HISTORY OF THE

U. S. FOOD AND DRUG ADMINISTRATION

Interview between:

Ronald T. Ottes, Retired

Director, Office of Regional Operatio:

and

Fred L. Lofsvold

Robert C. Porter

U. S. Food and Drug Administration

Rockville, Maryland

May 16, 1986

INTRODUCTION

This is a transcription of a taped interview, one of a series conducted by Robert G. Porter and Fred L. Lofsvold, retired employees of the U. S. Food and Drug Administration. The interviews were held with retired F.D.A. employees whose recollections may serve to enrich the written record. It is hoped that these narratives of things past will serve as source material for present and future researchers; that the stories of important accomplishments, interesting events, and distinguished leaders will find a place in training and orientation of new employees, and may be useful to enhance the morale of the organization; and finally, that they will be of value to Dr. James Harvey Young in the writing of the history of the Food and Drug Administration.

The tapes and transcriptions will become a part of the collection of the National Library of Medicine and copies of the transcriptions will be placed in the Library of Emory University.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Room 500 U.S. Customhouse
721 19th Street
Denver, Colorado 80202
303-837-4915

TAPE INDEX SHEET

CASSETTE NUMBER(S) 1,2, and 3

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

DATE: May 16, 1986 PLACE: Rockville, Maryland LENGTH: 150 Min.

INTERVIEWEE	INTERVIEWER
NAME: Ronald T. Ottes	NAME: Robert G. Porter and Fred L. Lofsvold
[redacted]	ADDRESS: U. S. Food & Drug Admin. Denver, Colorado

FDA SERVICE DATES: FROM 1957 TO: 1985 RETIRED? Yes

TITLE: Director, Office of Regional Operations
(If retired, title of last FDA position)

CASS. NO.	SIDE NO.	EST. MIN. ON TAPE	PAGE NO.	SUBJECT
1	A	0	1	Introduction, Summary of Mr. Ottes' Career Prior to Joining FDA.
		4	3	FDA-Minneapolis District.
		5	4	Clean Wheat Program.
		8	5	Rotation Chemists Program, Washington, D.C.
		16	9	Transfer to Baltimore District.
		18	10	Priority Handling of Imports.
		20	12	Move to New District Office.
		23	12	Reassignment as Chief Chemist, Baltimore District.
		30	14	Heptachlor in Milk.
1	B	0	15	PCB's in Milk
		5	16	Reassignment as Deputy District Director of Baltimore District.
		5	17	Self Certification Program.
		10	20	Baltimore District Tryout for New Programs.
		13	21	Transfer of FDA to Consumer Protection and Environmental Health Service.
		16	23	Kinslow Report
		18	23	Realignment of District Boundaries.
		19	24	Transfer to Headquarters.
		22	24	Establishment of Regional Offices.
		22	25	FDA Reorganization.
		27	27	Transfer of Biologics and Radiological Health to FDA - Relationships with the Field.
2	A	0	29	Bon Vivant Crisis.
		6	32	Canned Mushroom Problems.
		9	34	GAO Studies, Increase in FDA Staff, 1973-1973.
		12	36	Transfer of Product Safety Program to Consumer Product Safety Commission.
		17	39	FDA's Mid Level Training Program.

CASS. NO.	SIDE NO.	EST.MIN. ON TAPE	PAGE NO.	SUBJECT
2	A	27	42	Paul Hile Named Associate Commissioner for Compliance.
		28	43	Don Healton Appointed Executive Director of Regional Operations (EDRO).
		29	43	Reorganization of EDRO.
		30	43	Tampering Incidents.
2	B	0	43	Tampering Incidents, Continued.
		1	44	Reorganization - Merger of Office of Compliance and EDRO.
		4	45	Federal State Liason.
		13	50	More on the Clean Wheat Program.
		18	53	Industry Education Programs.
		20	54	Watered Oysters.
		22	55	More on the Self Certification Program.
		25	56	Intensified Drug Inspection Program (IDIP).
3	A	0	59	Salmonella in Rendering Plants and Animal Foods.
		5	62	Work with FDA Commissioners.
		6	63	Dr. Charles Edwards
		8	64	Dr. Alexander Schmidt.
		13	66	Dr. Donald Kennedy.
		15	67	Dr. Jere Goyan.
		16	68	Acting Commissioner Sherwin Gardner.
		20	69	Dr. Arthur Hayes.
		23	70	Acting Commissioner Dr. Mark Novitch.
		26	71	Concluding Remarks.
		30	72	End of Interview.

This is another in the series of FDA Oral History Recordings. Today we are interviewing Ronald T. Ottes, retired Director of the Office of Regional Operations. Also present are Fred L. Lofsvold and Robert G. Porter of the FDA. The date is May 16, 1986. The recording is being made in the FDA History Office, Parklawn Building, Rockville, Maryland. This recorded interview today is a very important one and marks the joining of the FDA history project by Mr. Ottes.

Ron, we'd like to start by asking you to give us a brief resume of your career, starting back as far as you want to go and bringing us up into the FDA.

RTO: I was born and raised in North Dakota, graduated from Jamestown College, a Presbyterian school in Jamestown, North Dakota, with a B.S. degree in chemistry in 1941. Shortly after graduation, I joined the State Laboratory Department in Bismarck. That's kind of a counterpart to the Food & Drug Administration in the State of North Dakota except that it had much wider responsibilities. In addition to foods and drugs, it carried out responsibilities for enforcing an anti-freeze law, a petroleum law that included gasolines, oils and had a paint requirement; feeds and fertilizer, both registration and examination; a beverage registration. In fact, it was kind of an independent department in the state, neither attached to the Health Department or the Agricultural Department and it was pretty much self-sustaining as far as the fees that it

collected for the registration of a lot of the products. I stayed with the State until 1957 when I joined the Food & Drug Administration at Minneapolis. I had a two year interim when I was in the Navy from 1946-1948.

FLL: What was your last job at the State?

RTO: I guess it would be considered as kind of comparable to a chief chemist job as far as the State Laboratory was concerned. One of the things I worked on there was -- vitamin analysis. We had gotten one of the early DU spectrophotometers and that was quite an event as far as the state was concerned and we utilized that in analyzing vitamins. Before that I had been analyzing, especially Vitamin D, by the old rat assay. We had a rat colony there and that was quite an experience. I can remember when we finally disposed of the colony. It was rather a sad day when we chloroformed all the rats.

We also were, I guess, one of the first states that had an enrichment law for bread and one of the jobs I had was a combination inspector and chemist. I had the honor if you could call it that, of going out and inspecting bakeries and then collecting samples. I'd get a sample of their enrichment if they used an enrichment tablet or if they used enriched flour, then a sample of their flour, and then the bread resulting from that and bring it back to the laboratory and analyze it for the enrichment.

I had reached a position in the Department to the point where I couldn't have progressed much further except going to what was my boss - the State Food Commissioner and Chemist - and there were some overtures made to me that maybe I should try for that job. They were trying to get rid of my boss who had kind of outlived his usefulness. In fact, the day that we were packing, after I'd accepted the job in Minneapolis, two members of the Commission - the Laboratory was operated then by a commission consisting of the Attorney General, State Treasurer and the Governor - and the State Treasurer and Attorney General came to visit me while we were busily packing and wanted to know if I wouldn't reconsider. By that time I'd had politics up to my ears and I said no - in a year from then they might decide to get rid of me and I'd made up my mind that I was going to get into the security of the Federal Government. So, I left for Minneapolis. That was in March 1957. I guess I had the distinction of being one of the first chemists hired in the field at a GS-9 level. At first, as far as my cohorts in the laboratory, it didn't serve me very well.

RGP: I can imagine.

RTO: I was only in Minneapolis for about 18 months but there were a few things of interest to me. We had a big grain program as both of you probably remember and we were collecting samples of grain in railroad cars and also at some of the little grain elevators, country grain elevators, and examin-

ing them primarily for rodent pellets. Every once in awhile it would be for pink wheat. When we would enjoin these elevators I had, again I guess the honor of going out with the inspectors when we would, what we called, recondition these elevators. And it was interesting. It was colder than all blazes in the wintertime in both South Dakota and North Dakota. We'd go out and sample every truckload as they would remove the grain from the bins and we'd have to examine it to see whether it would pass our tolerance for rodent pellets. I went on two of those, one in South Dakota and one in North Dakota, and it would take us about a week to 10 days depending on the size of those country elevators.

I also had an AOAC project of phosphatase in cheese. Phosphatase was a determination of whether or not the milk had been pasteurized properly. So, I would go out with the inspectors and inspect cheese plants and examine what they were doing and then collect samples and bring them back to the laboratory for examination.

I should mention that the District Director of Minneapolis at that time was Bud Kerr, the Chief Chemist was Norm Foster, and the Chief Inspector for just a brief period of time when I first came was Johnny Guill. He later was transferred to St. Louis very briefly.

FLL: He was promoted to Director of St. Louis and then was Director of Chicago later.

RTO: Joe Durham was the Food & Drug Officer. When Johnny Guill transferred, Joe Durham took over as Chief Inspector.

FLL: Ron, while you spoke about the wheat program, you mentioned pink wheat. That was wheat that had been treated with a fungicide?

RTO: Yes and, of course, what would happen a lot of times is that either the farmer had a little treated wheat left over and would mix it in with some wheat that he was bringing into the elevator and then that would get comingled. We were opposed to the use of that pink wheat in the cereal products.

FLL: The fungicide was methyl mercury.

RTO: Methyl mercury, right.

As I mentioned earlier, I was in Minneapolis for 18 months and was selected to participate in what was termed a "chemist rotation" program in Washington and so I left Minneapolis in July '58 and came into Washington. That was a two year assignment. It was interesting - I guess I was about the third or fourth one to participate in that from the field. It was intended to give you some of the technical expertise in the laboratory. You were assigned to three of the Divisions that were all a part of, I believe it was the, Bureau of Science: the Division of Food, the Division of Pharmaceutical Chemistry and the Division of Microbiology. At that time Rayfield was the Director of the Bureau of Field Administration. Fred Garfield was Chief Chemist. Ken Lennington the Chief Inspector.

My first assignment was in the Division of Food and I worked with Bill Cook on pesticides. It was really intended that the chemists on this rotation program should have a research paper out of each one of the places they were assigned. Sometimes that was kind of difficult to do. I worked on pesticides in Division of Food. Some of it was, I remember, the effects of sunlight on some of the pesticides. Of course, if you sprayed the parent compound, often times just through degradation - weathering, and effects of sun - the compound that remained on the crop was not the parent compound. We were interested in whether we could determine what the end product was and whether it was as toxic as the parent compound. I thought it an extremely interesting assignment and did a lot of work on paper chromotography. At that time the father of paper chromotography of the agency, Mitchell, was in a laboratory right next door to me so I used to consult with him a lot.

RGP: What was his first name?

FLL: Lloyd C. Mitchell, I think.

RTO: Lloyd, that's right.

FLL: ... Who had been at one time Chief Chemist at Minneapolis.

RTO: That's right.

From Foods I went to Pharmaceutical Chemistry and worked on several projects there determining various drugs by column

chromotography. I worked with Joe LeVine primarily who retired a number of years ago. He was really, I think, an outstanding analytical chemist where a lot of the drugs were concerned. Then to the Division of Microbiology and I worked with a number of folks there - Nicholson who had done a lot of work on x-ray of grains and coffee beans and things of that kind for insect contamination seeing if you could have any correlation between doing an x-ray of these coffees and things, grains, and what the insect fragment would be in the finished product.

Part of your education then was to spend a brief time in the headquarters of BFA and, I'll tell you, it was quite a contrast between the size of the field administration then and what it grew to over the years. If I remember right it was Rayfield who was the Director and Frank Clark was his Deputy. They had an executive officer and not much of a staff. Probably a secretary. There were two permanent reviewers one was Larry Warden and the other Jimmy Cribbit. Fred Garfield was the Chief Chemist and Ken Lennington the Chief Inspector. Each one of them had one person, I believe, that had been identified from the field, that seemed like a comer, that would end up maybe as a chief chemist and then also on the inspectional side, someone that they felt would make a good chief inspector. And that was about the size of the staff with a small clerical staff.

They didn't do, at that time, the planning for the field. That was done by a separate unit.

RP: Bureau of Program Planning and Appraisal.

RTO: Right.

FLL: That's where you were.

RP: Not yet at that time but that's where I ended up.

RTO: I think Shelby Gray headed that up, at least while I was with BFA. It was a real interesting assignment. The only problem of it was that you were intended to go out as really a technical chemist back at the bench.

Well, in the interim, from when I entered the program and when I "graduated" two years later, they had decided that they needed supervisory chemists. There had been some quasi ones in the field before that but they really needed some full time supervisory chemists. So, I went out then as a supervisory chemist.

I was scheduled to go to Dallas. That was at the time that they had started to build some of the new district offices and Dallas was one of them. Dallas was supposed to be opened in mid-summer 1960 but it was delayed, as most of these things are, and didn't get opened until the fall. So, Rayfield decided that I shouldn't be hanging around headquarters for that to open. And so he sent me to Baltimore. In all candor, I just objected to that. I thought that Baltimore was about the end of the world at that time. But, as many of

you knew with Allen your appeals went for naught and I ended up in Baltimore as a supervisory chemist in July 1960. We were located at that time down in the appraiser's stores building on South Gay Street which was very near, just across the street from the harbor. Dick Williams was the District Director, George Sooy the Chief Inspector, Ed Hoshall the Chief Chemist, and Jim Green was the Food & Drug Officer.

At one time we had the entire professional administrative staff, in a carpool. We lived out north of Baltimore in the area of Lutherville. Armond Welch, Jim Green the Food & Drug Officer, and Dick Williams lived out there, and the other Supervisory Inspector, Adair.

FLL: Fermer Adair.

RTO: Fermer Adair and we were the drivers because Hoshall and Sooy both lived in the city. We'd start out there and then pick them up on the way. We used to remark that if we ever ended up in a serious accident, that it would probably help the agency out considerably

The interesting thing there was that it was my first exposure to spices. As you know, Baltimore is quite a spice port with McCormick there and when I first went into that laboratory, that was all I smelled was the variety of spices. We examined spices primarily for filth. We had the old Bayline ships that used to dock right across the street from the appraiser's stores building there and we were always having

problems getting our imports up from the port of Norfolk. There had been several congressional inquiries generated by the people in Norfolk about being able to expedite the handling of the imports coming in there. So, the agency had arranged with Customs, to do a lot of the sampling for us. The samples were put on the old Bayline and it would leave Norfolk at night and in the morning it would be docked at Baltimore. So we'd be able to go over and pick up the samples that had been collected for us. That was when I first learned that imports really had a high priority as far as the agency was concerned and we moved those imports in and out real fast.

Shortly after I got there they started to build a new building for the Baltimore district. It was part of the entire Rayfield Laboratory Program and in 1964 we moved into the new building at Madison that was just across from the state offices. And, oh, we were so happy to get into that new building after being in the appraiser's stores. And, I'll tell you the appraiser's stores - the location of it - was down almost what you would consider skid row and getting to it wasn't the best. You had to go through the famous block in order to get there.

RGP: Was that the area that has now been all rebuilt and redone?

RTO: The harbor, yeah. The block is still there but just south of that is what they really rebuilt. But the apprais-

er's stores building is still there. They've done an awful lot in the rennovation process.

We moved into the new building in '64 and shortly after we moved in, Ed Hoshall decided to retire and I'll back up just a bit and give you at least my understanding of maybe why he decided to retire.

Shortly after I got to Baltimore, I guess it must have been in about '62 or '63, Dick Williams left the agency and went to Richardson Merrill. Of course, George Sooy and Ed Hoshall, one the Chief Inspector and the other the Chief Chemist for some time, were both prime contenders for the District Director's job. Through some process George Sooy was selected as the District Director and that didn't set very well with Ed Hoshall. Ed was eligible to retire and, in my understanding, had been offered another job in Washington if he would take it. They knew, of course, that there was a little bit of friction between George and Ed. But he didn't want to leave Baltimore and so he decided to retire. I was named then Acting Chief Chemist after Ed retired and shortly after that made Chief Chemist.

FLL: And what year was that?

RTO: That was in '64. That was the summer of '64. We had expanded considerably. We had in the laboratory at that time about 50 chemists. It was a three bay laboratory and we had chemists, two to a bench. We also had microbiology labora-

tory. Before that we had no microbiology capabilities at all. The samples that needed any microbiological analysis, we'd bring them to the Division of Microbiology in Headquarters and they would examine them for us. And I had one supervisory chemist for those 50 and I imagine that we must have been training 25 chemists or so. So those first months in that new building were really something as far as the samples flowing through and trying to coordinate the collection of samples with the inspectional staff and being able to keep a flow of samples through the laboratory to keep that number of chemists occupied.

RP: That was a very difficult time when they decided every district would have one supervisor in each branch and how were you supposed to divide up the work when it didn't really change the span of control very much. It maybe gave you an extra hand to work on the problems.

RTO: That's right. And we first had a Microbiology Laboratory. In all we had two microbiologists which really didn't help you much I didn't think. You had some microbiology capabilities but in order to do any kind of work at all, you needed a bigger staff than that. The supervisory chemist that I first had was Ernie Brisson who came out of Boston. He didn't know anything about microbiology and neither did I. We had two microbiologists, one that had been in the agency in another district, I forget now where he came from, but one we

just hired from the outside. In my ignorance of microbiology, I always felt I got conned by these two microbiologists as far as what they could and couldn't do.

But you're absolutely right as far as trying to divide up your span of control. It was not unusual for both of us to carry the worksheets home at night and review them and all of the training reports that you had to submit. We finally got another supervisory chemist which helped a lot. And then eventually they decided that some of the laboratories should have what they called an assistant chief chemist and Bill Clark became Assistant Chief Chemist.

We really got into the middle of all of the pesticide problems. I remember we began finding heptachlor in milk and we ended up cooperating with the DC Health Department examining samples for them. They had no pesticide capabilities and so through cooperative arrangement we would examine samples of milk for the DC Health Department. A lot of the milk, of course, that came into DC came out of the same milk shed that was servicing Baltimore. That lasted, I guess, for several years that we had this cooperative arrangement - the DC Health Department would collect samples from most of the tank trucks that were coming into DC. We worked out some pretty fair arrangements with some of the big milk producers here so that they ended up having capability of their own. We trained them and usually you would collect a sample from a tank truck that

might represent half a dozen different producers. Well, you would screen that primarily for heptachlor and we'd arranged - and I've forgotten exactly what the cutoff was - but if we found a particular level of heptachlor, then we'd go back and have to sample each one of the producers that contributed to that tank truck. The work load was just horrendous.

A little later on, I think we were one of the first places, that found that we were having some problems with PCBs and we were finding PCBs in milk. It took considerable sleuthing to find out that where we were having most of the problems were where the cows were feeding in pastures where you had the big transmission lines going through. They had the transformers and as those things erupted or anything, why at that time they didn't think anything about it. So they would dispose of them and we found out that we were getting a lot of contamination in the milk from the transformers in those transmission lines.

I guess in about 1967 or '68, Gordy Thompson, who had been the Deputy District Director, was selected to participate in the ...

RGP: Executive Development Training Program.

RTO: So he came in and that left the Deputy's job vacant. I thought while I hadn't learned everything that I needed to know about the laboratory, I wanted to know a little bit more

about the agency from a broader viewpoint, so I applied for the job of the deputy. Maurice Kinslow had come in to be the District Director. George Sooy had been elevated to the position of Regional Assistant Commissioner. That was at the time that they had decided that most of the regional offices were going to have a regional assistant commissioner to give us a little closer working relationship with the department. We were in Region III and the Headquarters for Region III, DHEW, was Charlottesville and so George Sooy went to Charlottesville as the Regional Assistant Commissioner and Maurice Kinslow came over as the District Director. I can remember Winton Rankin coming over before it was announced. It was always rumored, you know, who might be coming over and they'd had this executive development program and most of the people who were in that came back out as district directors. I can remember Curtis Joyner was a member and I forget who else but that was one of the people who was rumored as probably coming to Baltimore as the District Director and the other was Maurice. But Winton came over and visited us. I was Chief Chemist at the time and Tom Kingsley was the Chief Inspector and he talked to us both individually. While he didn't mention any names, he asked me if I thought I could work with someone that hadn't really come up through the ranks. And, of course, as you know, Maurice had not started out as either a chemist or an inspector but had been in a departmental training pro-

gram and had come into the agency in that way. They had decided that he would probably do well in the field. It did-not bother me whether he had come up through the ranks or not and shortly afterwards Maurice was named as the District Director. When I got selected for the Deputy Director's job, I forget exactly when - '67 or '68, somewhere in there - shortly after that we embarked on the Self Certification Program with industry. One of the first plants that we had was the General Foods plant in Dover, Delaware. That was just before, if you remember, they reorganized and realigned all of the district boundaries but at that time Delaware was a part of the Baltimore District. I ended up as the Baltimore District's liaison or coordinator on the Self Certification Program with General Foods.

RGP: What in the world was the Self Certificaton Program?

RTO: Well, that was a program whereby you set up certain requirements with the industry that if they met all of these, then theoretically you should be able to lessen your surveillance over them. They had to submit periodic reports to you on their carrying out of certain aspects of this program. They had to do a statistical sampling of their products and the examination and then they would submit reports and we would review them. So, in theory I guess, it was a good idea. You should be able to lessen your surveillance over them. The requirements for getting into that program were such that it

was probably only the more sophisticated and better plants that could ever meet those requirements. So, in some ways it was kind of defeated because they were the plants that you probably wouldn't have much problems with anyway. But, it was interesting and we would make periodic visits to General Foods - not only here but also the corporate headquarters in White Plains in setting this up. It was interesting to me to see that aspect of it.

FLL: Actually you were working mostly with the quality assurance people.

RTO: Right.

FLL: And if their quality assurance program met these criteria that we had established, then that meant that the firm could be in the program.

RTO: Yes.

FLL: But still had to report to us deviations when they occurred and ....

RTO: Any deviation. And, of course, they would have liked to have been able to get some publicity on this - be able to put a shield or something on their products but as you know we decided against that. That might be unfair.

I remember one incident. I got a call from the manager of the Dover plant. He was all excited. They were bringing sugar in. They would bring it in carload lots and they were putting it into their conveyor system in the plant and some-

body saw a rabbit run into an open area, I guess, and the rabbit disappeared. So, he called to report that.

FLL: Did the rabbit get diluted?

RTO: They did some examinations and couldn't determine whether the rabbit had gotten into the conveyor system or not but I thought it was rather interesting that they at least reported it. He was really excited about that because there was considerable dollars involved in that particular amount of sugar.

FLL: Do you know how that program came about?

RTO: Well, it was my understanding, and you people can probably refresh my memory on it. It was my understanding that Goddard, who was the Commissioner at that time, meeting with the head of General Foods, can't think of his name right now, thought there could be a better working relationship. And so they started to talk about having this kind of a program. And that is my understanding of how it came about and initially we were the only district that had such a program with General Foods.

Later on it was expanded to a few others - Green Giant I think was one that came into the program later. It got to the point where industry didn't feel that they were having the benefits from it because they were required in some instances to have much stricter quality assurance programs than what they would have normally had. There were some of the firms that said, well, we meet those anyway so there is no problem.

But really when it got down to it, all the reporting and things of that kind cost them something and so I guess it was four or five years later that the program kind of died of it's own.

RP: You know, that brings up kind of an interesting point. You were the first district to try out the new program. It was my experience when I worked in Headquarters that Baltimore was where you went to try things out, simply because it was so close that Headquarters people could go there easily and cheaply. Was that generally true of many different kinds of things that happened?

RTO: Well, we always thought that but, in fact, there were many who felt we were not really a field laboratory but an extension of Headquarters. We felt we were really put upon, especially the resident post in the Washington area. It changed several times but it used to be a one person post and they were stationed down in South Ag. here along with the rest of FDA and it got to be kind of gofor for the agency in a lot of things. We moved it eventually over into Virginia but there were a lot of people here in Headquarters who felt really that that resident post was assigned to them.

FLL: Somebody they could send out for lunch.

RTO: As a -- oh -- I remember carrying some of the court papers and things of that kind. They thought nothing of calling them to do that and never coming to the District. We used to

kind of get on the resident post folks for not accomplishing some of the assignments they had and then they'd remind us that they had all these other assignments. So, I hope over the years that has kind of slackened off a little bit but I remember while I was there we always felt that we were put upon. You know, a lot of it had pluses though because there were a lot of things that would happen eventually as far as the field and we were one of the first ones to get involved so it had some pluses. We always felt as far as staff was concerned that we were probably - there was more siphoning off of staff in Baltimore to Headquarters job than any other district because a lot of the people would just turn their car in a different direction. Instead of reporting to the District, why they'd come over here.

I guess the other thing that I remember mostly about this period was that it was at the time that we went into CPEHS.

FLL: Consumer Protection and ...

RTO: ...Environmental Health Service. Remember that was short lived but while it was there, at least I felt, it caused me some trouble. Because as I mentioned, Maurice was the District Director but he also had some special assignments in the Headquarters. One was the famous Kinslow Report as far as a look at the agency so that he was in Headquarters a lot and I became Acting District Director for awhile and also the regional offices were established. So, for awhile I was Act-

ing District Director and Acting Regional Director which required my going down to Charlottesville and we had to, I remember, develop a CPEHS work plan. Our part, of course, was for the Baltimore District and for the region. Philadelphia ended up as a part of Region III and I remember we had at that time San Juan also as part of Region III before it got transferred to New York. So that as far as the work plan was concerned, we had to coordinate with Philadelphia and also with New York in developing this work plan. I don't think anything ever happened to that. It was an awful lot of paper work with developing that plan. I had to go to Charlottesville every month while the Regional HEW Director had his staff meeting and we were expected to attend. They knew little -- the region at that time, knew very little about FDA. It was almost ...

FLL: That was the HEW region.

RTO: ...HEW region and it was almost as if - you leave me alone and I'll leave you alone. We tried to keep them informed of major things but there was very little even at that.

FLL: Well, did the Regional Administrator of CPEHS try to interfere at all in the operations of Baltimore?

RTO: No. Not as far as I was concerned. We had to keep them informed, had to send them reports of things, but no there was

very little that I could see in the way of direct interference from at least that Administrator. And I think it was probably like it has been in later years regarding the degree of interaction that the Regional HHS Director has with FDA. Some places they are rather close and other places it's again kind of "just keep me informed of major things so that I'm not embarrassed by some of the big political emergencies that might come up."

FLL: You mentioned the Kinslow Report. What exactly was that study that Maurice Kinslow chaired?

RTO: Well, it was kind of a ... let's see if I remember right ... Wasn't Herb Ley commissioner at that time. There had been some criticism of Food & Drug regarding why we couldn't do better in a lot of the program areas. I forget now who all was on Maurice's committee but they were given the assignment from the Commissioner of looking at the agency and coming up with recommendations as to how the agency might be better organized to better deal with the problems. I think that emerged, if I'm not mistaken, in 1969.

FLL: I think somewhere around there. I think it was after Dr. Goddard left in '68, so it would have been about '69.

RTO: Then in about '68 or '69 there was -- the boundaries of the districts were realigned. Before that -- Baltimore District had the northern half of North Carolina and the the Atlanta District had the southern half. With that reor-

ganization Baltimore District lost all of North Carolina to Atlanta; Delaware went to Philadelphia.

FLL: That was the reorganization that was ordered when we were ordered to conform our boundaries to those of the HEW regions.

RTO: Right. And about that time or in about '69 somewhere in there, the Regional Office of HEW was moved from Charlottesville to Philadelphia.

I came into Headquarters in 1970. Let me back up a little bit. I guess in some of the changes in the agency we had really lost what was the Bureau of Field Administration and the Division of Field Operations and we'd ended up, in the Goddard era with a FLO which was a field liaison officer. Each one of the districts reported thereotically to the Commissioner and we had been ordered to establish regional offices within the field. That was in late 1969 and early 1970 and Commissioner Edwards came on board. There had been a reorganization in the agency. Harris Kenyon went to CPEHS and Sam Fine came in as kind of a liaison officer but was given, my understanding anyway, a little bit more than just a liaison function. When Commissioner Edwards came in the agency was reorganized and it was reestablished that there would be more direct line authority over the field with an Assistant Commissioner and Paul Hile was named the Assistant Commissioner for Field Coordination. Then in 1970 I came in as Paul's Deputy.

FLL: Paul had been deputy to Sam but Sam moved up to the Associate Commissioner for Compliance.

RTO: Right. Some of those early dealings with some of the folks in the department in establishing these regional offices and the coordination of that was really traumatic. We survived it but we weren't sure that it was always necessary but I guess it has been relatively successful. About that time with the reorganization in Headquarters Bureaus were established with authority, thereoretical authority I guess, maybe actual authority over specific products. Foods, for example. The Bureau Director was supposed to have complete authority over the foods and cosmetics and drugs the same way. Before that there had been central compliance that had pretty much established compliance for the agency for all products. But now with that reorganization, the Directors had been given *authority, entire authority.* So you started in to have - If I've got authority over foods, I want complete authority, and ownership really of that portion of the field that is doing food work or drug work. So we started in to having to combat little uprisings, trying to take over that portion of the field.

RP: There were some of the Bureau directors who felt that literally the field should be split and they would have their own field force for foods and their own one for drugs, etc.

RTO: That's right.

RP: That's what would have happened if they had really gotten their way.

RTO: And you know it didn't end with that either by any means. You usually had to have the Commissioner set down - this is the way that we're going to operate. We always had to try to sell the idea that we were a diverse organization and that an inspector wasn't totally a food inspector or a drug inspector and if you ended up with emergencies, they were going to do everything.

FLL: I guess the real thing that kept the generalist field force was the fact that it would have been incredibly expensive to be made separate forces for each of the Bureaus.

RTO: Well, I think we'd had a little bit of a sampling of that when we'd had the consumer program change a little bit. During CPEHS, you remember, the Consumer Affairs Officers were assigned to CPEHS.

FLL: Yeah, all the consumer education function was to be conducted by them.

RTO: But they were physically located in our offices and you had to provide them support. CPEHS only lasted what, about a year and a half, I guess, or something like that.

FLL: About that.

RTO: And then we returned to the way of doing business as before.

That was some of my early recollection of coming into headquarters. Somebody was always nipping at your heels trying to take away the field. You know, it's continued on. Even with the, I think it was '72, that Radiological Health and Biologics came into the agency and I think they're still, in a way, fighting that. They have there own staff and Biologics, had been doing their own inspections.

FLL: From Headquarters.

RTO: From Headquarters here.

FLL: And Radiological Health had had their own representatives in the field.

RTO: When those rad health reps - were transferred to the EDRO Organization which was the successor of field coordination, I guess they decided that we change the name to show that there was more than coordination; there was more line of authority over the field. I think that came about in 1971.

FLL: That would be Executive Director of ....

RTO: ...Regional Operations. We were trying to convince both of those new Bureaus that we had capability in the field to do the investigations that they had been doing but as far as biologics is concerned, they're still doing a lot of the inspections. They have transferred to the field the Blood Bank and things of that kind. But I can remember Paul and me meeting with Hank Meyer and his staff and telling them about how we trained our inspectors. That first we trained

them to be inspectors and then they might attain some specialty. Hank said we give them that specialty first. They work in our laboratories and they get to be an authority over a particular area and then we send them out to inspect. We always felt that they weren't necessarily good inspectors. They might be fine professionals but that we could help them as far as inspecting.

And they were the same way with Rad Health. In fact, it wasn't long before I retired, we were still kind of fighting the battle of the generalists with Rad Health. They felt that they would like to have ownership and that ownership was hard to define. We always felt that they really wanted to have a Fred Lofsvold or a Bob Porter, that was their person and that they could give them direct assignments. That wasn't what they said they really wanted, but they wanted to know that the Bob Porter's and Fred Lofsvold's were trained in their program and that they wouldn't be diluted in their expertise by having to go and do a sanitation inspection in food or whatever.

RTO: We can appreciate some of the Bureau's concern over whether the investigators have the expertise to do the investigations for those particular centers. Maybe, over the years, we stressed too much the generalists concept so that they don't appreciate the fact that we do have a number of investigators and chemists who have a specialty.

It seemed to me that from my Headquarters stint here that every time that we got a new commissioner, which was about every 2 years or less, that some of the center directors, or bureau directors, would decide that they were going to flex their muscles again and see if they couldn't get more direct control over the portion of the field force that they felt that they owned.

Aside from some of those organizational things, I guess the first big emergency that hit the agency and the field after I came into Headquarters was the problem that we had with Bon Vivant. There were a number of cans of their soup that had been underprocessed so that they had botulism and caused several deaths. I never will forget that because I guess typical of things that happen to the agency, most of them happened either on the weekend or over a long holiday. And this happened over Fourth of July. It broke and I was especially sensitive to it because Paul Hile had decided he was going to take some leave. So, I was here when that broke and we had to decide immediately what we were going to do as far as the stock of that particular plant was concerned. There were some in the agency that felt we should more or less put a hold on all of their stock and not just those which were highly suspect. But it was decided initially that it would be those products that we had found, at least that were highly suspect of botulism, and we started in to try to determine

just how much was out in all of the warehouses. I never will forget that weekend because it was horrors. Many of the places had closed down for the weekend and we wanted to find out just exactly what was in the warehouses and make sure that there wasn't any further distribution. I remember Reo Duggan who was Sam Fine's deputy at the time. I was dealing mostly with him and he was unwilling to take an answer that these warehouses were closed and we were unable to get anybody responsible to even open them to see what stocks were there. He was insisting that if necessary that we get ahold of the State Police in a lot of these areas and get in.

Many of us felt that as long as the warehouses were closed, while we would like to know what the stocks were, that they weren't going to be distributed anyway until they opened up. That was really the first big emergency we had and as you know, it pretty much changed the way that we started in to inspect these places. We had been in that plant a couple times within the previous year but we really hadn't gone over their processing controls and records. We had gone in and inspected them for sanitation and from that standpoint we'd given them a clean bill of health. As a result of that problem we started to follow - later we termed it - the Hazard Analysis and Critical Control Point Inspection. That you'd go in and really examine those points in the process from a time and

temperature standpoint in those low-acid canned foods. The soup problem carried on for a couple of years before we were really - as far as Bon Vivant was concerned - able to seize all the goods out of that particular plant. It really bankrupted that particular firm.

FLL: Wasn't that problem made more acute too by the fact that the company would not voluntarily recall the article ...

RTO: That's right.

FLL: ... because they couldn't afford to and ultimately went broke so that we then in the field had to actually go around and do the job that a voluntary recall by the company would have accomplished.

RTO: You're right, Fred. And that's, I think, the reason that it took so long for us to finally get all those goods removed. But it really changed, I think, the way that we do business as far as the inspection of these places.

FLL: Well, I think it lead also to the formal regulations under Section 404 to give us the emergency permit control over low-acid canned foods.

RTO: Right. And we started in all of the programs as far as low acid canned foods.

FLL: It always fascinated me that we took Section 404 for that purpose because it was originally not intended for canned goods but for fresh oysters and products of that sort. Then we used it to our advantage here. I was even more surprised

when we learned from an earlier recording that the original suggestion of using that section in this way came from the regulated industry.

RTO: Kind of turned back on them a little bit.

FLL: I think they had the idea that we should use it on a voluntary basis and we decided to make it mandatory.

RTO: I think the next really big problem that we faced was with mushrooms. We had a series of problems with canned mushrooms - a little bit different - because they had changed their way of packing, at least some of the firms had. They used kind of a vibrator in filling the cans which ended up with more solid material than some of the original specs at least for processing had contained so that we were finding out a lot of these places hadn't even considered doing any time/temperature controls so they hadn't changed their processing times to accommodate that. So, we had several mushroom crises and in most of those instances, I remember, we didn't encounter the same problem as with Bon Vivant because we were able to get them to recall.

RP: But that, in the case of mushrooms, involved a substantial part of the industry.

RTO: Oh yes, not just one plant. That's right.

FLL: Didn't we also about that time, somewhere after Bon Vivant, have the problem with Campbell's soup plant in Texas?

RTO: Texas, that's right. Well, it was just shortly after

the Bon Vivant that we encountered that.

FLL: And if I remember correctly, that happened on a weekend because I remember a phone call on a Sunday afternoon at my home out in Denver.

RTO: And I never will forget shortly after that, I've forgotten the specific instance, but I remember it was out in Seattle and it was on a weekend too. Frank Clark was the Regional Director in Seattle at that time. He reported the problem that a firm was having that was somewhat similar to Bon Vivant. It didn't develop to that extent. We got a call, I think it was on Saturday. I was new to this whole thing and I went to staff on Monday morning and I reported this particular problem but it was all under control. Staff no sooner broke up than Charlie Edwards who was the commissioner at that time said, "Ron, I want to see you in my office." I went in there and he and his deputy, Jim Grant, really leveled me. Don't ever do that again, come in with something of that significance and report it casually at the general staff.

A lot of those things develop so that we soon learn that regardless of what we thought the significance of these things, you'd better notify the commissioner. I'll never forget I really felt tender for awhile about that but I learned - don't hesitate to bother the front office about these things. And, of course, since then we've learned that

that is one of the first things that we do whether we feel we have it under control or not. I remember I discussed that with Frank. I told Frank, boy, I really got chewed. He said, gee, what was the problem, we had it under control. And I said, well, we had it under control but the commissioner did not know we had it under control.

RP: But he didn't know you had the problem either so he should have been happy.

RTO: Why worry him?

But as a result of some of those ... Well, it was about that time too that GAO started to live with us, if you remember. They had done an intense investigation of us and concluded that the sanitary condition of the food industry was appalling. At that time. In their reports to Congress report that they felt that the agency didn't have resources adequate to do the job that was intended. As a result of that report, we got a substantial increase in staff. That was about '72 or '73, somewhere in there. That was the first big increase that we got and we ended up putting on about 900 - well, I think the agency got total of about 1,000 or a little over that in an increase in staff. The bulk of the increase went to the field. Since then GAO has been living with us and Paul Hile gave me the responsibility for liaison with GAO since initially a lot their investigations were directed toward the field.

For a number of years, I met periodically with GAO and tried to keep them happy, at the same time not give away everything. I remember several instances where they had requested complete copies of our inspectional reports which I resisted and they appealed to the front office and we lost. But that was some of the early problems that we had with GAO and the first encounters and we wanted to be very careful about the access that they had. With that increase in staff we really started to increase the number of compliance officers that we had in the field. I remember we conducted a big, what amounted to almost a lottery because we had so many employees that applied for these jobs. All the districts would make a selection and it was not unusual that more than one district or region wanted the same person. So, I sat here trying to resolve those differences and not always to everybodys satisfaction. In fact, I'm not so sure that Fred wasn't a little bit unhappy with me about the resolution of one of the staff that I was involved in. It was interesting to deal with the large increase in staff. I'm sure it could have been handled differently but it got the job done.

One of the things that we really had problems with was when the Bureau of Product Safety was established. There were a couple of outsiders that were running that and they had no truck at all with the field organization. A man by the name

of Jensen headed that up and he was, in my judgment, a most difficult man to deal with.

RGP: Do you remember that to try to keep somehow on an even keel with them, Paul got Jensen to agree to a monthly joint meeting where Paul's top staff and his top staff and the two principals would meet. The first meeting, Jensen and some of his top staff attended. We all went over - you and Paul and I, I think, and some other people. The second meeting Jensen didn't come but his deputy was there and a staff person or two and by the time of the third meeting we had a junior staff person from his whole bureau. And here was Paul, Bureau Director, with his top staff and so that was the last time we went over there. Paul would never go back, we couldn't accomplish anything.

RP: What was Jensen's first name?

RTO: Malcolm.

FLL: Mac Jensen he was known as.

RTO: Mac Jensen, yes.

FLL: I've been told that he arrived at the agency without even the commissioner knowing that he was to be the new director. You ever hear that at all?

RTO: Not at all. Could be. That's interesting.

Well, Sam Hart was his deputy. Not by his choice because Sam and Malcolm never got along. In fact, I think Jensen would have liked to have had Sam someplace else. I guess the

only saving thing was that Sam, who had come up through the field, had some appreciation for the field's problems. After these meetings kind of fell apart it was decided, I guess Sam and I kind of decided, that we'd get together just to see if ... but there was nothing that either one of us ... we kind of resolved some of the minor issues or we discussed some of the minor issues but there was still that conflict between Jensen and Paul as far as how things should be done.

RP: I think there was conflict between Jensen and any other given person.

RTO: Well, not only in the agency but outside as well. At that time with the establishment of ... then when they established the Consumer Protection - no, what was it? CPSC, Consumer...

FLL: Product Safety Commission.

RTO: Yes, Consumer Product Safety Commission. The agency gave up some dollars and it seemed to me about 400 positions, somewhere plus or minus.

FLL: That was established by law ...

RTO: That's right.

FLL: ... as a separate agency.

RTO: Yes. And so I kind of as far as the EDRO Organization took the lead for first getting volunteers, if you remember. Getting volunteers that would go and then those that had been

working kind of strictly on product safety were tapped to go. And there were a lot of folk that weren't very happy about being designated as being transferred to CPSC.

FLL: Of course, it was somewhat to our advantage because in so many cases, volunteers were people who felt frustrated because they had not been promoted and they thought they had an opportunity for promotion in the new agency and left us. So, in effect we lost some people that weren't our best people anyway.

RTO: Yes. Some of them we were very willing to volunteer.

FLL: Right. That's so.

RTO: One other thing that I got involved in was - we'd had the executive development program. They decided that maybe it would be well to have what we called a mid-level program. So, I was asked to be chairman of the committee that administered that first mid-level program. I really enjoyed that assignment. There was a total of about 12 or 14 from the agency that participated in that. It was to last about a year or 18 months. I think we had about 7 or 8 from the field that participated in that program.

FLL: What grade level was involved?

RTO: Well, it could start out at 11 or 12; most of them were 11s and 12s, there were some 13s involved but it was in that particular range. There was no guarantee that they'd get a promotion at the end of the thing and we tried to stress that.

The majority of them though did end up with a promotion out of it or at least a new assignment so they didn't go back to their original position. The problems that we had, not from the field because here again we had selected people from the field who really had potential but some of the centers or bureaus at that time selected people that, quite frankly, they would hope that they would not come back to them. And, I can remember when graduation was about to take place and through the process most of the people had found new jobs for themselves and in some instances we helped them. But there were 3 from the Bureau of Drugs that were in the program and they hadn't found any positions outside of the Bureau. They had talked to their Bureau people about it and they couldn't help them any. And so I met with the Bureau Director and tried to explain to him that they had a responsibility for these employees. And there were 2 of them from that particular Bureau that finally left the agency because they were unhappy and 1 that went back and, as far as I know, never did get a promotion out of the program.

Several years later, after these programs had been laying dormant for awhile, we met with Sherwin Gardner, who was Acting Commissioner at that time, trying to decide whether some of these development programs should continue - like the executive fellows program and the mid-level Program. I made a strong pitch for continuing the mid-level program but with

some changes in it and making sure that the sponsoring organizational unit had some responsibility for the employee that they sent into the program. They did have ... There's been 2 more of those mid-level programs. That was really an interesting assignment dealing with that. I felt very strongly that it was probably more important to look at that mid-level program the way it was than to go into the executive fellows program which was usually up at the 14 level and the fact that you were going to develop the new executives for the agency when in many instances they were coming from the outside. At least that's true in some of the offices and the divisions from the bureaus. As a member of that particular development program for the agency there were several meetings with other groups from PHS that were wrestling with the problem of trying to develop an executive program. We finally concluded that it's nice to be able to have people coming up in the organization but if you are going to gear this towards, for here, bureau directors that we all know in the last number of years how many bureau directors have come from within the agency. They are usually selected from the outside so that maybe it would be better to gear any of our efforts at lower levels in trying to develop competent people for less than at least the bureau heads.

FLL: What kind of training did the people in the mid-level program get?

RTO: There was ... you had some formal training like the Civil Service training courses and things of that kind. We allowed them to take some academic courses. There were a series of rotational assignments within the agency and we tried to get everyone of the participants in that program, that had come out of the bureaus to have an assignment in the field. I thought it was interesting because just about everyone of those people, we got them into various districts as acting chief chemist or something less than that and just to a person they came and said that was one of the best assignments they'd had. You get people in the bureaus that have a narrow view of the agency, they have no idea what really goes on. We had kind of a wrap up session after that first course and I remember going over the comments from the people and just about everyone that had gone into the program from the bureaus said that the most important assignment they had was the one in the field where they really learned what the agency was really all about. Of course, all three of us have parochial views on that. It always did me well to hear that. We had a number of people from the field that really went in, not immediately but since then have gone into chief chemist and chief inspector jobs and directors of our compliance units and things of that kind. There was some trauma connected with some of the assignments we made but fortunately they worked out very well.

I guess it was about, one of you guys can correct me, '76 or '77 that Sam Fine decided to retire and Paul Hile was tapped to go up to be the Associate Commissioner for Compliance. I was Acting EDRO for a period of, oh I don't know, 6 months, 8 months, something like that. Mac Schmidt was the Commissioner at that time and I guess I'd be less than honest if I didn't say that I felt I was a contender for the EDRO job. I had mixed feelings about it, whether I really wanted to be the director or if I was more content to be the deputy, but I put in my oar for consideration and when I wasn't selected it was with some degree of disappointment but I guess through the years I probably felt that it was fortunate that I didn't get to be the EDRO. Don Healton came in as the EDRO then and as you know he came out of Chicago as the Regional Food & Drug Director. Shortly before Paul was tapped for going upstairs he and I had talked about a reorganization in EDRO and so we had kind of started to think about a better way of organizing the EDRO organization. Well, when Don came in, he had different thoughts about how he'd like to have it organized and so about a year after he came in, we reorganized EDRO.

We encountered a number of emergencies in this next segment. We ended up in a cookie crisis, the Girl Scout Cookie crisis. We had the first Tylenol crisis out in Chicago.

RP: Those were tamperings?

RTO: Tampering. Of course the Tylenol one in Chicago resulted in a number of deaths. The cookie was more of a nuisance as far as pins and paper clips and things of that kind. We were never able to determine with the Girl Scout Cookies that it was any manufacturing fault. A lot of the tampering that was reported to us was probably done at the home but it created a lot of the "me too's." Prior to that, with Tylenol, we learned too that it was not a manufacturing fault but that it had to be done sometime after it was in retail channels.

That resulted in some efforts to have tamper-resistant packaging and also a change as far as the making these tampering incidents punishable. The FBI gets involved early on if we can determine if there is some tampering and we, just in this last year, learned that it is pretty hard to make these things tamper-proof by any means, you just can't. People are going to find ways of being able to do that.

In about, I guess, '82 or '83, the Commissioner was looking at ways that things could be reorganized and started in to look at ways of combining the Office of Compliance with the EDRO Organization and a proposal went in to Commissioner ...

FLL: Hayes.

RTO: Hayes, yes. Commissioner Hayes to combine the 2 offices and the Commissioner accepted that and so I think it was in

'83 that that was accepted and so Paul got back to have more direct authority over his first love - the field - and so the 2 organizations were combined and reorganized. Healton, who had been the EDRO, went to Dallas as the Regional Food and Drug Director. Phil White, who had been the Regional Food and Drug Director there, came into Headquarters in the office of Medical Devices and Radiological Health. I was named Acting Director of one of the 3 offices in the new organization, the Office of Compliance, the Office of Regional Operations, and the Office of what amounted to Resource Management.

The Office of Compliance merged what had been the Compliance office in the old EDRO organization and the Office of Policy & Regulations in the Office of Compliance. Resource Management, the Office of Resource Management pretty much took what the EDRO organization had had in the executive office and the data processing, planning and evaluation and combined that into one group along with the administrative functions. I thought this worked very well and I was finally named as the Director of the Office of Regional Operations and stayed there until I retired a year ago last April. I don't know if there is anything else that you would want me to add.

FLL: Ron, you started out, as you said, with the State of North Dakota and that particular agency you worked for was the agency that was engaged in liaison with FDA. What was your

view of federal/state relations, FDA/state relations at that time when you were one of the state officials?

RTO: Well, it surely wasn't the sophistication that we have today. Some of my early exposure to FDA was Bill Queen, who I'm sure you know. Bill was kind of the federal/state relations man. Almost a one-man show if I remember right and he and my boss were avid hunters. So, Bill always arranged a trip to North Dakota during pheasant season, and I guess he felt he had to justify his trip there by at least coming and meeting with the staff. So, we'd go in and sometimes it would be on a Saturday when we weren't open and listen to Bill recite things and it was almost like listening to the findings of fact. He had that down to a science, telling us about things in the Food & Drug Administration. I was just fascinated by the way that he described all those things. Other associations with FDA were at meetings in the North Central Food & Drug which comprised ...

FLL: That was the North Central - what were they called - North Central States Association ...

RTO: Yes - North Central States Association of Food and Drug Officials. That was North and South Dakota, Iowa, Nebraska, and Minnesota. Participation of Food & Drug in those meetings at that time was nothing the way that it is now. I remember Hubbell who had been the Director in Minneapolis before Bud

Kerr and he used to go to those meetings but his participation was minimal. Bud Kerr used to go, but he participated a lot more than Hubbell did. But that was about the only representation of Food & Drug there. I'd had several contacts with investigators coming out of Minneapolis. When they'd be examining some of the warehouses in Bismarck and find a problem they'd want us to put a state embargo. And I remember assisting several times. Like I said, I guess I was kind of a quasi-inspector as well as a chemist and I'd help them inspect some of these places and then slap a state embargo pending the Food & Drug Administration being able to seize it.

FLL: To hold this particular lot of violative goods.

RTO: Yes. And you talk about federal/state relations. It used to annoy the daylights out of us. We'd put a state embargo on these goods and it was seldom that Food & Drug would ever let us know when they seized the stuff. I can remember after I came into Minneapolis to join FDA, that was one of the things that I complained to Bud Kerr about as far as ways to improve federal/state relations was to at least let the states know after you embargo this stuff when the seizure has been effected.

FLL: Was there any effort at that time to involve a state organization such as yours in any program, coordinated programs, with the Food and Drug Administration.

RTO: No, Fred. Not the way that we have now. I don't remember any at all at that time. Another exposure to Food & Drug was that we did a lot of mold count work in the state, in butter for example. The mold count was an indice of the quality of the cream that went into the butter. There were an awful lot of creameries in North Dakota that made butter so that we did an awful lot of sampling of butter that was made in North Dakota.

FLL: This was sour cream butter from farm's separated cream.

RTO: That's right. And we'd sample the butter and examine it for filth, butter fat and then we'd do a mold count. We had one microbiologist in the laboratory at that time and we were at her mercy as far as getting samples out. At that time the Chief Chemist thought we needed more capability on that and I don't know why I was tabbed to do that but I went to Minneapolis and took a course at the District in mold counting. At that time Food & Drug didn't do much mold counting on butter, most of it was on tomatos and tomato catsup. I learned how to count mold and was able to do some mold counting for the state. But it was about that time that I decided that Food & Drug probably wouldn't be a bad place to work.

But, no, the federal/state relations surely wasn't as sophisticated as it is today. It was in the mid-seventies before we started in to have the contracts with the states to do any work of that kind. I always felt that maybe if there was a niche in Food & Drug, that was when I first came into the agency, that it would probably be in federal/ state relations because I had spent 14 or 15 years in the state so I felt I knew their side of some of the problems. I surely learned to appreciate the federal side of some of the problems too.

The thing that always annoyed me when I was in the state was the fact that we weren't able to really do much with the violations within the state. If you had a creamery that consistently had low fat or high mold in their butter, that you wanted to do something about, you had to go through the state's attorney. The state's attorney was a politician and the owner of the creamery probably was a good contributor and so you'd try to get something done - forget it. About the only way that we could correct anything was to put out an annual report and through publicity you might have been able to get people to say I'm not going to buy their butter or ice cream. We ran an awful lot of ice cream in the summertime for fat content and artificial colors. We tried to do the things that were not subject necessarily to interstate commerce

because we felt that the federal government was going to be able to do that and so with limited resources we would do the work on products that were strictly intrastate. But along the border for example, bakeries and things of that kind or creameries the stuff would probably move in interstate commerce.

FLL: Was there any coordination at all in the feed work between the state agency and the federal government? I know that in some instances the FDA brought cases in an earlier time on the basis of state analytical results.

RTO: I don't know of any instances where that happened while I was in North Dakota. It probably was, like in so many states, that our inspectional force was something to be desired and whether you ended up with a representative sample, was very questionable. I think, appreciating from the federal side, whether or not they could take action - I doubt it. I don't know of any instances where that happened, where they took any results of our analyses. But we did an awful lot of work on both feeds and fertilizers because the industry was paying a fee.

FLL: Yes, and that supported the program.

RTO: That supported the program, that's absolutely right.

FLL: You mentioned also in talking about your early days with FDA in Minneapolis, that you were working on the grain program. Would you talk a little bit about just what that program entailed.

RTO: As far as the agency, a lot of our work was strictly sanitation work at that time and we had kind of progressed to the point of inspecting the bakeries and flour mills to improve the sanitation. So we were going back a step into the food chain and going into elevators, sampling grain to see as far as insect contamination, bird excreta, and see if we could improve the entire program. So, that's what led us to go back into the grain elevators, well not just the grain elevators, we sampled carloads of grain. And a lot of that was for rodent contamination and, as I mentioned, for pink wheat. The majority of the problems that we had though were with rodent contamination. And then we'd go back to the source if you found a carload of grain that pretty much exceeded the pellet per pint, I think that was the tolerance at that time.

FLL: Started out I think at two per pint but maybe by then I think it probably was lower.

RTO: We were improving the thing. Then you'd go back to the grain elevator where that particular car came from and sample that. You got some pretty big ones like Cargill, for example, had a lot of grain elevators out in that area. I remember that was one of the places, I think it was in South Dakota, where we sampled one of their grain elevators. It was a pretty good sized operation to recondition. But I think it really woke up the industry to some of the problems and the

way that they started to handle grains.

FLL: When you reconditioned an elevator, what did you do?

RTO: We would use as a unit a truckload, for example, and these were usually just, oh I don't know how many bushels they'd contain, but not the big semis but almost like a farm truck and that would be the unit that we would sample. They'd draw that off from the bin and we'd sample it then as they put it into their pit and they'd hold that. We'd have our microscope and go through and examine it and pass or reject. If the lot was rejected, it had to go into one bin; if it passed, it went into another bin.

FLL: The stuff that did not pass was then converted ...

RTO: Converted to feed.

FLL: ... animal feed.

RTO: Yes, animal feed.

FLL: And as a result of that, when you did that, that didn't mean though that the injunction would be lifted.

RTO: Oh, no. No, no.

FLL: That was simply to take care of stocks on ...

RTO: Stocks on hand because in addition to that after they had gone through that process, they had to show what program they had to really improve the holding of the grains and things. Their sanitation program.

I think before that program a lot of those elevators and even out on the farm, they never really felt that grain was a food.

FLL: A commodity like coal.

RTO: That's true. This I think made everybody more aware of the fact. I can remember they had no control in these elevators of pigeons and sparrows and everything else. That's a problem in a grain elevator like that and even with rodents. I can remember as a kid, my dad worked in a grain elevator in this little town that I was born in. I remember going into the kind of a basement of this elevator and, my gosh, the rats! It was kind of scary. Those rats would be scurrying around there. But they started in just from an economic standpoint of trying to control the rodent population because of all the grain that they would eat. But I don't think that they really considered even then that the grain, or the wheat that was there was a food.

FLL: Do you think then that our program then had a general overall effect of getting the industry's attention that they needed to improve.

RTO: Oh, I think so. I think it did anyway. I think that it had a decided effect on it.

FLL: At that time did we have the educational programs also?

RTO: They were beginning.

FLL: With industry and FDA sponsorship.

RTO: Yes. I don't remember of ever participating in any out there but it was shortly after that that I remember we had those educational programs. And of course I think it led to not only in the grain industry but educational programs in other areas too that we started to put on. There were workshops and things.

FLL: That really came later I guess with about ...

RTO: Oh, in the middle ...

FLL: ... the middle sixties.

RTO: Yes, that's right. Because when I was in Baltimore one of the big problems we had there was with crab meat and the problems of processing crab meat and we started in then putting on workshops for a lot of the crab meat industry. You talk about some of the pictures that Harvey Young showed yesterday in his speech about those processing places, some of those early crab meat picking houses were not much different than what he showed.

The other thing is watering oysters. He mentioned that yesterday, and when I first got to Baltimore we were still trying to do something about watered oysters. And that was a frustrating thing and we soon ... that was - the State of Maryland was really unhappy with us because they were very protective of their own oyster industry but the stuff coming in from Virginia, for example, was always bad. And I

remember the State Health Department officials calling and saying, won't you please do something about the stuff coming in from Virginia. Our skirts are clean but they're bad. By that time we'd kind of decided we didn't have any program. We lost that case.

FLL: We'd already lost the case that declared the standard unconstitutional.

RTO: That's right. And so what else could we do. Some interesting times.

FLL: Well, while you were at Baltimore too, about the time that, or you described that self certification program. From your point of view and your experience with it, do you think it was a successful program?

RTO: Well, I felt it was successful. I suppose if you started in to really measure the amount of resources that you put in to try to administer that program, maybe it wasn't. But there were, I think, certain pluses regarding that program. One is that you certainly learned to know the management of the plant that you were involved with. I got to have an awful lot of respect for the people that we dealt with at that Dover plant. I think they were very, very conscientious about adhering to the requirements that had been set up, that they were supposed to follow. I think on both sides probably you'd find out that you didn't have any lessening in the amount of resources that you had to put in because it took an awful lot

to administer that program. We'd get in every month, I think it was every month their reports on their adherence to the quality assurance program and we'd go over that and they had to report any deviations and you've got to accept a certain amount of trust that they were telling you the absolute truth. Some of the things that were in there were kind of esthetic from a standpoint but the things that really would have made any difference - I don't know - I'm sure that they reported factually to us. But we poured a lot of resources in until we were assured that they were complying with it, so we still inspected that place. Down the road the principal of it was that soon you wouldn't have to devote time because they were complying.

I guess if you went on a bigger scale that you may have found out that it wasn't cost effective but from at least a human relation standpoint in understanding their problems and they understanding some of ours; I thought it wasn't bad.

FLL: Well, about that same time we had a somewhat comparable program in the drug industry where we, I think they called it the Intensive Drug Inspection Program, where we spent a lot of time in plants. Did you have some experience with that?

RTO: Baltimore wasn't necessarily a big drug industry but we had A. H. Robbins in Richmond and we had some smaller ones in the Baltimore area and in West Virginia. There again, I think the principal of this was you either inspected them into

compliance or else if you felt they couldn't get into compliance, you were going to get them out of business. You got to know at least management on these. I don't have any horror stories. I do remember one. It was a - and the firm is no longer in business - but it was an OTC manufacturer in Baltimore that was a subsidiary of some other - I've forgotten the name of it. But as the result of some of our early inspections, they were using these to try to convince corporate headquarters that they needed all these improvements in order to comply with the Food & Drug Administration. And I felt that the local management sometimes were almost using us. I can remember meeting with local management and the corporate officials to try to explain to them what was really needed and, yes, they really need this. Of course, we'd been kind of discussing this with the local folk for awhile and they told us what they were going to do so they had kind of set our script in a way. We thought if we can get them to spend the money, it will be to our advantage.

But some of the firms came in and they were still very hostile. If you remember, the program called for calling the firm in before you started the inspection to kind of explain the process and everything and there were some of them that weren't very congenial at all about it. In fact, they would try to get us to postpone initiating the inspection until, I

suspect anyway, they could get their house more in order and usually it was under the guise that the quality control guy Wasn't going to be avail- able until such and such a time but that program had some pluses in it too. I think that was started about the time that, wasn't it Goddard?

FLL: Yes. It was started during his era.

RTO: And that kind of opened up, I think, communications with the industry. I can remember a small firm that we found some of their product violative and we just seized it. The firm was really unhappy because they felt that the least we could have done was called them, notified them what the problem was and that probably would have led to a recall. Later on I think it was a change in the way that we did do business too because you found some of these things and the first course was to notify management and it wasn't like back in the early days where you wanted to seize something because this was another notch on your belt. A district director's success on some of these was almost measured by the seizures.

FLL: I guess the prevailing philosophy was that the tools that the Congress provided to enforce the law were these legal remedies and that's what we ought to use.

RTO: Yes, that's right. I can remember inspectors telling about when they would get a whole lot destroyed. Some of

their bosses would say, don't do that, seize it, my gosh just don't - I guess it's a good thing that we've changed.

FLL: Ron, I believe it was during this period that we had a program directed at Salmonella in rendering plants. While you were in Baltimore, did you get involved in that program?

RTO: We would inspect them and collect samples. We had one, I think the name of the firm was Bishop Rendering out towards the Eastern shore. It was an atrocious operation. The way that they handled things and the way that I think most rendering plants at that time processed things, it wasn't unusual that we found a lot of Salmonella in it. We finally did prosecute that firm. And I can remember that about that time we were a part of CPEHS and Bill Goodrich called and they were about ready to take some action against the firm for polluting the atmosphere under the ...

RP: Air pollution.

RTO: Air pollution and wanted to know if we had any cases about ready to go and so I told him where we were on this particular one and I never did know how we were going to - he thought maybe we could bring them both together at the same time. One from the pollution aspect and then from the FD&C. I don't know whether we ever proceeded on the air pollution side, but we did from Food & Drug.

The other thing was that as a part of this program, in order to control Salmonella in animal feeds, we would sample

just about every lot of imported fish meal that came in from various countries. One of the biggest ports that we had for fish meal was Wilmiongton, North Carolina. A shipload would come in and we'd sample, and if it was positive, we'd detain it. The industry got so that they would try to recondition it and run it through - I forget now what the process was, but at least sterilize it hopefully - but that was quite a process to do. And we got an impassioned plea one time not only from the Port because we almost had the port blocked with detained fish meal but also from a lot of the - and it was chicken producers - in North Carolina that were waiting to get this fish meal to blend it into their chicken feed. Congress got involved too because we were about ready to shut down their constituents operation. But whatever, I forget now the name of this kind of process they had, but they were just going to automatically run it through this before we even sampled it. And what we discovered then was that some of that fish meal that was coming in was clean but as they run it through their process, they contaminated it. And they had quite a time of cleaning that up.

And I guess it was after I got transferred over here that we were working with the Bureau of Foods whether we were going to continue this program of trying to eradicate Salmonella from the food chain by getting back at the animal feeds and

the program pretty much kind of subsided on that. But, yes, that was kind of interesting.

I remember when I was in Baltimore, we'd gotten a tip from the State Health Department there that there were some chickens that were contaminated with Salmonella and wondering if we'd sample them. Interestingly enough, it was just at Easter time. Well, the chickens that were contaminated were the live chickens that were being sold for pets but the inspectional staff set out to sample these chickens thinking it was chickens ready for food and come back in with one of those nice little cardboard boxes of live chickens.

RP: Baby chicks.

RTO: Baby chicks and we said get them out of here before we really have a contamination problem.

FLL: I guess the program finally just died, didn't it?

RTO: Yes, it did.

FLL: People realized that it was never going to be possible to eradicate Salmonella.

RTO: There was kind of a pilot rendering operation in the Washington area someplace that was going to be kind of the showcase of the rendering industry and all of the precautions that they took they found out that it was still almost impossible to totally eliminate Salmonella from rendered products.

RP: The world's full of it, isn't it?

RTO: It surely is.

RP: We try in these interviews, Ron, to have people talk about their associates, the commissioners they worked for, telling us something about their management style, their personality, their relations with them. More or less anything that you think would be interesting in regard to the commissioners and then you can talk about your peers too if you'd like and others.

RTO: And others.

RP: I know you have no peers so it must be others.

RTO: Well, I guess really the first of the most recent commissioners that I had more or less direct contact with would be starting with Charlie Edwards when I got transferred here. I knew, of course, George Larrick and Goddard very briefly and Herb Ley, but I really hadn't any direct association with any of them. After I got transferred here Charlie Edwards was the commissioner and I guess he was the first one that I really got to observe kind of close hand - some of their styles.

I always appreciated Charlie Edwards. A lot of people felt that he was kind of cool and distant in a way but, other than for the time that he kind of chewed me out for not keeping him informed, I always thought he was ... I got along fine with him. He was I guess a different manager than some of the others that had come up through the ranks. He came out of a very - the Booze-Allen group and so that a lot of his

management styles were not as personal as some of the others had. His Deputy, Jim Grant, I took a trip to Alaska with Jim Grant. We went out to Seattle and picked up Jim Swanson and one of the investigators from Seattle and went up to Alaska to inspect some salmon canneries. So, I learned a little bit more about Jim Grant's personal side if it was possible to learn anything about it. Sherwin Gardner came in after Jim Grant left. Sherwin who had been the Assistant Commissioner for Planning came in as the Deputy Commissioner then after Jim Grant left.

The next commissioner that we had was Schmidt. Dr. Schmidt - I guess the best way for me to characterize him is he was one who liked to try to manage by consensus. He was the one that really established the policy board and was going to use the policy board for making all of the vital decisions for the agency. And I think a lot of issues kind of bogged down. About that time Peter Hutt was the General Counsel and I remember in the absence of Paul Hile I got to sit in on some of those policy board meetings. And my personal view was that it was quite a waste of high power manpower trying to accomplish some of those things by consensus. During Peter Hutt's reign we started in to develop the administrative procedures and all of the regulations. Part of the use of the policy board was to proofread these regulations. You'd spend hours and hours on that.

FLL: Was this policy board style of management something that he brought over from his university experience of dealing with faculty senates or something?

RTO: It could be. I really suspect so because it was surely something that he had definite ideas about how that policy board was to operate and so I'm sure it was something that he brought with him. As you know, each commissioner has a little different management style.

RP: Are there universities that have faculty committees or something that do that kind of thing? I don't really know.

FLL: I don't know either.

RTO: I don't know.

FLL: The university president must deal with these deans in some fashion.

RP: I can't remember, you know, Harvey and I interviewed him the year before last and I don't believe we brought that out.

RTO: I remember one of the things that he used to say was that in talking, and I remember one time when he was talking to the RFDDs and the DDs when they were in, was saying a little bit about his management philosophies and things and the fact that he felt he had a team here and if you didn't want to be a team player, so long. And that's not unusual. Most people like to have team players but I think at the same time that was part of his scheme as far as management by consensus.

Some of the things that I remembered. We were dealing with some of the problems of chicken waste and whether or not we were going to use that in animal feed. Remember?

FLL: Yes.

RTO: The agency was trying to get a policy out on that. I remember he used to say, one of the things he didn't want to be remembered for was the chickie-poo commissioner. I remember during that time there were some of us who went North Carolina to visit some of the poultry farms. Sherwin Gardner went along, Schmidt didn't go, and they took advantage of the fact that they had some of this chicken waste, and this one guy grabbed a handful to eat and Sherwin wasn't about to sample it that way. But, I'm convinced that part of the purpose of that trip was to show us just exactly how that waste was going to be used.

FLL: How effective do you think Schmidt was as a manager?

RTO: Well, I think there's been those that have been more effective. It is nice to have consensus but in order to get consensus, it is very difficult and there were times, I think that the agency needed to make a decision and it could have been made and there'd have been a few people that felt I'm not in total agreement but that's the way the decision is made and if you're a team player, you'd better play along. But I think he felt that he wanted to get everybody in step first so that

he wouldn't have any dissention on it.

Let's see, Jere Goyen - no.

FLL: Don Kennedy.

RTO: Don Kennedy - and he was altogether different than Dr. Schmidt. I think he was one of the most effective outside people that we had as far as being able to represent the agency because he had a rapport with, I think, Congress. Anyway from where I sat the things that he said were believable. I used to say that he could say something and it was believable; somebody else could have said the same thing but they probably would have challenged. But for some reason he had excellent rapport. He was a good speaker. I didn't particularly care about his management because he was somebody that didn't care about lines of authority. If need be, he'd go down several levels and give somebody an assignment. I've been at staff meetings where he has given a subordinate one, while the bureau director sat there; gave them assignments rather than going through the bureau director. Some of the people used to say that they felt that Don still liked to have the kind of relationship that he had with a lot of his graduate students, and maybe so.

Jere Goyen was someone that I've always felt sorry for. He came in kind of an interim period and he had a situation where he had a general counsel that had a direct pipeline

to the secretary and so that I think that anything that Dr. Goyen would have been going to present to the secretary had already been presented by our General Counsel, Nancy Buck. So he was somebody that, I don't know, I just always felt he never really had an opportunity to show what he may have been able to do and maybe he wasn't one of our strongest commissioners, but I just always felt he really didn't have a chance.

And, during these periods of time we had Sherwin Gardner who was the Acting Commissioner, I think he provided a good stable continuity for us in a lot of those things. I was, quite frankly, very amazed at the grasp that Sherwin had of a lot of the agency's problems. When Charlie Edwards put him in as the Deputy, I know I personally wondered what was happening here because, quite frankly, Sherwin hadn't shown me that much as the agency's planning officer. But I guess there was again his background that he was able to grasp a lot of our agency problems and I thought he dealt very well with them. One of the things that the EDRO Organization tried to promote was compatibility in a lot of our data systems. That's one of the things that I just always feel that Sherwin let us down on because he didn't feel there was a need for total compatibility and he often times - maybe it was that he wanted to avoid confrontation - allowed the bureaus to develop their own systems. Granted, there is probably a need for some

individualized systems to capture the information. We had our own needs that weren't necessarily needs of the bureaus but it would have seemed to me that if we would have had some compatible systems so that we could get information out of some of the bureaus programs. For instance, the drug listing - when we started to try to get information from there it was almost a total impossibility. We felt that the inventory in the agency - we've always in the EDRO Organization and then ORA felt that the OEI was the official establishment inventory. And there were times when we had trouble with people in the front office admitting that it was because the Bureau of Biologics, when they came to FDA, had a little different system for maintaining their inventory. It took some time but I guess we're getting there now and that's one of the things that with Dr. Young's initiative was to be able to have at least a compatible data system and kind of a uniform one in the agency. How far they achieved that, I don't know but at least that was one of the goals.

But after Jere Goyen, Dr. Hayes. I liked Dr. Hayes. From management standpoint there were probably some things that I felt from the EDRO side that it could have been done a little differently and it all depends on who is telling the story. Because, as I mentioned earlier, it was during his administration, it was decided that there was going to be some thought given to combining the compliance - Office of

Compliance - and the EDRO Organization. And we started in to hear rumors that this was going to happen. I have some friends in the organization that kept telling me that there were some things that they heard were going to happen, wanted to know what I knew about it, and I knew nothing at all about it. I talked to Don Healton who was the EDRO and he hadn't heard anything about it. Whether it is true or not, I don't know, whether there had ever been any discussion between Dr. Hayes and Don that they weren't entirely satisfied with the way that he and I were running the field. If that's true, then I think it was remiss on Dr. Hayes' part for not telling us that there were things that they didn't like and given us an opportunity to improve.

As far as the merger was concerned, I mentioned before, that there were some definite advantage to that so I don't condemn anyone for the way that it went. But if some of the faults hadn't been communicated, especially to Don at that time who was the EDRO, I think that was a mistake. I've heard that it had been discussed, I don't know.

Then in between Dr. Hayes and Dr. Young, Mark, who had served prior to that part of the time as commissioner, served again.

RP: Mark Novitch.

RTO: Mark Novitch. And, Mark again provided good continuity. With the changes in the commissioners that you have, I think

that it is important that you have someone in that front office, I always felt that should be a career person. Of course, that isn't the case now. Have to see in the future years what happens. If the commissioners come and go the way that they have in the past in order to provide at least some kind of the intelligence for the agency, I think there should be some of the key positions in the office of the commissioner that are not subject to political appointment.

I probably haven't given you the insights into the commissioners that some people can, but I haven't had really that close contact with them other from where I sat here as a deputy in two instances under Paul and also under Don. It gives you an opportunity though to look at them from that vantage point. And I don't know whether a melding of some of the commissioners we've had into one individual would be the ideal.

You asked if I wanted to talk about some of the peers. I've enjoyed working with all of the people. There have been differences in personalities that we've all had to overcome but to single anyone out, I don't think I can do that. But it's surely been a ... When I decided to retire, it was not that I was unhappy with my position, it was I just felt, and I told Paul this when I decided to retire, that it was about time to step aside. It was harder and harder for me to get myself emotionally psyched for not the real emergencies, like the Tylenols and the Girl Scout things, but for the

other emergencies that were always coming up and, quite frankly, I guess it is something you're going to have to put up with here if you're going to have changes in the administration, in the front office anyway; that you're going to have to be prepared to go over and update all the briefing papers that you did two years before and up to that time. And the last few years, in my judgment, there got to be more external influence from Congress than there were in some of the earlier years. Maybe it's because some of it I was closer to, but it just seemed to me that there were more times that we were having to kind of back track and develop briefing papers to justify some of the actions the agency took on things. I'm not saying it is entirely bad but I felt a lot of times that if they would leave us alone, maybe we could do the job that they thought we should have done. And I felt that same way with GAO - I used to tell them that - that you've got staff that is about twice our size to look at us, it's two persons for every one, but they've got a mandate from Congress and they've got to do their job too.

RP: Well, we've pretty well run out of subjects, haven't we?

FLL: I don't think of any other questions that I wanted to ask. Can you think of anything more, Ron, that you would like to add.

RTO: No, I don't think so. I expect that in the process of reviewing this, at least if there were things that were gross-

ly omitted, that there is an opportunity to interject them at some point in time.

RP: Absolutely. When you get the rough draft, you can make additions and deletions as well as fix up the grammar or whatever else you might want to do. We don't want to leave an accidental misstatement there if you catch it or anything like that. Nor would we be at all unhappy if you wanted to attach an appendix of a page or two covering things that you really would like to get in the record but we didn't cover today. That's fine.

FLL: Or if you found enough things, another recording session or supplement. After all, when we did Dr. Kenneth Milstead, why there are three separate recordings over a period of about four years.

RP: Or if you have any printed or typed papers, speeches, anything else that you think might sort of supplement this record, we'll attach them.

FLL: Attach them and make a reference to them in the appropriate place in the script.

RP: So, don't hesitate to do that and I will get this in for typing Monday and hopefully can pick it up the next Monday. I will go through it. The typist often just doesn't understand a few words and leaves a space. So, this will end the tape today. Thank you very much.