we? I think you get a bias sometimes. Harvey Wiley had a bias against benzoic acid, if you recall, and he had a bias against saccharin, and Teddy Roosevelt didn't. If you look back at the original reports on saccharin, essentially back in 1907, those levels were the same levels of use that were being described years later and essentially are established by law. Now they're based on risk assessment; then they were based on digestive upset to the stomach. It's amazing. Wiley thought that if you ate too much saccharin you'd have these digestive upsets.

The coal tar colors . . . Coal tar was always associated with cancer, and so once you say "coal tar color" . . . And they had been producing coal tar since Fido was a pup. The biases there . . . They are cyclic compounds. You know, you have to have this resonance and symmetry to have color. So they have a lot of structure to them, and they're very electrophyllic. If I feed very much of any of these materials to animals, I know that they're going to induce effects of some sort or another.

RO: Well, with some of them, wasn't there more of a problem with the impurities rather than the basic compound?

RR: Well, the colors could be produced in a variety of ways. I never understood why in the beginning we didn't essentially say, "Here's the structure that I'm interested in, and we're going to regulate these colors to be sure that you do that by regulating the process." The way I end up with a particular color with a particular purity is say what has to be done by this process. They never did that, and they don't

to this day. So they say, "Well, you can make it anyway you want, but it has to end up being this amount of color with this family of impurities." Because of its cyclic nature, you're always going to have impurities, whatever the impurities are, if the main color turns out to have the functional group blocked, as it often does, the impurities won't. So they'll be more electrophyllic, and so they'll interact with cells.

The liver is an amazing thing. I was on a program called "The American Way of Cancer" back in 1970. Dan Rather was the interlocutor. I remember I used Dr. Lehman's office for the interview because it had a nice flag behind the desk. I always came out of these things smelling like a rose, for some reason. Everybody else seemed to get shot down. The reason that they let you on is because the bosses, the commissioner, and the other people, they didn't want to be shot, and they knew that there's nothing good personally that could ever come out of one of these things.

So they sent you out as a lightening rod. In fact, Dr. Edwards described me one time as a lightening rod. He said, "What we do with you, Dick, is we see whether or not you get struck with lightening. If you get struck, we don't know you. If it turns out well, we're happy you did it."

So I had, on that particular incident, essentially ordered the field through Paul to inspect the chloralkali plants where we had no regulatory authority at all on the mercury in fish business. And it ended up on the front page of *The Washington Star.* Roberta Horning wrote a column about that. It scared the wits out of me because my name was all over that column. It was in the Sunday paper, and Dr. Edwards and company saw it. At the staff meeting on Monday, Edwards thought it was a good story: "These are the kinds of stories we want." And so that's when he told me that, you know, if lightening would have struck, we'd have said we didn't know you.

RO: Well, have we covered food additives? We could probably talk all day about food additives.

RR: Well, the sulfites are a good example of what happens. If you do a literature search on something it is difficult to cover all of the journals. One of the journals that we did not cover was *The California Journal of Allergy* or something like this, and a guy named Simons had reported that he thought there were allergic problems associated with sulfites. We didn't pick that up in the GRAS review. So we were ready to do that.

"60 Minutes" had found out from Simons. Simons had, in fact, called "60 Minutes" about it, because we were going to regulate sulfites. FDA was going to approve it was GRAS. So "60 Minutes" asked to see FDA. Dr. Miller was busy. Corbin Miles comes over, and he says, you know, "'60 Minutes' wants to talk to us." The press office wanted somebody to do it. I said, "Well, I don't want to do it. I don't know anything about sulfites. You do it, Corbin. It'll be OK."

Poor Corbin gets destroyed because they had this information that it had caused deaths, in fact, and we were unaware of that. He was unaware of that when it happened. And now that program was so successful, that "60 Minutes" shows it again and again. So Corbin had to watch that maybe four or five times over the years as they rerun it.

(Interruption)

RR: The mechanism in sulfite toxicity really is still unknown. It appears that it has something to do with the sulfites as a gas. So if you put a heavy amount of sulfite on say a salad bar, on lettuce, constantly replenishing it, you would inhale these sulfite fumes as you're eating the food, and this is what causes this anaphylactic shock for asthmatics. Sulfites is widely used for everything from Ritz crackers to Potato Buds or whatever you want. So it's heavily used. But when it reacts with the food, as it does in potatoes, apparently there's . . . We've never found any illnesses associated with that.

So the theory was after the "60 Minutes" program was that the problem would be with sulfites that was not labeled, and so the salad bar kinds of situations or any unlabeled uses of sulfites we really had to get rid of. So that's been essentially the strategy. If you have an allergic response to something, clearly it is individual, and your only protection from that is to know that the product is in something that you're going to consume. So our insistence was on labeling, to do that.

In some products, if there were deaths associated with the products, from its use, and this seemed to be an either/or. Either you died, or it didn't bother you. So there were sixteen or eighteen deaths involved, and in any of those uses, we thought very strongly about banning it. That did not carry over to alcoholic beverages. There are people that have reacted strongly to sulfites in wines. I believe the alcohol, tobacco tax people are labeling it in U.S. wine products, but still foreign wines . . .

RT: Didn't we have some concern about sulfites in potatoes, such as in restaurants and so on?

RR: Because they're not labeled. They're not labeled for the consumer, yes.

RT: But it was questioned.

RR: Now that's being adjudicated. We didn't have a good administrative record apparently. Some things were left out of the administrative record, so it was overturned on the basis of an inadequate administrative record. But there was a big market, and not so much anymore, but there was a big market in pre-cut potatoes that would go to McDonald's or wherever.

RT: What was a hazard there? Olfactory or smelling, or was it more ingestion?

RR: We thought that there could be that same salad bar risk. The big risk there was we thought unlabeled sulfites, at a pretty good level. We even found out sulfites were being used in things like shrimp that we didn't realize as preservatives and other sorts of things, which we took action against and stopped.

Chilean grapes. The grapes are kind of interesting. Dr. Young was told by APHS (Animal and Plant Health Inspection Service) in Chile that somebody had tampered with the grapes and that the grapes were poisoned, in fact. We discussed that inside the agency. Dr. Miller had retired, so I was acting director for about three years. My advice to him was to get a hold of the person at the state department which was involved with terrorism. They had a person to assess the level of the threat, and whatever his advice was, we would follow, because clearly you could make a threat against any food product that you wanted. So that pretty much was the decision.

I then went off to a meeting in Hague. I was the U.S. delegate at a food additive committee in the Hague. So I went and I got a call from Dr. Schmidt on Monday. I understand back here that senior FDA managers were at a "go-away." So John Taylor was at a go-away at Harper's Ferry, and so was Dr. Shank, and whoever was in charge were pretty much away. There was another threat over the weekend. So Dr. Young decided that they would start looking at shipments, ships that were in the roads of Philadelphia and other places. Most of the Chilean grapes came to a port in Philadelphia. I guess there were seven ships up there at that time.

So he told me what he was doing. I said, "Well, what will you do on Friday?" He said, "What do you mean?" I said, "By Friday, every place in Philadelphia is going to be full of grapes, and you know that that's the source of fruit here in the United States." It comes from Chile at this time of the year. So they decided they would analyze this. So then when the *Alamar Star* was being unloaded, as you know, in the first part of that shipment they found some grapes that had cyanide in them.

There's three grapes, pictures of grapes, big, black grapes with little white marks on them. The white marks were probably calcium. The calcium or either it could be little sugar marks. But probably, in my view, they probably were calcium. But it did turn out that they got positive results. In the testing, they'd put them in a twenty-five millimeter erlenmeyer flask with a filter paper, and shook the flask and got a color change. In hindsight, if John Taylor would have been involved, or if you would have been involved, or if any of the old chemists would have been involved, which they were not, we would ask for the filter paper. Say, "Send us the filter paper." Because you can work with it. You know, you can just reverse it with ammonia. You can bring it back and forth. There are all sorts of things you could have done with the filter paper.

They did a check analysis on the second grape, I understand, and got the same result, and then the third grape went to Cincinnati, and they didn't get a positive check analysis. Not surprising, because I don't think the white mark on there had anything to do with it.

As you recall, some grapes and a lot of leaves like marijuana, if you're doing marijuana, one of the things that you can look for and decide that it is the leaf you're interested in is a calcium content. Put a little drop of acid on it, and it will fizz like an Alka-Seltzer tablet under a microscope.

Cyanide is also part of the ripening process of fruits. Ethylene oxide and cyanide are gases that are given off by decomposition of food. After it was over, we went and we talked with a lot of people in California and other places. The center carried out some studies to see what the effects would be and how these things might look, and Cincinnati did too. I think that probably they found cyanide. There's no question in my mind that they found cyanide on the grapes. Where it came from is anybody's guess.

There are things that interfere with the color test. Unfortunately calcium is one of them. I did not know that at the time, but after it became a problem and we started to go back and look, of course, what the chemists would do right away was

go back and look at the basis of the AOAC (Association of Official Analytical Chemists) tests in the first place. These were modified AOAC method that they were doing, but you would go back and find out what it was that would in fact interfere with this analysis.

The EPA had a published study on sewage treatment where a lot of cyanide and other sorts of things were involved, and they had a lot of interference with that color test on the basis of calcium that was in the product. You're talking about just a small amount of cyanide. Cyanide dissipates in air. Cyanide is not poisonous below two hundred parts per million. Cyanide either kills you or it doesn't. So it doesn't have any aftereffects to it. So that was that.

RO: Do you think the agency should have done what they did?

RR: The agency didn't follow its procedures. It would have followed its procedures if Dr. Young hadn't gotten involved. That's the mistake all commissioners make, and he made it more often than anybody else that I ever saw. You learn on your mother's knee around here. You don't report results out of the laboratory until it's time. The chief chemist would say, "Hey, keep the inspectors and everybody out of here until we're done, damn it!"

The other thing is that the check analysis system of Food and Drug would have, if followed, would have never, ever, ever, ever made that mistake if it was made. The thing that John Taylor would have done if he'd have been, because he's a chemist, or Don Healton or any of the people that were in charge, Ron, anybody else, was we would have gotten the filter paper and analyzed the filter paper. Cyanide's still in it. It isn't gone. That was critical to keep those and then not to throw out those solutions. They unstoppered them. You've got to have your wits about you when you're doing analysis, and the people that were doing them were inexperienced. They were not experienced people.

And this is hearsay. I had heard from others that that laboratory had trouble with cyanide analysis. There had been a yogurt sample some months before that was suspected of having cyanide, and essentially Philadelphia couldn't do it. They had Buffalo do it, essentially.

But once you say you found cyanide, I don't think there's anything else the agency could do. The solution was superficial. But, you know, once you start analyzing thousands and thousands of grapes, everybody thinks you're doing something, and, you know, it sounds good. It's not like the Tylenol tablets. Let's do a million Tylenol tablets, and everybody feels better. But the likelihood of you finding that defect is nil.

So I think . . . I don't doubt that they got the response that they got. In terms of an outcome, we'll be criticized forever, but I don't know what else they could have done. Once they decided they found cyanide, they had to do something.

RO: What about infant formula, Dick?

RR: Infant formula is interesting in that you find out things that you don't know. Nobody realized that infants had a chlorine requirement. So the original infant formula injuries came from that side of the house. The Pilots were here. The fact that a Food and Drug official's child was injured I think also highlighted it more than it might have been otherwise. If it happened to some poor person someplace else, they would have never detected it. But a very aggressive lady whose husband (Larry Pilot) was in charge of compliance in the Center for Devices was injured, and it became a cause for her.

Vitamin analysis and formula analysis has always been much more of a problem than people imagined. There's still to this day no good methods for Vitamin D, no good methods for some of the isomers of D. You know. There are still animal tests. I think what we didn't realize was that the requirements on infant

formula were much tighter than we thought they were. So I think the Infant Formula Act coming along was an appropriate response to that particular problem.

I was surprised since I retired to hear about this nonsense where the infant formula essentially was counterfeited, for God's sake. And for quite some time. I think it again points out that, you know, for us to discharge our responsibilities with the staff that we've got is really an enormous problem. You can't ever let things say what everything is, routine, you know. If you say, "Well, we won't inspect this because nothing's ever wrong there and whatever . . ." I was in Dubai when this happened, and one of the things that I was surprised at was that the same requirements for export did not apply to that product as the domestic product. That you could in fact export a substandard infant formula.

RO: Even if it wasn't properly labeled?

RR: Apparently, you could . . . You know. It would have to be labeled. Yes, it would have to be labeled. But it wouldn't have to be labeled in a way that highlighted its deficiency from the standard here. And the trouble with much of the world on infant formula, it doesn't have any standards. So technically we're supposed to have a letter from that country prior to the time it's exported that they are exporting a product that doesn't meet the United States and you don't care about.

But I think that some of the infant formula companies knew about it. They had to know about it. God! The business is too small. There are only five firms involved, and if you ever lose $50 million worth of business to somebody, you certainly know about the $50 million worth of business that you're losing.

RT: Yes, you would think so.

RR: Altadena was a disgrace. Altadena Dairy raw milk business. Dr. Young, I think, was an interesting guy in a lot of ways. He was a very active commissioner

and very aggressive. In a lot of ways, he was strange. He really responded to political pressure. He saw himself as part of the political process.

For instance, on the sulfites, we went over to see some commissar, Helms, over at the department, and Bob Temple was with me. I was glad Bob Temple was with me. But they questioned that we should do anything about sulfites. Because they said, "Well, how many deaths do you have?" And we said, "We have sixteen where we've had hospital records of that." "Well, that's not very many. And maybe we could handle it some other way. Maybe this, you know, this and that." And Dr. Young said, "Well, you know, the allergy is a problem. I have this allergy." Whatever it was, he always had the problem.

So my wife had just come out of the emergency room. She has severe asthma, and she came out of the emergency room, and I was kind of in a bad mood. So he said, "Well, people could carry a syringe of epinephrine around with them." I said, "Dr. Young, that's the dumbest thing I ever heard a doctor say. No doctor is ever going to recommend that an asthmatic carry a syringe of anything around with them. They want them to go to the emergency room if they feel bad. They're not going to have them injecting themselves with nothing." And then Temple jumped all over him, and that was the end of that.

Altadena was the same thing. Because nobody in his right mind thought we shouldn't ban raw milk, including the commissioner, who was an excellent microbiologist. But the California delegation didn't want to do that, so that was one of the things that was done.

Proposition 65 was in effect in California at the time President Reagan was ending his term in office. Food and Drug (Scarlett) actually drafted that regulation, which would have overturned Prop 65 and would have exercised federal preemption. That was hawked around the country by Coca-Cola, and they hired Norris, who was retired at the time, as a consultant.

RT: John Norris?

RR: Yes, to get the meeting with Reagan. Reagan was outgoing. This was November of the year he went out. So he got every secretary to buy on it, including the secretary of HEW, and went and saw Reagan and showed him a giant-sized bottle of Coke. It says, you know, Coca-Cola, apple pie, and Chevrolet. That's the United States. We don't want and you don't want a bottle of Coca-Cola which is sold worldwide to have reproductive toxicant on it for the caffeine business, and the only way it's not going to have that is you have to exercise federal preemption. So Dr. Young was masterminding this, because he thought it would get him in good with everybody and had Scarlett draft the regulation.

Wright was OMB director, acting at that time, and they simply wouldn't publish it, even though it was done, even though President Reagan said to do it, they wouldn't do it anyway, because they wanted Wilson to win the election in California, and the whole reason for not doing anything on federal preemption was so that Wilson would win the California election. Unbelievable.

The politics got to be a real problem in Food and Drug right around that time. Really with Dr. Young. Before that . . . I remember Sam Fine and I went over on the tuna fish; we went over to the White House. Flannigan was Nixon's man in the White House. Bumble Bee was in complaining to Pat Nixon about their problems with Food and Drug, because we'd detained tuna fish. We detained one-third of all the fish in the world at that time for both mercury and decomposition. And this was decomposition.

So after the meeting was over, they beat up on us in front of Bumble Bee. After the meeting was over, Mr. Fine asked Mr. Flannigan, who was the domestic advisor to the President, "Well, what do you want us to do?" And he said, "Well, Mr. Fine, do whatever you think is right." (Laughter) But that pretty much was the way that the White House handled Food and Drug.

Jimmy Carter, when I went over there with saccharin, I went over there and Midge Costanza was their consumer person. They had whole train loads of people from Atlanta, the Children's Diabetes Society, you know, Juvenile Diabetes Society

Association, I think. And, you know, you had to feel some sympathy for them, but . . . So they beat up on me and made fun of the length of my title and all these bureaucrats and all that sort of thing. Stuart Eisenstadt was over there at that time. He was the domestic advisor. So when I came out of there, I said, "Is there any message to go back to FDA?" He said, "None whatsoever. Do what you think is right." So really with the advent of the regulatory management group in OMB, Shauna Carlson and some of those people, by the time I left FDA, it was intolerable. It was just intolerable the amount of ignorant oversight that was ongoing at the agency.

RO: This was at OMB, not the department.

RR: Not the department. OMB. The department . . . Other than Mac Haddow and his teddy bears. We were against refilling of bottles, because you can't adequately clean them. And someone out in Mac Haddow country, out in Colorado or someplace, had a machine that would do this, and they were going to peddle this. Actually, it is in western states. So you could bring your Coke bottle in and fill it up at the tap and seal it off and take it back. They had some sort of a capping device so that it would recap the bottle so that it would keep the carbonation in it. We were against it, and we said so.

It was part of the food service program really. It was advice to the states. The states were against it, and they wanted us to advise the states that FDA wasn't opposed to it. John Taylor was the associate commissioner at the time and we got called over to see Mac Haddow, who essentially told Taylor that's they way it's going to be. John told him, "Well, that may be the way you think it's going to be. I will allow this letter to go out, essentially that says that it's the state's responsibility over my signature, only if while we're sitting here you let me call this person in the state and tell him exactly what I think about it." And I thought he was going to get fired, but Haddow gave him the phone.

But Haddow even got involved with wharf inspections, and some products of Utah, and all that stuff. One of the things about which Pitt Smith was proud of me at that time was we had oil of evening primrose. We had seized oil of evening primrose. A Canadian company was selling it in the United States, and McNamara was their lawyer. Pitt found out that they were going to come see me about filing a GRAS affirmation petition for this. So Pitt called me and says, "Can I send my compliance people down?" I said, "Why do you want to do that?" "Because I'm afraid you're going to give it away, and they won't give it away if my compliance people are sitting right there." I said, "Well, that's for sure. Send them on down if you want."

What he was trying to avoid was getting all of these seizures put together and combined in Denver, because if we got in that court in Denver rather than where they were at, New York and a number of other places, then a judge might in fact overturn these seizures, as we had had problems before with that particular court.

So McNamara came in, and he wanted to discuss the science. I told him, "We'll discuss how you file a GRAS affirmation petition if that's what you want. But we won't discuss the merits of it at all, whether oil of evening primrose has anything to do with heart disease or anything. We don't want to hear the claims that you're making." So he brought a scientist from England with him, a guy named Sir James Black, and I told him not to bring him, but he brought him anyway. So Pitt's gang is there, and so McNamara asked if he could come to the meeting. I said, "Well, Dr. Black, I'm sorry that you came all the way from England to make a presentation, because we don't have any scientists here. We're all compliance types, and all we're going to talk about is procedures, about how you file a GRAS affirmation petition. So even though I would find it interesting, I'm sure, I'm not going to let you make your presentation." He was a little disgusted.

So I'm over in Beijing, China, with Dick Adamson for the National Academy of Science Forum, he being the head of cancer cause and prevention at the National Cancer Institute. We were discussing who's going to win the Nobel prize. We

decided it was going to be Felchi and Montgain together . . . It was going to be . . . Well, the other guy. It wasn't Felchi. The other guy from the National Cancer Institute. They'd win it because they made up and all this sort of thing. The winner of the Nobel prize was Sir James Black for beta blockers.

So I get back, and a week didn't go by until Pitt called me up, "Hey, you're okay." I said, "Why's that?" He said, "Because you threw a Nobel laureate out of your office." (Laughter) I said, "You know, this is the second one." (Laughter)

The other time we had a Nobel laureate in, it was very interesting. It was on Vitamin C. We had Linus Pauling in, and he and Dr. Forbes debated Vitamin C for us, and they both decided that each of them would quit misrepresenting each other's position was the outcome of that.

One of my prize possessions, I have a picture of Linus Pauling and myself having lunch. I was the president of the AOAC at the time at the one hundredth anniversary, and I'm actually making a point to Linus Pauling. I had my finger up in the air, and Linus Pauling is sitting back in his chair and actually listening to something that I had to say. (Laughter) The AOAC gave me that as a present when I retired. It was really nice.

As for Altadena you know, we were going to put out a regulation to essentially ban raw milk sales in the United States. I don't know if they're still in business or not. I think they're not for some reason. I don't know.

(Interruption)

RR: The canned salmon recall, I think, is the greatest example of what Food and Drug will do, and it's the greatest thing . . . Since I've retired, I've been doing some trade things for the Department of Agriculture. I gave a seminar on shelf life of food products in the Arab countries, and I've been to Russia and Korea on shelf life problems and other sorts of things for them, for the Foreign Agricultural Service. But one of the things that impresses people, especially in Dubai--when I was over

there a guy was very critical of U.S. products--was to say, you know, in 1977 or '78 the salmon pack from Alaska was recalled on the basis of one death in Belgium. I said, "You know, the United States and the Food and Drug Administration, where we have product, recalls the problem." It isn't just in our own country that we do this. You know, that was an enormous thing. The entire Alaskan salmon was recalled at one time.

That's kind of . . . It was kind of an interesting phenomenon too, as you recall, because the can machine was actually making a hole shaped like a triangle in the product, but the product was so dense, that it was sealing up the hole well enough to keep the spoilage organisms from spoiling the product, but keeping out the air so the botulism would grow.

RO: Do you know if they're still using reformed cans or have they gone to only formed cans? Because wasn't that the problem shipping the flats up there and reforming them at the plant?

RR: Well, Jim Swanson wanted to call that a salvage industry at that time, and was precluded from doing so, and I think he was right. The United States fishing industry's main problem, I think, has been with being undercapitalized. Our fleet back in the days of the tuna fish problem, if you recall, the American fleet was going out and seining tuna, bringing them on board ship, putting it on ice. They were decomposing on the way back to the canneries.

The Japanese had cannery ships that were out on the seas. The only problem they had was the fish were drowning as they came in off these long lines. The line might go out forty miles or something like that, and they would drown while they were being brought in. So they were decomposing in the water before they were brought on board ship and then canned. But, you see, if you had a cannery ship, you could solve that right away.

The Alaskan industry is an industry that only operates part of the year; it operates with people that are not skilled in food technology. The lots were all combined. They were shipped from Alaska in bright cans, and then the labels were affixed in Seattle--you know that. So they had had all kinds of problems in the distribution system so that you couldn't identify specific packs. You know, the lots would be lost essentially in the process if they didn't have adequate can codes to go back on specific packs. So the label was not a good indication of where it came from or anything else. Not even a good indication of the manufacturer in many cases. So I think that they still have some of those can reforming machines up there.

RO: Do you think the agency overreacted on that?

RR: No. No, I think there's only been a relatively small number of botulism deaths from canned food. But for whatever reason, we've always held canned food to a pretty high standard.

The Bon Vivant incident many years ago is a case of where a guy made a real nice tasty soup, but he didn't know anything about processing food. Cooking the bejesus out of something always affects the taste. But it's safe, you know. Food is pretty fragile, and there's always a compromise between maximum taste, and nutritional characteristics, and food safety if you're going to have to preserve food in some way, either with preservatives, or with canning technology, or with freezing, or any of the other kinds of technology, radiation, whatever. Radiation is OK; it would certainly solve the salmonella in chicken probably if it were used. But you have to be sure that people don't reirradiate things to essentially disguise quality.

My principal beef with radiation standards that we have is that there is no code of practice that goes along with them that essentially guarantees no reirradiation. So that if you had a fish, and it's starting to smell, and you irradiate it, you bring it back to freshness. It's not fresh. You know, and the expectation is a quality product. And my . . . What I pay for it and everything else is based on

characteristics that are assumed about the product. So I think there needs to be a code of practice to go along with anything else that really outlaws reirradiation. I think our regulations do that, but international standards don't.

It's going to be very difficult for us to maintain our credibility while we regulate new technologies such as radiation, biotech, and the other kinds of things that the public doesn't understand. Biotech is a solution looking for a problem. It's hard for me, even with the limited scientific background that I have, to imagine how you could get into a situation where you're eating the same sorts of bacteriological moieties as are in the tomato through biotech as were in there in other things. There's no way in the world that you're going to eat something, and it's going to get in your gut, and bring about changes in the microbiological flora of your gut so that there's going to be reaction products or changing any kinds of disease codes or anything else.

RO: Can we detect reirradiation?

RR: No. There are a couple of methods that we've done with shrimp. Luminescence-type techniques. There is, in fact, a moiety that has photoluminescence that is associated with irradiated products. But all it would tell you is the product's been irradiated. It wouldn't tell you whether it's been reirradiated. But I think fish products are, in fact, reirradiated worldwide.

The Netherlands, even though it doesn't by regulation, requires that all shrimp that's brought to the Netherlands, shrimp and prawns, be irradiated on the basis of an outbreak of shigella from prawns in old people's homes in the Netherlands. So at the Port of Rotterdam, at Amstar in Rotterdam, they irradiate most of the shrimp that's coming from the Far East, and then it's reshipped to the United States. So they bring it into that plant and do it there, then bring it over here. The only clue that we have when that happens is that there isn't any microbiological flora. It's too clean. But I don't think that if we ever were challenged on that, if we ever had to

report on that, it would be pretty tough. I mean, the court would want more proof than that.

RO: What about nutritional labeling, getting back to the old problems?

RR: Well, the nutritional labeling, of course, came out of the White House conference on nutrition, on the aging. The last one they had. They have one going on now. I found one I'm bringing out here to the history office. I've got a bunch of stuff that I have to bring out here. A big, long sheet of plans from the White House conference. How to implement all the suggestions from the White House conference, who was supposed to do it, when they were supposed to do it, and all that kind of stuff. But sodium labeling changes, standards, nutritional labeling, some talk about infant foods was all in that conference. But changes in standards was the big thing in that conference, and nutritional labeling was part of that.

Allen Forbes was very much for that, and Oggie Johnson before him. Ogden Johnson, of course, was director of the Division of Nutrition when the Bureau of Foods was formed in 1970, and he went on to become the senior vice president of Hershey Foods Company in Pennsylvania. But Oggie was pretty much behind that.

I remember we gave a talk on nutritional labeling down in Atlanta one time, and Oggie weighed 260 or so, and I'm not small either. I was weighing about 250 then. He gave a talk a nutritional labeling; I talked on whatever. It was a big consumer meeting. There were a thousand people there. Atlanta had set it up. Some lady got up and said, "You people from Food and Drug, you ought to talk about nutrition! You're all nutritional disgraces!" Oggie said, "Well, yes, I guess you're right." I said, "I should lose weight for health reasons, but I never would do it for cosmetic reason. I never would do it for that."

But I think that points out that it is tied together. Most people will lose weight and will control their fat intake based on appearance. They don't want to

look bad. The public knows that there are consequences to fat ingestion, but then their behavior hasn't changed.

RT: That kind of leads maybe into another aspect of foods, and that would be the drug claims for certain kinds of foods. There's been some concern about that, hasn't there?

RR: Yes. When we went out to seize Kellogg's, we recommended we seize Kellogg's for cancer claims, and, of course, Dr. Young wasn't about to do that. We had a meeting, Paul Hile and I and Bill Schwemer. Paul says, "What shall we do? We've got to solve this thing some way." And so we decided then that if there were legitimate claims that could be made about disease and health, that we were going to allow that, if in fact you could scientifically demonstrate that it was true. So the truthfulness of the claim. It was actually Paul's idea to change the wording away from "health claim" to "health message." So you notice how that changed so that we wouldn't be saying that.

And then our other goal was to get out that notice not to allow health claims. You know, one of the things that OMB did to us on that was they essentially said "this proposal on health claims is an advisory opinion." So it has the force now so that . . . The preamble of that could be used now, so any health claims that are ongoing now, even though we didn't finalize it. So it was more of a policy statement than a proposal. So we had to get all of that out of there.

So it took us then months to get Young to agree. Joe Levitt was a great help in getting Young to change his attitude and say, "OK. We want that out of there. We also want these to be health messages, and the health messages essentially have to be only those messages that the surgeon general's report essentially said have validity. I think that was a fair outcome of that.

RT: In the process of those deliberations, is it correct that the National Cancer Institute got involved on a pro signing of that issue?

RR: Well, cancer cause and prevention is part of Adamson's division, and Adamson and I have talked about that a lot of times. Peter Grüenwald really believes that diet and cancer are very much involved, and it's part of cancer prevention. The greatest intervention that you can make is dietary. Maybe he's right. I don't know. There have been a lot of studies, studies in China and elsewhere that they have funded.

So Peter Grüenwald's unit was behind that, and Kellogg's went to them and got them to agree to the cancer claim. Once that happened, there's no way in the world you can sit down with the commissioner and explain to him. "Well," you know, "it's making a claim." "Well, so what?" It doesn't make any difference whether the claim is true or not. If making a claim makes it a drug, and there's a disease for which there's no cure, blah, blah, blah. So, you know, the statute is very easy for us on that standpoint. They've made a drug claim, and we've always not allowed that.

So that's why we changed the wording away from "claim" and "message." That was a sandbag. Peter Grüenwald sandbagged us and did it very deliberately and very effectively.

RO: Do you think Taylor Quinn retired over that? You know, he retired about that time, and there were some that said, "Taylor retired over health claims on foods."

RR: Taylor retired because Taylor was a lot like, you know . . . Taylor is a giant as far as Food and Drug is concerned, and as far as I'm concerned. Taylor thought he didn't get Sam's job when Paul got it because he wasn't tough enough. I said, "Taylor, that isn't it." I said, "It isn't tough enough. You didn't get it because you're inflexible, and you're perceived as inflexible. People don't come in and ask you

questions, or ask you questions because they think they don't know they law. They know the law as well as you. They are coming in here to get around it, and sometimes you have to give a little bit. If it's reasonable, you have to give a little bit, even though you realize . . ."

He quit because Young reprimanded him about a meeting he was at. Yes, it was right at that time. And Taylor said what Taylor thought was right, and he reprimanded him for saying anything at the meeting. Quinn told him, "Well, if I'm not in charge of what I think I'm in charge of, I'll find something else to do." Yes, he was very much hurt by that, and I don't blame him. I don't blame him.

RO: Well, of course, like you said, Taylor was inflexible. I can remember Tom Scarlett saying, "Taylor stakes out his position, and then the rest of the agency has to scramble around trying to defend a different position than Taylor had."

RR: Yes. He would never change.

RT: Well, I think, too, as you've indicated . . .

RR: What the industry liked about Taylor and what they . . . It was harder for some of the commissioners. The last few commissioners we've had, and Kessler's the same way as Young. Young, Schmidt somewhat, but not nearly as bad, Kennedy, all of them, thought that every day was a brand new day and that every problem was a brand new problem. So I've got all the degrees of freedom of solving this as though it doesn't have an impact on other things that have been solved. Industry hates that, because what they want to be sure of is that you tell the same thing to everybody, so that they have a level playing field on whatever it is that they're going to do.

Even something that's as mundane as the food standards. Mayonnaise is mayonnaise, percentage of fat. Salad dressing is imitation mayonnaise. Imitation salad dressing, you know, the low-fat salad dressings, are imitation imitation

mayonnaise. And CPC pretty much had staked out the quality mayonnaise market, Hellman's--as far as food technology is concerned, the quality mayonnaise. Better than Kraft. Kraft has the quality salad dressing. Those kinds of things.

So when you come out with something that you say, "Well, there's not . . . You know, this is really imitation mayonnaise, this low-fat thing." It wasn't imitation mayonnaise. It was imitation salad dressing, because it contains some ingredients that are not in mayonnaise. Now that may not seem to be something that you go to the mat about, but it's something that Food and Drug has to enforce in the marketplace, and that's what standards are about. Fair dealing in the damn marketplace.

Now, Quinn was committed to that. Quinn was committed to fair dealing in the marketplace, so he . . . If Peter Hutt came in and said he wanted peanut butter with jelly in it, Taylor was going to say, "There ain't no standard for that." And, of course, others, Paul or some others who were a little more reasonable in terms of some of these things, they never really figured that out. Commissioners never figured out that it seemed too inflexible; it seemed unfair in some cases to do it that way. Saying, "Well, nobody's going to be hurt, nobody's going to do that." All that's true. But I think the only way that you're a fair regulator is if you decide to give in on a point, then give in on a point for everybody. It goes back to everybody you ever talked about it to or whatever. But you don't give somebody a temporary marketing advantage over that.

One time Tom Brown tested Virgil Wodika when he was center director. Hunt Wesson had a marketing permit for tomato wedges. There's no standard for it. Then they went and made so many cans of tomato wedges that even after Virgil retired and came to work for Food and Drug they're still around. So we went to seize the tomato wedges, and Tom did that. But we seized these tomato wedges, and I always thought Virgil was wise in not having anything to do with it. He said, "You know, this is really dumb." I said, "Yes, but it's legal." He said, "Yes, you're right.

You're right." But, you know, if you don't enforce those things, then people do take a marketing advantage. They do make too much of the stuff.

I was astounded when McKinley, a guy that worked for Hoffmann-LaRoche who had worked at Center for Veterinary Medicine, came in on the color additives, and they were talking about canthaxanthin in fish feed. And I said, "Why do you have to have a color additive petition for that? You know, since it's not provisionally listed for that use, you're going to have to wait until . . ." He says, "Oh, no. Not at all." I said, "What do you mean by that?" He said, "No, we can go ahead and use it in the test animals that we use, then we can sell them." I said, "Like hell you can." So he went and got the book of regulations down and showed me in the regulations where they could do that in veterinary foods, even with color additives. He said, "I know that, because," he said, "I wrote that regulation before I left here."

You know, there's a number of little things like that that seemed just awful arbitrary that I think that that's not right. And you can't give variances for those sorts of things.

RO: What about the last reorganization of CFSAN (Center for Food Safety and Nutrition).

RR: Disaster.

RO: What really caused Foods to go in that direction? They abolished the compliance unit as such, the Office of Compliance, and . . .

RR: Mary Jo Veverka. It was her idea. They had a go-away with the center people. I didn't get the job as director for Center for Food Safety for two reasons. One, I was not a Ph.D., which I myself thought was a disability, and the other was because Young didn't care for me at all, and one of the things that Young wanted

to be sure of before he got out of here was that I was out of that job, which he did do just barely.

One of the problems that we had then was . . . I think Fred (Shank) is a good guy, and I don't think Fred did anything behind my back to get the job, although they were more compatible. Fred was the kind of guy that was selected because he follows orders. He doesn't see himself as a policy maker; whereas, I did, and Dr. Miller did, and certainly Dr. Wodika. Our impression was that we had product oriented bureaus so that the bureau could, in fact, set the policy for that particular area, whether it was veterinary drugs, or foods, or whatever, and that we were very much involved in policy development. Fred was much more likely to follow the direction of the commissioner.

So that became a problem in the reorganization because Mary Jo Veverka said, "This is the way I want it." Nobody in the center wanted it that way. But . . . Then Doug Archer didn't want it that way. She came up with this idea, and it was pretty much . . . One of the troubles with doctor doctors, M.D.s, is that they always think they're going to organize something like a hospital, and a hospital is, you know, every department has everything it needs. They stand alone. Well, that's not the kind of system that seems to me works in a smaller organization like Food and Drug.

We had twenty-two scientific divisions, and you essentially had to buy time between them, you know, which required care for coordination between the offices. But the regulation writing was in the Office of Compliance, and the evaluation was in other offices for foods additives, and it was the job of the person that was going to manage the food additive program to see that there was a coordination between these groups, and it required a good deal of cooperation between these units.

She saw that as a big disability. That you couldn't hold somebody responsible for all this. Yes, you can hold somebody responsible. You can hold the managers responsible, like anything else. She wanted to hold one person responsible for all of those sorts of things, and the fish program coming along where you're going to break

fish out for visibility and all that. That kind of helped this along at that particular time. But a couple of things happened.

If you look back historically at Food and Drug, going way back to the beginnings, it always reinvents itself, and what happens is the Bureau of Chemistry found out that this Food and Drug business is a zero-sum game, and we want to do research but the compliance people are getting all the money. So the only way for us to do is get away from those people. So they broke away. The Bureau of Chemistry became the Agricultural Research Service; the Food and Drug became the Food and Drug and Insecticide Administration.

But after it broke away, it wasn't very long until it decided, "I need scientific advice to do this." So it started bureaus again. It started to have a science arm. So it always had this science arm because it had a big science component to it. It found out it was much better for its own scientists to interpret science than to have outside scientists interpret science or not to be able to interpret science.

This is a lot more recognized with drugs I think. But with (Center for) Foods, everybody thinks they're a foods expert. They know everything about food. So we were having trouble validating the fact that there was knowledge within the Center for Foods that was valuable enough in terms of advice to keep it there. Now, the only way you can keep that kind of advice around is that you have to have laboratories. You have to do the tasks that you're going to ask other people to do to be competent in it. Once we didn't . . . Once the food additive amendment came along and there was no necessity for us to test the additives and those sorts of things, the animal side of that place always had trouble validating itself, because it couldn't point to something that it had to do to keep these laboratories going other than methods development techniques and that sort of thing.

The Division of Microbiology was a world standard. It had been for years. It went back for years, back to Howard's laboratory back in the old Bureau of Chemistry. There had been in the Food and Drug Administration forever a premiere microbiological food laboratory. That's gone. That's scattered to the four winds.

Chemistry started going downhill. One of the things I think that started it downhill was my old buddy, Donald, and one of the things that was in Don Healton's psyche, I think, that I recognized even as a chemist when I worked for him in Kansas City was he felt very, very strongly that he was as good a chemist as there was around.

(Interruption)

RR: Yes. Don thought he was as good a chemist as there was around. And one of his bugaboos, and I don't know why, was Horowitz. For some reason, Horowitz did something one time or something that, you know, Don didn't like or something like that. So, for whatever reason, Don always seemed to . . . And if I was running the field I would be doing the same thing. I would be trying to build up the science capabilities of the field. But the centers, Center for Foods especially needed the field to need them. So in the pesticide area, with Jerry Burke and when they had that kind of capability, the field always felt it needed that kind of capability. When we had the old Division of Foods and Lowrie Beacham's gang and all that, and we had really food technology experts in there, they felt the same way about it.

Dr. Olson, when he was director of Division of Microbiology, criticized the field unnecessarily in the microbiological area one time and brought a lot of bad blood there for a long time. Field science getting transferred one time to the Bureau of Science under Horowitz brought a lot of bad blood to that that never recovered from it.

But as the critical mass in the science units . . . As we didn't get people, we didn't get people, we didn't get people for so many years, and the center went down from fifteen hundred down to eight hundred, we lost a lot of the people that the field and other people depended upon for the kind of expert advice that they were truly an expert. And so when we have to justify it . . .

So here comes Mary Jo Veverka along, and you want to sit down and say, "Here. What have you done? Look at all this nice stuff that I've done for you lately." Didn't have it. I thought we had it in the microbiology area, but we'd lost out in the chemistry area over the last fifteen years pretty dramatically, too. And toxicology didn't have any reason to exist.

What I think you're going to see happen is the whole wet side, and that's the remainder of the Bureau of Science. The whole wet side of the Bureau of Foods is going to be gone within five years. There's no money. No money to run Beltsville; there's no money to run the laboratories. There's nobody thinking. You know . . . What kind of good stuff have you got for me?

Even on the fruit juice business, there wasn't . . . You know, we got involved in the fruit juice. There was nobody you could turn to in the center. For God's sake, I was the international U.S. representative of the fruit juice committees of Codex, and I don't know diddley about fruit juice. So that brought that about. The only reason that the center has for a living now is infant formula, nutrition labeling, and food additives. So I don't see those laboratories surviving. It's going to hurt the field more than the field imagines right now. And it already has because of this nonsense of moving everything to NCTR and all that kind of business.

RT: Do you think that might lead to the termination of what's left of (Center for) Foods with agriculture? There's been some legislative proposals to do that, I guess, in the past.

RR: Well, we were there before. I don't think it's beneficial. Yes, I think you're probably right. The drug people aren't happy with . . . It's kind of like Al Barnes' conversation with me, you know. Is everything over? Aren't there any problems out there to solve? That kind of stuff. And, yes, there are. There really are a lot of problems out there to solve. And do we need laboratories? Yes, we need laboratories. We especially need field laboratories. The lack of laboratory

information in compliance actions, the drop in compliance actions and the drop in court cases, the inability of us to get time with the U.S. attorney, you know . . . For them to think that what we are doing is important enough to have a trial essentially has made everything . . . Well, production is everything.

You know, the grapes would have never happened in a trial-oriented environment. It happens in a production-oriented environment. The chief chemists are criticizing, you know, how many samples have you done and all these kinds of stuff and things like that that came about. You can only do so much inspectionally.

But I think that clearly one of the things that Food and Drug is going to have to do, it has to sit down and relook at its mission, relook at the areas that it wants to be aggressive about, and it's only going to be able to do that if we do a whole lot more surveillance. I think we ought to have really big sample-based national surveillance programs that are run out of the field laboratories that can give you a true compliance picture of the country. You can't do it inspectionally.

RO: What do you think of Dr. Kessler's organization and his immediate office?

RR: Oh . . . Dr. Kessler is an enigma to me. I knew him in other reincarnations. The first time I ever talked to him he called me on the phone from Hatch's office, and Hatch wanted to write a paper on risk assessment for a law journal. He said, "What can you do to help me?" I said, "Well, when do you have to have it?" He says, "Oh, about Thursday." This was like Monday. So I took a paper that Scheuplein had written and gave it to him, and he fixed it up and then published it. I told Scheuplein, "That paper that you wanted." He said, "It's awful. We're not going to let it out of the place. This is awful." OK. So after it published, I took it down and said, "God, this looks familiar, doesn't it?" (Laughter)

He changed a lot during the time . . . Dr. Kessler I think has done a lot of good things for the agency. I'm very suspicious of guys that don't have any sense of humor and can't make small talk. And, boy, he is one of them. He seems to be

on . . . Outside appearances . . . Public appearances outside . . . He relates outside. He doesn't relate inside, I don't think, at all. And his organization is craziness.

RO: I would think that the centers would really feel isolated . . .

RR: Well, they do.

RO: . . . compared to what it was before, where the center director reported to the commissioner. Now . . .

RR: You don't need them. See, the centers are baggage other than the work that they do for themselves. Food additives, infant formula, we do that for ourselves. That's work generated ourselves. The labeling primarily was work generated ourselves. What do they do for an encore? I told Betty, "What are you going to do for an encore?" And she doesn't know.

But the . . . You know . . . I think that the centers are baggage. Devices does its own thing; biologics does its own thing; drugs does its own thing, and they've got quite a bit of an inventory to work on. They've got a lot of things to do. So what holds them together? What held Food and Drug together? Well, the relationship to the field is the only thing. Devices and Foods were as different as night and day. Villforth and I used to laugh about that. We have nothing in common. We have nothing in common except a common statute and a common organization of apparatus in the field.

So that was . . . The field was the only coordinating factor in the agency, and as that kind of drifts away, and the direction for that drifts away, and the input for direction drifts away from the centers, then that coordinating influence isn't there either. Without the field, you always lose your way, because you forget what it is that you're doing.

I think that was the principal thing that took away from field experience was the fact that you are a regulatory agency and that you are regulating people, and the reason that you do a good job, you do a better analysis than any university is ever going to do, is because people's civil rights hang in the balance. On the basis of what you say, you can take away somebody's right to vote and everything else in this country. It isn't a trivial matter that you're dealing with. You're going to say that this guy has done wrong. This guy is before the court; he's done wrong. That's not the output of a new drug application, and it's not the output of anything else like that.

RO: Well, Dick, is there anything you want to add? We've covered a lot, and we really appreciate your time. If there's anything else you'd like to add, why . . .

RR: No, I think the only thing I'd add is I think I owe . . . I've had a wonderful career in Food and Drug, and it went, I think, far beyond anything that I deserve from my background and my own abilities. But I just can't say enough about the people that I worked with at Food and Drug. The people that I worked with in the field, the Harry Conroys and the Andy Allisons and the Al Barnards and people like that. There's . . . It's hard to see the folks that are here now matching that in terms of prestige and effective and everything. These guys were giants. Taylor . . . They did what Horatio Pate . . .

They used to list their occupations when they had these big conferences, and Stalin was a whatever he was, and Anthony Eden went to one of these conferences and put down that his occupation was "gentleman." And the gentleman burns with a hard gem-like flame. And you know that these guys really were, Barnard and Taylor and people like that, were really consumed by Food and Drug. They burnt with a hard flame all the time, and they really had a . . . They were on a mission. They really were. And it made this place tremendously exciting. Couldn't have had a better job.

RO: Well, thank you, Dick, and we'll end this interview then.

RR: Yes.