History

of the

U. S. Food and Drug Administration

Interviewee:	Raymond K. Dawson
Interviewer:	Robert G. Porter
	Ronald T. Ottes
Date:	May 8, 1996
Place:	Rockville, MD

INTRODUCTION

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

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

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DATE: May 8, 1996   PLACE: Rockville, MD   LENGTH: 160 minutes

INTERVIEWEE	INTERVIEWER
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FDA SERVICE DATES: FROM: June 1963   TO: January 1996

TITLE: Director, Division of Planning, Evaluation & Management
(Last FDA position)

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Raymond K. Dawson

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RO: This is another in a series of interviews on the history of the Food and Drug Administration. Today we are interviewing Raymond K. (Keith) Dawson, retired director of the Division of Planning, Evaluation and Management (DPEM). The interview is conducted in the Parklawn Building, Rockville, Maryland. The date is May 8, 1996. Present are Robert G. Porter and Ronald T. Ottes. This interview will be placed in the National Library of Medicine and become a part of the Food and Drug Administration's oral history program.

Keith, before we start this interview, would you tell us a little bit about yourself: where you were born, educated, any jobs you had prior to coming to the Food and Drug Administration. And then we'll cover your career in the Food and Drug Administration.

RD: All right. My synopsis of that is going to be rather light, because I didn't have a large number of jobs. I was born in Washington, Iowa--curiously enough, the same name as the city where we virtually are right now--in 1932, June 20. I lived there with principally my mother and grandparents for about nine or ten years, attended public school all the way through my education. I later moved to Cedar Rapids, Iowa, which about the only thing I can say famous about that area, at the time we lived there, is that it had a terrible stench from a starch factory. That's something that I've remembered my entire life. From there I went to Chicago, Illinois; I lived there for about five or six years. And the bulk of my life has been on the East Coast, Washington D.C. area.

I attended the University of Maryland, got a B.S. there in food technology. It was originally called dairy technology, because that was the principal subject of the food technology course. From there I went into the U. S. Army, was drafted. I was in Japan for about eighteen months of that twenty-four month period.

From the service I went directly into National Dairies, and I was with them for about seven years. I started out as a management trainee. After a one-year training program, I directed the quality control program in the Washington D.C.

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plant and later went down to Charlotte, North Carolina, where I was ice cream production superintendent. Not long afterwards, I returned to Washington as assistant production superintendent here for another few years until 1963 when I joined the Food and Drug Administration. I was in FDA my entire federal career.

RP: Excuse me. Put a couple dates in there, will you? When did you graduate from the university?

RD: I graduated from college in 1955.

RP: And how long did you work in the dairy industry?

RD: For about six to seven years totally, from 1957 to '63.

RO: What were some of the products that National Dairies were involved in manufacturing.

RD: Depending on the plant . . . The Washington D.C. plant was exclusively frozen dessert-type products. National Dairies had multiple plants in the Washington area. The one I worked in has been closed for some time. The Charlotte, North Carolina, plant was a full range: milk, cheese, ice cream, everything of a dairy product nature that National Dairies produced.

RO: What prompted you to leave them and join the Food and Drug Administration?

RD: Well, I really wasn't looking for a job. That's the odd thing about it. I had a quality control trainee working for me that was not getting along with the second-line supervisor above him. I didn't know he was looking for a job. He talked with

me about what I thought he could find a job doing. He didn't want to transfer out of the Washington area; his family was all here. Frankly, at that time I had never even heard of the Food and Drug Administration. I never had seen a Food and Drug inspector in the plant anywhere I ever worked. There were a lot of city, county, and state people in there, but I had never seen an FDA inspector.

Anyway, the fellow apparently had an interview at FDA, and during the course of the interview, he was told that they were hiring up, that they needed a considerable number of people, and dairy background was one that they were seeking. Following the interview, he told me he was thinking about taking the job if it was offered to him, and told me they were looking for other people, and suggested I go have an interview, which I did. The uncomfortable thing about it is they offered me a job and didn't offer him one. (Laughter)

RP: Who interviewed you?

RD: Shelbey Grey and Dr. Glen Underwood.

RO: What year was that?

RD: I was hired in June, 1963 by the Bureau of Program, Planning and Appraisal (BPPA). The office had a number of people with significant careers almost exclusively in the Food and Drug Administration. People like Charlie Pyatt, Ray Surgeon, Alex Mallos, Cloyd Russel, Rolly Walthers were in that office. Bob, as I recall, you came in to BPPA about three months later.

RP: You had Walter Ernst?

RD: Well, he wasn't in my immediate group. He was in the data collection, T & P area.

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RP: He ran his own little area.

RD: In fact, you took his place, as I recall.

RP: Yes, right.

RO: What grade did they hire you at?

RD: GS-11. Yes, I came in at eleven, $8,060, as I recall. That wasn't much more than the $7,500 I was making at National Dairies, but I could tell from what the company was paying me and some others above me that I had a better chance for advancement in the long run with FDA. And secondly, my family just did not want to leave the area. Most of the Sealtest National Dairy plants at that time were in the South.

RO: What job were you hired for, and what did your dairy background bring to it?

RD: I was hired as a program planner.

RO: And what did your dairy background have to do with that program?

RD: I was supposed to review current programs, policy, regulatory actions and develop new programs that had primarily to do with dairy products. Each individual in the office specialized in a class of products. As I recall, Ray Surgeon was in drugs. There were more people working in the food area than anything else. You think of that today and it's rather amazing how times have changed. The devices and drugs budget is much larger than what foods is today.

RP: At the time you came in, the whole work of the Food and Drug Administration was more food oriented. I don't mean we didn't do drug work; of course we did.

RD: Anyway, I was primarily responsible for dairy products, and within a very short period after that, about three months later, there was a total reorganization of the Food and Drug Administration--and that's when I got the shock of my life.

I had not been aware when I was being interviewed and subsequently hired that it was a job that was of a temporary nature. It wasn't until I reported for duty and signed the papers that I saw the term TAPER (Temporary Appointment Pending Establishment of Register) after the position title. I asked the guy, "What does that mean?" And he told me, "Temporary, Pending Establishment of the Register." I said, "Are you telling me that I'm going to be out of a job soon?" And he said, "No. This is a temporary job, but there isn't any definition of time limit on it." He said, "It could last a year. It might last ten years. It depends on what happens."

Well when the reorganization was announced, that scared the hell out of me. I'm sitting there with a family. There was no way I was going to go back to Sealtest, although when I left they offered me a thousand dollar raise to change my mind. And I told them something along the lines, "Well, if I was worth a thousand bucks more now, I must have been before."

RP: That was the reorganization of 1964 that took place I think in January of '64.

RD: Yes, it created several new bureaus. Shelbey Grey became the head of the new Bureau of Education and Voluntary Compliance (BEVC), as I recall the name of it. Based on a talk I had had with Shelby Grey, I thought I would be assigned to BEVC, but I ended up in the Bureau of Regulatory Compliance (BRC).

RD: Ken Lennington was the division director; Tom Brown was the deputy; and you were head of one of the branches, as I recall, and the other one later on was Paul Hile.

RP: I might just mention, because I was there, too, in these times . . .

RD: Well, if I got any of this wrong, go ahead . . .

RP: The old bureau that we came into was rather remarkable in that it didn't have a hierarchy of divisions, and branches, and things like that. Each of us had our own sort of little cell of work, our little category, but we all worked for the boss. Isn't that right?

RD: That's about right. It was kind of loose.

RO: And that was the Bureau of Compliance overall?

RD: No. It was the Bureau of Program Planning and Appraisal (BPPA). BPPA they called it.

RO: I thought you were talking about the reorganization?

RP: Then the reorganization changed that, and at first they brought us all into the Bureau of Compliance. We worked for Kenny Lennington in the Division Of Program Analysis. The idea was we would be divided into branches, but he was exciting us all up to see who was going to be branch chief. That's what it amounted to. Because we had some old-time FDAers, and we had some Ph.D. statisticians, and all kinds of people I think each one of whom thought he should be the branch chief. I think I won out simply because I was well-established, and my background was all

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in the field of Food and Drug Administration, and that appealed to Kenny probably more than any other attribute.

RD: Even though as I recall you had a rather bad taste of Lennington previously.

RP: I didn't like Lennington, and I grew to tolerate him pretty well in those years. But Lennington was really not a good personnel man at all. He was hard to work for.

RD: Actually, though, over the next year between him and Tom Brown, they arranged to get me converted to a regular appointment. I took what they called an Unassembled Examination and through a combination of things, I ended up first on the list. I got about a ninety-five on the thing. I was surprised to see my business background really scored heavily in that review.

RO: Then did you stay in the same type of work with the reorganization? Were you still in planning?

RD: Well, I was still in the planning group, but that's when I started getting into the pesticide business that we were talking about briefly before we started this interview. I and a couple of others worked on a combination of things, such as pesticides, and food additives under Jonas Bassen, a very meticulous and a very dedicated individual.

Every product examined in the field for pesticides was submitted in writing to headquarters on a pesticide reporting form, for want of a better term.

The form contained information on the name of the product, where it came from, the conditions under which it was sampled, whether it was official or not and so on. It even had the time of day that the sample was collected, what residues it was examined for, and who was the responsible person or company involved with the

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product--it could have been a farmer if it was collected out in the field. In those days, the two primary things examined for, particularly on raw agricultural products, were chlorinated and organo phosphates. The form also contained information on the pesticides found, the level of pesticide in parts per million that were found--in those days, things were not exquisite enough that they could find parts per billion--and whether the product was considered in their opinion to be violative or not.

The field considered a product violative if they could do something about it. It wasn't necessarily just violative if it merely exceeded a certain level of residue.

RO: Weren't there tolerances for pesticides?

RD: There were tolerances, and there were guidelines. There were not too many pesticides at that time that had specific tolerances. A good example of one was DDT and its allowance which was seven parts per million. One of my duties was to review the form to be sure the coding was appropriate and accurate, that if it said apples, then the product code for apples was correct. If it said whatever pesticide it was and if the parts per million that were present, whether the classification as to whether it was violative or not was correct. A large number of the forms were not correct, and had to be changed before the information was accumulated with other data available on product residues.

The unfortunate thing about the program, I always felt that there should have been feedback to the field, and copies of forms that contained data we changed should have gone back, but it never did. It was just like Washington was one big hole. Everything came in here, but I never saw much in the way of feedback going to the field. Maybe it did through some other management personnel above me, but I never saw much.

The field couldn't get a sense for what was correct and not correct from the cumulative reports on so many thousands of samples. At that time the annual FDA goal was 25,000 sample analyses, mostly raw agricultural products. But at the same

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time they had what they called a pesticide in egg program, pesticide in dairy products program, and so forth. So everything was compartmentalized by type of product or grouping of products. Reports were made on what residues were found, the levels of them, and what was considered to be the seriousness of the levels found over a period of a year or more.

RO: Reports were for the administration use only.

RD: That's right. The administration and for Congress.

RP: You're the one that produced those reports.

RD: I produced a healthy part of it, yes. But the one that was really responsible for the evaluation of the data, and the final sign off was Jonas Bassen.

RP: Can I go back just a minute to something you said? You said the field didn't know exactly what was correct or something like that. That was the coding, wasn't it?

RD: What I was saying was . . . Yes. The field might classify something as nonviolative when in a strict sense if the level of DDT for example was found to be 7.01 it is violative technically. But nobody's going to do anything about 7.01 ppm. So the field didn't call it violative. But when it got to headquarters, it was considered violative because it exceeded the 7.00 ppm tolerance. When you think about some of the things that have happened in the last few years on pesticides in apples out in the far west and others, I mean the critics are just pulling at these data in all kinds of ways, and I think it was a good thing that we did draw the line and say, "If it crosses this, it's violative. Period." So nobody could ever say we weren't doing a proper and consistent job.

After I spent a couple of years editing/correcting the pesticide information, I collaborated later on some of the pesticide evaluation reports with Reo Duggan . . . He gave me my first opportunity to analyze the significance of the findings, as well as to consolidate pesticide information and for having my name on articles.

RP: Who was Reo Duggan?

RD: Well, at the time he was the deputy of regulatory compliance. I cannot recall who his boss was.

RP: (Allan) Rayfield.

RD: Rayfield, up until . . . Let's see, he was gone after about '67 or '68, wasn't it?

RP: If you're talking about the period between '64 and '68, it was Rayfield. But I can't remember the configuration after that.

RD: Yes, I remember Rayfield very well. He was a character. He did not like people doing things on their own. He wanted to put his "stamp" on every decision made. For example, you will recall I was in a large room with five other analysts. We had arranged to have some separators put in the room so that when we had conversations on the phone or with visitors, the sound wouldn't reverberate off the walls. We had six desks in there, three on each side, and we were facing each other. When you were talking with somebody or had a visitor, everybody in the room could hear everything. So we wanted to get some of those soundproofing separators, and we had put tape on the floor as to where we wanted to have these located. One day Mr. Rayfield came into the room, and saw the tape on the floor, and asked why it was there. He blew a gasket. He was not going to have walls put up. He liked open space, and by God, it stayed open. Do you remember that?

RP: I remember that was very traumatic. I think we all remember it, because he really laid us out. Rayfield had a way about him. He could have indicated his desire to keep it open without hollering and yelling and hurting everybody's feelings, but that was Rayfield's style.

RD: He just made a complete ass of himself.

RP: Yes. That's just the way he was.

RD: There were a lot of different things we were involved in at that time. As I said earlier, I was involved with the food additive petition publication. That had a lot of detailed work, somewhat more so than the pesticide sample results. I remember one very embarrassing situation that Bob ought to recall. The Code of Federal Regulations (CFR) Food Additives List proofs that were made for photographing were about, oh, two and a half to three feet long, and every month they had to be updated. Well, the information was updated on individual sheets of paper about a half inch wide and inserted in slides on this plate. So if you wanted to just update a code or citation of the CFR you didn't have to change everything on the plate, all you did was just pull out one, update it, and slide a new one into it, and then the whole plate would be photographed.

Well, I did a real dumb thing one night before it was to be photographed the next day. I had all the plates, about twenty of them, sitting on top of the trash can next to my desk. I was using the trash can as a table. I came in the next morning and the plates were gone.

RP: He was working for me at that time. You can imagine how I felt. (Laughter)

RD: Do you remember that? And we searched high and low for them. We even had people going out in the trash to try to find them. Never did find them. I had

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to recreate the whole damn thing. It took me about a week to recreate the plates. That was embarrassing, really embarrassing.

RO: I'm not real clear on what you did. Review the food additive petitions that came in, and this was . . .

RD: Right. It was a combination of the *Federal Register* documents and the requests from industry and so forth. And I had to review them with the precedent information from the FDA files. Because people would make claims that the food additive they wanted to use in a food was no different than what had already been approved for something else. But as you well know, that ain't quite how it works. So the combination of that and dealing with the scientists, we'd get the information straight, and would publish what products the food additive was approved for use, in the *Federal Register*.

RP: Just the physical aspect I think is of interest. It was not like now when things are done on the computer.

RD: Oh, yes. That was all by hand and typewriter.

RP: Yes, and these plates, I don't think anybody would hardly even know what you were talking about. But they were just the means of getting the damn stuff printed.

RD: Right. They looked like the wall menus in the old time restaurants. It was easy to handle. Never had any problems other than that one I just mentioned. But it was, as you were just saying a minute ago, Bob, there were no computers around. I mean Bob had one of the first big experiences that I recall with the RCA computer. FDA bought the damn thing but the department took it, as I recall.

RP: Our data system was the first system put on that computer, that Remington computer, and the Remington computer was the first one in HEW so we actually justified the use and the expense for the . . .

RD: Yes, but we lost control of it.

RP: Sure, because the only room they had for it . . . At that time computers took vast rooms and air conditioning and all that stuff, and the only space was over in the department's office. The minute they saw what they had, what FDA had, why there was no question of what was going to happen. They took it over.

RO: You did the food additives listing in connection with the pesticide data gathering. Is that right?

RD: Yes, and then later on Lennington and Bob in their great wisdom stuck me with the Regulatory Compliance actions, seizures, prosecutions, and that type of thing. It all came in headquarters from the field on paper, too. So in putting data *together for the various reports, I believe for your T & P reports, I compiled that* data. So those were the three main things that I was working on for several years.

RO: So this dairy background you had really fit in to all of this statistical work you were doing now.

RD: It fit into some of it, but obviously other things it didn't. Once they found out *that I could deal pretty well with numbers, they started sticking me with numbers of* every kind you can think of.

RP: Keith was very conscientious, and careful, and somehow seemed to be able to just keep dealing with numbers, and so we kind of piled it on. A lot of people would not have been as accurate as he was on that job.

RD: They found out that same thing when I was in private industry with National Dairies. It was appropriate in one aspect. In the quality control job, I was responsible for the loss control program, and that was a very important program because the company's profit depended to a significant degree on how well we controlled the loss of dairy products and other materials such as packaging, liquid sugar, flavorings, and so forth.

(Interruption)

RP: I would think you'd want to keep control. You wouldn't want people to throw important things away in the trash can, for instance.

RD: No, it was little things like at the end of, say, a thousand gallons of milk or cream that you made into ice cream, some people when I first came into the plant, would just rinse the storage tank out onto the floor and it would go down the sewer. And that was . . . I just couldn't understand that kind of an attitude. So I started making them rinse the empty vats down and put the rinse into ten gallon cans and sterilize and test it and at the end of the month we would have hundreds of gallons of material that consisted of 4 or 5 percent fat that just would have been going down the drain. When management found out some of the things that I had changed, really without even talking to them about it, and the fact that the losses that were 2 and 3 and 4 percent a month had dropped down below 1 percent. The procedure became a company policy. The only thing I was unhappy about was I didn't get any of the saved money. Instead I got stuck with the job as the plant loss control coordinator.

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RO: How long did you stay in this kind of work, with FDA?

RD: Well, in one way or another I've dealt with data for my whole career. Actually, I was with Bob almost the total time he was in Washington in one way or another. After about 1968 or '69--when Sam Fine came in from Texas?

RP: Close.

RD: Yes.

RO: Goddard was here as commissioner from what, '66 to '68.

RD: Well, Sam Fine was the assistant commissioner for field coordination, ACFC. That was his title. And Paul Hile was his deputy.

RP: And we were assigned to that office.

RD: That's right. If you look back through the paperwork, that went on in an indefinite status it must have been for a couple of years. But all during that time, I was getting more and more into the planning and evaluation data working with Bob. Sterk Larsen was here from about '66 on. His principle job was planning.

RP: Keith really became my principal assistant from . . . That's not something that there was a certain date it happened; that's just the way it developed. He saw to it that I did the things I was supposed to do.

RD: He was always ribbing me about going through his "in" basket. I thought I'd say that before he did. (Laughter) Bob did considerable travel and/or was on special assignment. Every time Hile wanted something special, Bob was on his way

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upstairs. There were times when I didn't know what the hell he was working on, so I was kind of left with . . .

RP: Oh, it was all secret. (Laughter)

RD: But I guess you might say, to a degree, I was Bob's alter ego during that period of time.

RO: That would bring you up until about 1970 then when . . .

RD: Sixty-nine or '70, yes.

RO: . . . when Dr. Edwards came in as commissioner, and there was another reorganization at FDA.

RD: Well, for about a year, year and a half, I was in the Executive Development Program. Bob recommended me for that and it was approved, and I went in.

RO: What did you do in that program?

RD: You name it, I was involved in it. I was in Atlanta for I guess it must have been at least four or might have been as much as six months as acting deputy director of the district. And in that job, I decided when I went down there, unless they told me not to, I was going to get involved in everything that I thought that job should do. So I did. And it was interesting. I learned a lot in that job. I also became the butt of the Golden Shoe Award down there. (Laughter) That was an award . . . I didn't know that they considered it, but a suck-up award. I got it when I was invited out to lunch by the director.

RO: Who was the district director when you were there?

RD: Well, (Joe) Milunas was the deputy, and he was just kind of moved out of the way and getting another job.

RP: (Les) McMillan?

RD: Yes. With a big cigar in his mouth.

RP: He was a good guy to work for because you learned all the things you shouldn't do.

RD: Anyway, on my first day I was there, he invited me out to lunch. And when I came back there was this beat-up, golden tennis shoe sitting on my desk. And I looked at that thing, and I thought, "What the hell is this?" I looked around; everybody's laughing like crazy. Hayward Mayfield was the chief inspector. So I went in and asked him, "What the hell is this thing?" He didn't know I had gotten it. But he laughed. He always liked a joke. He told me what it was about. He said, "Well, you weren't even here a week and you already sucked up to the boss, so you got the golden shoe." It must have taken me a month to get rid of that damn thing.

RP: You know, on a serious note, it was important in Keith's career development to get him some field experience. His background didn't include direct work in the field, and yet he was dealing 100 percent with data that was generated by the field and beginning to make reports to field directors and things like that. I think the three of us know that field directors consider some experience in the field essential for anybody in Washington.

In any event, both Paul and I thought that he better get that experience, because it was obvious that he was going to be in a position where he needed it.

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And I think that was real great to go down there and go down there a long enough time to not just sample it, but to really get into it.

RD: Yes, it worked out well. When I left, my last day, I'm at the airport waiting for my plane, and this announcement comes over the loud speaker: "Will Mr. Raymond Keith Dawson report to so-and-so." I go and pick up the phone, and there's this damn Joe Milunas and Hayward on the phone saying, "You forgot the golden shoe!" (Laughter) They said, "We'll send it to you." I said, "Like hell you will." (Laughter)

So other than that detail in Atlanta, in that year and a half I spent a few months in OPE, Office of Planning and Evaluation. And I spent approximately the same amount of time in the Bureau of Product Safety. I had never had any involvement in any of those kinds of products before, so that . . .

RO: Who was the head of OPE at that time?

RD: If I had some of my old records I could . . .

RO: It's all right.

RD: By golly, I just don't recall. He was a very dry kind of a guy. I haven't heard his name in probably twenty years. I keep trying to say something like Apple, but that's . . .

RO: What happened when you finished the Executive Development Program or "charm school" . . .

RD: Thanks a lot. Then you had a choice of returning to your old job or seek out other employment. At that time, you got a promotion at the end of it, so that's when

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I got a fourteen (GS-14) when I came back. I guess technically, I don't know if I was called deputy to you or whether I was a branch director at the time.

RO: What year was that?

RD: Seventy-one.

RP: I think actually when you came back we were reorganizing, and they were forming the division, and Bradley Rosenthal came in. And I kind of had my nose out of joint because I thought that was logically my division, partly because when they formed the division I became acting division director, and you took my job. And that's about the time you came back. We had to call an acting, but you were the branch director.

RD: Yes. I got the job in '73.

RP: So when Rosenthal came in, I was made Paul's special assistant.

RD: To get you out of that situation.

RP: I was unhappy. I don't know how unhappy Paul was, but he did feel it had been crammed down his throat to bring in an outsider. Fortunately, Bradley Rosenthal did a pretty good job. I didn't feel too badly about that. But in any event, you became, to all intents and purposes, long before you were designated branch director, you ran that branch.

RO: Well the branch was on the evaluation side. You also had a branch for planning then?

RD: Yes.

RO: And Sterk was the director of the planning branch?

RD: They were sections.

RP: We didn't really use the word *section*, I don't believe, but maybe we did.

RD: It was either section or staff.

RP: Yes. But I had been in charge of both, and I don't really know at what time they made a separate planning branch and gave it to Sterk, because Keith had the whole thing for some period of time. You might remember that, Keith.

RO: Well, I'm not clear now as to when they established that division . . . It was a division then when you're talking about Bradley Rosenthal coming in?

RP: Right.

RO: Before, when you were head of that, did you also have what is now known as the Division of Information Systems?

RD: That was a separate branch under Brad.

RP: That's right. The computer people you're talking about. No, I never had the computer people.

RD: In fact, there were three branches.

RO: Were there?

RD: Yes, the third branch was the one that John Lechus came out of. It was a special projects kind of branch. Let's see, who was the fellow that was a supervisor.

RO: Cumberbatch?

RP: That's right.

RD: Floyd Cumberbatch was the director of that branch, and several people, John Lechus worked for him and a couple of others, at least one of which is still in the information area, was working there. And then there was your branch.

RP: Except when that happened, I still had a branch, but I became acting division director, and I was acting division director for a whole year.

RD: Before Brad came.

RP: Before Brad came.

RD: That was 197- . . . See, the reorganization you're talking about in '71 is when ACFC became EDRO, executive director for regional operations. That was 1971. There were an awful lot of things that happened in that two or three year period. The agency changed its entire planning and budgeting system in '71. In that reorganization, we picked up some PHS programs. I mean it was a very, I guess you could say exciting, and yet at the same time a very difficult period of time.

RP: But in terms of your career, when that division was formed, I remained the permanent branch chief, but I became acting division director for a year, and you

became the acting branch director for that year, and I never came back to the position. At the end of that year, Paul took me up into his office, and I was special assistant to Paul for probably a year, but in the meantime, you became permanent branch chief. So that would have made you . . .

RD: Jim Weixel became the Evaluation Branch chief, and Sterk became the Planning Branch chief. Or I should say staff at that time. It wasn't a branch. I was the branch chief. They were staff or sections; I forget which they called them. Most likely sections.

RO: About that time then you had an evaluation group and a planning group. Were the computer people then also on . . . ?

RP: And the computer operation was another branch under the division.

RD: And then a few years after that, if you want to jump all the way to 1980, they eliminated Cumberbatch's group, split them up. And about that time I lost my evaluation branch director. Bob Spencer and John Lechus came into the position on a lateral. He was already a fourteen (GS-14). After Bob left, after 1973 until I retired, which was twenty-three, almost twenty-four years later, I essentially was doing the same job. I was either a branch or division director during that period of time.

The only other field experience I had at any time occurred in 1979 when I was acting director of Baltimore District. And it ended the very day the Three Mile Island incident occurred. Dick Davis, of course, was the RFDD at the time. As you recall, Ron, Dick Davis asked you and Don Healton to talk to me about transferring to Baltimore to be the district director there, but I turned it down, because I knew it was inevitable that I would be transferred again later somewhere else, and I had already gone through that with my family once before, before I came into FDA, and I knew that wouldn't work. So I didn't accept.

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RO: So in your last twenty-some years then, most of your time has been spent in the planning and evaluation aspects of the Food and Drug Administration's field organization?

(Interruption)

RP: As the division director, you also had the data retrieval operation.

RD: Well, I had the responsibility for the programmatic aspects of EDRO/ORA's data systems, but not the formation of the system itself.

RP: Well, it was a branch under you, wasn't it?

RD: No.

RP: It wasn't?

RD: No.

RO: How have those two things changed over the last twenty years?

RD: What two things?

RO: Well, the planning on one side, the field planning primarily, and the evaluation.

RD: Well, system wise, EDROs and then ORAs, which as you well know came into being in 1983 when Paul Hile returned, the planning system is relatively the same system today as the 1970s. Computerization of ORA's planning system started out,

while you were still here, with On-Line Corporation in Cupertino, California. We had been doing everything by hand up to that time. That's when we really started getting into the computer end of the business, computerizing the field workplan.

I think it was . . . It might have been somewhat forced on us by the agency changing its planning and budgeting system. Prior to about 1971, the agency's planning system was based on what they called categories: things like sanitation, microbiological contamination, pesticides and chemicals, human drugs, devices, that type of thing. In 1971, as you well know, you were on the agency committee to develop a new agency-wide planning system. I'm not sure whether Bob was on that committee or not? Were you on the agency committee on the development of the planning system by projects?

RP: No, I was on the Data Retrieval Committee about that time. But I don't know. I don't think I was on this other.

RD: Well I know Ron joined us, because we used to meet first of all in OPE, and then we met downtown at Foods a couple of times. In that respect, after months of work, as you will recall, we ended up with what we called PMS (Program Management System) a project system based on how the agency was broken out into various aspects within each of the then-bureaus. You had major programs such as foods, veterinary medicine, human drugs, and devices, and biologics. Each major program consisted of multiple projects. Unfortunately, try as we might, we couldn't get total consistency, and some projects were problem oriented, such as food sanitation; some were program oriented, such as DESI (Drug Efficacy Study Implementation); some were even based on offices that were in the structure of the then-bureaus.

But at any rate, we ended up with that kind of a situation, where we had gone from about thirteen major program categories to forty or fifty projects. And we had to do all of our planning within those projects, which to some people didn't make a hell of a lot of sense since the field was involved with doing work by product or

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commodity. Everything the field did was based on problems associated with various industries of one kind or another. The bureaus didn't look at things that way. So in ORA headquarters we had to develop a workplan for the field that represented a "crosswalk" between the bureau's way of thinking and the field's traditional activities. For a while it was a nightmare.

(Interruption)

RD: At any rate, the field planning system was developed and computerized around 1970-71. Bob, I had some involvement in that, but the primary responsibility within the branch was really Sterk and you, Bob. It was a rather long and involved process in putting together, and other than some kind of tickling, you might say, to the system--a few things that we've added and taken out a few other things, none of which are really that important--basically the concept is the same today as it was then. It's been reprogrammed two or three times, once by John Lechus after he became Evaluation Branch Chief, to try to make it more accessible and quicker turnaround and so forth. And then it was done again by the Information Branch people. But essentially the system itself is the same--programmatically today as in 1971. Sterk had full authority in the entire area. I didn't really push my nose into it too much in terms of how things were done and so forth, but programmatically I was always fully involved in development of the workplan and so forth.

RO: I want to back up just a little bit. You mentioned the On-Line Corporation that was first used for computerized planning and evaluation for the field, or was it just the planning?

RD: Planning. How long did we stay with that company?

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RD: With that company? I would say it was no more than a couple of years. We might have been done with them by the time you went to Denver, Bob.

RP: I had a terminal on my desk to access our planning model, for about a year before I left. It probably lasted for a time after I left.

RD: Well, if I had to guess I'd say it was . . . See we were paying for that service. Every time you entered the system, you were paying a service. And the more you used it, the more expensive it got. That's why we had John Lechus rewrite the system in-house, that saved hundreds of thousands of dollars over the coming years, not to mention the fact that it became a better system.

RO: Was there hardware involved with the On-Line, or was it just a system of theirs that FDA was using?

RD: Do you mean, did they own the computers we used?

RO: Yes.

RD: No, we owned those. They were providing the software and the system to be able to do our planning in a computerized model.

RO: So really, they charged us then for the amount of time that we were on their system.

RD: Right. And we were using their developed system, so we were paying a standard monthly fee plus so much per minute when you were on the system.

RP: Well, correct me if... My recollection is that while we had our own terminals, actually when we went into that system, but we were operating through a computer in California.

RD: Right, Cupertino.

RP: We didn't own that computer.

RD: No, no, that's true. I was just considering that as all part of the contracting system. But yes, I can see what you're getting at. No, we didn't have a mainframe computer that could do the work that they had at that time. But during later years, EDRO and ORA got larger computers. And also, then, a number of years later, we got our own computer in-house in the division, and the planning model was on that. So we went from the Cupertino, to PHS, the computer downstairs, to ORA's computer, to our own division computer. That's the manner in which the system . . .

Now, in development of the workplan, everything is based upon compliance programs. At one time, up until about I guess it was '70, '71, the bureaus only provided specific compliance program documents to the field covering 25 to 30 percent of the field's resources. We at headquarters planned all of the resources available, but in a much more general nature. We planned so many inspections, so many samples, and so forth by what we called the thirteen program categories, before we got into the PMS project system. But the field had tremendous latitude on the use of their resources. When you consider that 70 to 75 percent of the total resources they had were not specifically required against any one compliance program, they could do almost whatever they felt was necessary in their respective areas.

Then a very critical thing occurred around '71 or so. Paul Hile was in a staff meeting with the commissioner and the bureau directors. And the bureau director,

for product safety, was getting some heat from the commissioner and some of his staff about accomplishments of various assignments and so forth in the field. As I recall, the director blurted out, "Well, I don't have any control over those resources. Paul Hile controls all those field resources." Paul got upset about that and called us into his office and said something like, "I'm never going to have that happen again. From now on, we are going to plan 100 percent of the resources by compliance programs.

So we provided 100 percent of the resources after that, and up to this day, in the respective program areas--foods, drugs, whatever it might be--that's available to the field under the budget to the center, and they plan all of it. Prior to that, they were only planning much less than a third of it.

That has created a lot of problems for the field over the years. When only 25 to 30 percent of the resources were planned for specific compliance programs there was no excuse for the field not meeting a workplan. But now suddenly every budgeted position of their resources was planned under a compliance program, which meant that every time they had to do something that didn't meet a compliance program, something that was budgeted and planned wasn't getting done, which meant that people in each of the centers were sitting there keeping track of resource usage and complaining that, "You're not doing this or that. You didn't collect those six samples of apples in that program, or you didn't do those inspections." It was a constant wave of criticism from the bureaus and later the centers regarding field accomplishment of program objectives.

RO: How did the bureau track the accomplishments?

RD: Well, all of the investigational and laboratory accomplishments in the field could be tracked through the PODS system (Problem Oriented Data System) which Bob had a considerable amount to do with its development . . . as I think he has been referred to as "the father of PODS."

RP: Yes, I've been referred to as that.

RD: I've been referred to as "the mother of the developed PODS" and things like that.

RO: Is PODS an acronym for what?

RD: Well, originally it was Problem Oriented Data System. "Problem" became "Program" in later years. It's been known as PODS for probably twenty years.

RP: Actually, initially it was known as Product Oriented Data System. We changed the name, but the acronym remained the same.

RD: You see, when PODS was put together, I think in around '69 . . . Is that about right?

RP: I can only say in the sixties. I don't know.

RD: Data was reported into the system not only by what was then called program categories, those thirteen categories I mentioned earlier. It was also reported in by what was known as HIADC, Headquarters Initiated Assignment Data Codes, which was used in PODS to identify resource usage in hours to carry out bureau assignments in the field. Similar codes were used to identify work done by the field in compliance programs. Problem codes were also reported. There was one for salmonella, one for shigella, another one for total plate count, another one for pesticides of one kind or another, heavy metals, and soon all of these data were reported based on the product covered. The entire data system was structured around the who (CFN--Central File Number), what (product/problem), when (date

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done), where (state, etc.), and why (assignment, C.P., etc.) relative to products involved. Do you recall those, Bob?

RP: Yes.

RD: There was a whole series of them--I'd say a hundred or more codes. So therefore, when the field went out and did an inspection, it reported it into PODS, into the data system. The information would be broken out into the various things that they did. If they did some sanitation work, they'd report the sanitation problem code. If they did some pesticide work, they'd report that as well. And they reported hours against each one of these. And there was a classification of the inspection based upon whether it was considered to be in compliance, voluntary compliance, or out of compliance. There were various codes that identified these terms in the data system. Basically you could get information out of this system, using standard reports on a monthly, quarterly, or annual basis, or on an ad hoc basis using a special routine to get some specific information upon request. You could cut the data a thousand different ways.

That was one of PODS' strong points, but it was also one of its weak points. The fact that you could break down an inspection or sample collection or sample analyses into so many different pieces created problems. Almost every time an investigator did a food inspection there was sanitation time reported. And usually there was an add-on inspection spent on food additives or pesticides, and they usually would look at the raw ingredients to see what materials the plant was putting in to see if it agreed with the label of the product that was being produced.

As a result time would be reported for each of these various pieces of the inspection. Sample collection usually was a little bit more finite. A sample was collected for pesticide reasons or for filth or any of a number of other things, but usually for only one or two reasons.

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All of this information on whatever work was done was put into the computer and reports came out on a monthly basis. Unfortunately, the field historically has had the awful feeling that they were submitting this information and it fell into the big hole in the sky in headquarters. The information was entered in their local computers, and the data was submitted on a monthly basis to headquarters.

RP: The PODS system was really begun when Goddard came in. He appointed and brought in from outside the agency an associate commissioner for planning.

RD: Well, then it had to have been before '69, because he was gone in '69.

RP: His philosophy was that we were really interested in the problems that harmed the American consumer and that, taking salmonella as an example, it was important to know that somebody was poisoned from salmonella, but in his narrow viewpoint, it didn't make any difference, whether you got the salmonella from this kind of a food or another kind of a food. Well, I suppose we could evaluate work on that basis, but you sure as hell couldn't plan it on that basis. You can't plan on inspecting a salmonella factor. You've got to plan on inspecting the bakery or a cannery or whatever it is. And I fought that fight with him . . . Well, I couldn't beat him; he was an associate commissioner. But at least we were able to maintain product-oriented information as well as problem-oriented, because for planning you had to have it. There was no way out.

All of this was thrown into the pot with the Booz Allen and Hamilton Study made at the time all of this was fermenting, so that the PODS system resulted from my need--and I'm not saying I was alone. I worked with people who also believed that. We had to have data on a product basis to do planning. We had the general philosophy of the associate commissioner for planning, which I've just described, and then we had the recommendations of the Booz Allen and Hamilton company, their report, and PODS really flowed out of all three of those forces.

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The group I was in--which Keith and I were in--had the responsibility of drawing all this into something to be given to the field, and it was done on a very short basis. We got the system devised and got mimeographed instructions and went out to the field and tried to teach them how to use this system; but the fact is that all of the computer programming had not really any more than begun. And that was a long process. And the field did get the idea that Keith stated that they weren't getting anything back. And the reason they got that idea was that they weren't getting anything back.

RO: Well, couldn't the field have accessed that themselves?

RP: No, not in those days. There was no capability of doing that. Well, excuse me. I didn't want to go into too much here, but I think that really, it tells about the PODS system's genesis.

RD: And that PODS system in one form or another is still here today. Some things have been dropped out. The problem codes have been dropped out, as you will recall. I lobbied against that, as you recall, but Bradley went ahead and made a recommendation--I think it was around '76 or so--that they be dropped because it was just too complicated and so forth. But it provided a lot of information, and I think everybody a few years afterwards realized that it was not a good idea to have dropped it, because we kept getting all kinds of questions from Congress, from private citizens, and from the various groups that were always very critical of FDA's performance that could not be answered properly, if at all, without problem data. Even the field itself was asking for information across a myriad of industries for a given type of a problem. And the data wasn't there. It just was dropped as something to cut back on that the field had to report. That was one of the first critical things that was dropped out of the data system.

One of the heaviest times that data was dropped out was in 1983 when Paul Hile headed up the new ORA. One of the things he wanted to do was have quick favor with the field, because he had come back in charge of EDRO in the form of the new ORA organization because his predecessor had met with disfavor with so many field managers. So consequently, one of the things he said to me was, "What can we live without in the data system?"

So we reviewed PODS and our files to see what people had asked questions on over the years, and the kind of information we were providing to Congress, the agency, etc., to determine the things that we absolutely had to have to do our job. There were about fifteen operations all of the so-called operations that the CAOs (Consumer Affairs Officers) at that time used, and all of the compliance operations training, etc., that were eventually culled from PODS.

Once that happened . . . That made the field extremely happy. Compliance officers didn't report 95 percent of what they were doing anymore, because the only reportable operations were ones they usually didn't perform. They seldom did inspections or investigations. So they just very suddenly went from reporting 100 percent of what they were doing to reporting only about 5 percent. So they were very happy. In contrast, the CAOs who were reporting 100 percent of what they were doing prior to 1983, of a programmatic nature, were unhappy because they used PODS data frequently and the information on speeches, interviews, and so on were no longer available in PODS. As a result, they implemented a hard copy reporting system covering their activities.

The interesting thing, other than CAO and compliance officer activities, many of the other operations culled in 1983 have gone back into the system in the last five years or so. Training is back in. Voluntary Compliance reporting is back again for the third or fourth time.

If anything, I believe what we have found is that managers from various levels always want more information than what's there. But when you tell them what price

has to be paid to get the information, they will suddenly backtrack and say something like, "Well, we've lived without it this long; we can live without it longer."

Unfortunately, we in the division then were put into a position where we had to make estimates of things that are difficult to back up, and in some cases we couldn't back them up at all. And in other cases, responses to questions were made based upon historical knowledge and experience. And only your credibility from having provided information in the past that was not questioned or found lacking makes that information valid to people that are getting it today. I've had that experience for twenty years or more.

The field has never liked reporting information into PODS and other field information systems, and they will never like it. It's looked upon as taking time away from doing the important job of the agency. They will never be able to understand or appreciate that if you cannot demonstrate what you did, how you did it, and what the outcome of it was to people in Congress, press and so forth, as far as they are concerned, it never happened. If you can't prove it happened in some manner, it didn't happen. What is worse, you can not justify the use of appropriated resources without information.

RP: Fortunately, we've always had a number of field directors who did thoroughly understand the need for it and who really went along with it as long as we were reasonably pragmatic about it and it made some sense to them. But if they didn't fight us on the data, there were always a few who did and probably always will.

RD: But regardless of whether it was 1966 or '69, whenever PODS was developed, or today, it has been such for those some thirty years, people are always looking at pieces of the information, and if it doesn't show what they want, they're critical. Either the information that they want is not there in exactly the way they want it, or what they see they don't believe. Some people understand in headquarters, but I think a lot more don't, that you're dealing annually literally with tens of thousands

of pieces of information. There are inevitably going to be errors. It has to come down to what level of error is the agency going to be willing to live with?

Paul Hile used to use the term that "he wasn't running a bank," so on that basis, you're going to have to live with a certain level. Somebody said to him at one time, "What level of error do you think is reasonable to live with?" Well, out of this void came the term, "5 percent." And we've lived with that 5 percent figure as long as I can remember.

There have been times when Paul was much more stringent on his requirements. I recall around 1986, not long before he left, ORA "killed" its regulatory action data system called LAMS, Legal Action Monitoring System, because the centers were refusing to put their part of the information into the system, so consequently, the data system was dying of its own weight and was very discouraging to the field compliance offices. ORA's director of the Office of Enforcement recommended it be killed. Paul approved it and directed him to come up with a new system within thirty to sixty days.

The new system that was developed was eventually called RACS, Regulatory Action Classification System. The system was supposed to be temporary to last for a year or so, because a new computerized compliance system was going to be developed by the information group working with agency compliance people in the field and the centers. They wanted a new "shiny" system that all parties would support. It is now about ten years later and that hasn't happened yet. (Laughter)

So a system that was supposed to last about a year and was not really providing that much information, was not that difficult to handle, Paul told his managers he wanted that system without error . . . One hundred percent accuracy in that data system. Unfortunately, it never was a really accurate system. Numerous memorandums flew around between--almost all of which my staff drafted--Paul and the field, flew out of your signature, Ron, at one time, flew from (Ron) Chesemore to the field, and finally everybody just gave up. We kept saying we wanted it accurate, but it never was really accurate.

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Every time somebody requested that data I would cringe. GAO (Government Accounting Office) would get it. They would then go back to the administration's hard copy files and compare them with RAC's. It just was terrible. I wanted to kill the system years ago, but ORA had to have some kind of computerized file so RAC's is still here today.

That's been a critical problem in every data system I have ever seen, whether it was from flexite type hard copy records we used to get back thirty-some years ago, or it's with what you're getting now in regulatory compliance and so forth. You're dealing with so much information and with a large number of people to whom reporting data is an anathema to them. They just don't want to have to report the information. And no matter what you do or how easy you make it to report the data . . . (You can only make it so easy, because of the requirements of the system or the requirements of the data that you want.) The systems are usually filled with erroneous information and/or entirely missing some data. Why? Because systems are complicated. The instructions on what to report, when to report, how to report it, are complicated. The more data required to be reported, the more complicated the system.

RO: Keith, let me ask you this. You said GAO would go back to the hard copy and it didn't compare at all with what was in the system. Well, what was the difference in the inputting? Wasn't the inputting done from the same hard copy that fed RACS?

RD: Yes, but see, your errors can be of omission. Your errors can be just simply hitting a wrong character, and a device suddenly becomes a drug, or the district or date code is wrong, and so on.

(Interruption)

RD: Errors can be that a record isn't put in at all. I mean, it's one thing to look at data and tell that what's there can't possibly be true. If the description says it's apples, and the product code is for bananas, obviously one of them is wrong. Of course, if the record is for bananas that were imported from Russia, it's a pretty good idea that it must be apples not bananas since they don't grow any bananas in Russia. So some of these errors were easy to identify.

Back in the mid-eighties, the division began writing validation computer programs for the field to use to do periodic checks against their own data where they could go in PODS, the OEI and other systems and compare certain fields to see if they were logically correct. They might compare hours with that type inspection or part of inspection done. It's not reasonable for an inspection to take a half hour. The report writing would take longer than that. If a district saw a device manufacturer inspection that was only two hours, they should immediately question whether the decimal point's in the wrong place. They could understand it being twenty hours, but doing an inspection in two hours in a device plant is highly unlikely, unless it was really an investigation which was erroneously reported as an inspection. So we wrote programs that allowed them to review their own data. Well, the quality of data picked up considerably after they started using those kinds of programs.

Similar programs were done, oh, fifteen, twenty different programs or more on the OEI. The responsibility for the quality of the information has always resided in the field, but the responsibility for assuring the quality of it was a responsibility of the DPEM.

One of the things that Sterk's office would do is to look at data in the OEI, and things that just didn't look right would be questioned, and printouts of the data would be sent to the field for their review. They would check their hard copy records and make necessary corrections. At the same time, they had these computerized programs that they could run on a quarterly basis across their entire OEI looking for certain things that didn't make sense, like blood banks with food codes. (Laughter) I mean, it's impossible.

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RP: Well, in Transylvania it might be.

RD: But there were a lot of strange things like that from the data. Warehouse codes that didn't make sense.

RO: What do you mean, warehouse codes?

RD: Food additive warehouses as a general sense didn't make sense. What was happening was that when the field did a sanitation inspection of a manufacturer, they would look at food additives that were being used in making the product, and when they reported coverage of food additives on the inspection it was erroneously reported in PODS as inspection of a manufacturer of food additives which automatically updated the OEI for that manufacturer showing them storing or producing food additives. They weren't manufacturing food additives; they were using food additives.

So one of the things we did on the computerized program was run it against all of their manufacturers to see how many of them were manufacturing anything other than food additives. If they were manufacturing applesauce and it showed them as a manufacturer of food additives, the program would print the record out for review because the combination was unlikely. Of course, there would be instances where records they reviewed were found to be correct. But the vast, vast majority of those kinds of conditions, well over 90 to 95 percent were wrong. So it was an easy way to find things that were inappropriate.

Nobody was making those errors on purpose. Some of it was done, in fact, with computerized programs as described previously on the automatic updating of the OEI using inspection records.

RP: Discuss briefly why this is important and what effect it would have on the planning system.

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RD: Well, it can have a lot of different impacts from our own selfish situation here in ORA. It could allocate resources to districts for coverage of products that they shouldn't get. For example, in the food program, one of the ways that resources were distributed was by looking at each different major industry included in the OEI for that district by CFN. Using the example cited earlier, if the record showed a manufacturer of food additives, and let's say they had a thousand food establishments, and every time they went in they looked at food additives and put it on the OEI with manufacturers of some other kind of a product, they suddenly were picking up a thousand opportunities in the OEI to get more resources than they should have gotten, because the resources are distributed primarily for manufacturing, secondary for repacking and relabeling. Way down the list were things like warehouses, unless you had a special food program for warehouses, which we haven't had for years. Warehouses just about dropped out of the distribution of resources.

RO: An establishment could be a manufacturer of more than one product.

RD: Oh yes, yes. If you had a general food safety program which would cover all basic food items, then for each different thing that a manufacturer produced, the district would get what you might call a "tick" in the total system. Let's say, for example, that there were 50,000 food establishments. If they all produced or manufactured only one product each, then each district got whatever their proportion of the 50,000 establishments that they had.

So, Ron, if you had 1,000 establishments, and Bob had 1,000 establishments in his district, all other things being equal, you each got the same level of resources, no matter what the products were. Bob's establishments could have been producing millions and millions of pounds, and yours might only be in the tens of thousands. The size of establishment at that point in the distribution of resources wasn't considered. But if you then suddenly in your thousand establishments also had food additives listed for each of them, you got two-thirds of the resources and he only got

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one-third, when really you should have each gotten a half, assuming you and Bob were the entire Food and Drug Administration and each of you had a thousand food establishments.

Subsequently in the planning we added in things like the size of establishment and what the compliance situation was. We set aside 20 percent of the resources in the food area for compliance, and it went to those districts that had the worst compliance situations: VAI 3, Voluntary Action Indicated, Class III, and Official Action Indicated, which is another term for violative. If in your thousand establishments one hundred of them were violative, and Bob had none--obviously this situation wouldn't exist--but with this example, then that 20 percent of the resources for that food program would all go to you, Ron. The 80 percent would be divided up 50/50 on the basis of the products that you have to look at.

Of course, the situation changes significantly if the program is only covering a given industry, like tomato packing or something. Then you would go into your OEI and look for tomato packers--packer, repacker or manufacturer, whatever the term might be that you're doing--and the resources distributed to the districts on the basis of their proportional part of the OEI. Very simply that's the way it is, and it's always been done.

Where you get into problems is when somebody wants to break that industry down on the basis of, say, manufacturing technique, or they might want to break it down and only cover those establishments that had been out of compliance in inspections over the last five years or whatever it might be. Then you'd have to cut the data a different way and find out how many of those establishments have been out of compliance, so you can hit the bad guys first and whatever resources are left are used to inspect VAI or in compliance.

What's been happening over the years is foods is still by and large the largest inventory we have. Including warehouses, you're talking about around 50,000 plus. As your resources go down in a given period, less and less is being covered. The priorities in the agency when I left a few months ago, seafood was still the biggest

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priority in the food area. So we were trying to cover those once every two or three years. Other industries might be covered every ten or twelve years.

RO: What is the average now on foods?

RD: Average for all of them the last time I looked at it was between eight and nine years for foods.

RP: Has the proportion of our resources spent on foods and drugs changed over the years?

RD: I would say that proportionally in non-inspection items, we still do a lot of sampling of foods. An awful lot of resources get spent on foods, not to the bemusement of other centers, I might add, because of things like consumer complaints and emergencies, like a year of two ago when that microbiological problem in Schwan's ice cream in Minnesota. For a time, nothing else was being done in the food area except that. At the same time the field had priorities like, you *will* do blood banks; you *will* do your human drug work relative to new drug clearance. Certain programs had a very high priority. The mammography program now has a priority such that except for emergencies those programs are to continue to be done. And they're very sensitive programs. You can see why they would be that way.

RO: A while back you were mentioning that Paul Hile did this and did that as far as the data system. Paul left ten years ago, and there have been a number of other ACRAs, associate commissioners for regulatory affairs. Have the succeeding ACRAs taken an interest in the data system the way that Paul did?

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RD: No. In terms of interest in data and planning, Paul was always head and shoulders above everybody else in their concern of that. The only time that the other managers had a concern was when they were in trouble and they needed help to explain, "How do we take care of this problem? How do we deflect the criticism we are getting, whatever it might be?" Resources have always been a very high interest of all managers. I've always tried to keep people apprised of what seemed to be on the horizon, what was happening, and what to push for. Unfortunately, there have been times when I'd have to push so much with some people that it would irritate them. (Laughter) Then later on they were thankful that I had. But while you're trying to promote the importance of these things and somebody doesn't want to hear it, you have a great deal of difficulty.

Same thing's true of the data system as a whole. If you don't have support from top management, from the ACRA all the way down through the organization, emphasizing the importance of the quality of information, you're never going to have it. And that has been lacking as long as I can remember.

RO: What about the centers? Are they interested in the data system?

RD: The centers are interested in the data system in terms of information that they need to explain what their program area accomplishments are. There are a lot of things that the field does that has to be done in the centers' product areas, but you get the feeling at times that they really don't care much about it.

RO: "They" meaning the field or the centers?

RD: Centers. They know that it has to be done, but they don't really have their heart in the fact that that's where the resources are going. They'd rather have the resources in headquarters, in the center, than the field out there doing some inspections in certain areas.

The center that has always had the most interest in the data system in terms of the quality and the information in it has always been (Center for) Foods. And I think one of the reasons that they have been interested in the quality of it is so many of the people in the center came out of the ORA organization right here. Several of their branch and division directors came out of Bob's and my predecessor's organization. So they had a healthy appreciation for data. Lee Bowers right now is one of those. By the same token, because they had that healthy desire for the information and the quality of it, they can also be some of your heaviest criticizers. Devices has in recent years become very interested in PODS information.

Other people are just asleep. Drugs hardly uses anything out of the system. Biologics until the last few years didn't use much of it. CVM (Center for Veterinary Medicine), they were always in such bad shape on planning, it seemed like we were doing as much of it as they were doing their planning for years. Some of the people they have now came out of our shop, so they know the questions to ask and where to look for things, but they didn't know in the past.

RO: When they, meaning a center or a bureau, tries to get a look at their accomplishments in particular program areas, do they ask you for their data, or can they directly access information in the data system?

RD: Well, in the past they'd have to ask us, because other than the printouts that came out each month, they didn't have any access to the system itself. But in the last few years, they've had direct access on the PHS computer, and they also have accounts on the ORA computer. And they get microfiche of all the OEI if they want to look up things by state or so forth. They have never had an account on our planning model, but we've always worked with them on anything that they needed.

RP: Well you wouldn't want one to get into your planning model to a point where they could unilaterally change the plans.

RD: No, what you could do, and you could always do that in any system, is they could have read only access. That kind of thing is being developed in the new data system to take the place of PODS. Everybody in the agency, that has an interest, can have read only, but only certain people can input data, and only certain people can change data. PODS was not like that.

RO: Who were some of the biggest users of the data outside of yourself and the field organization?

RD: Well the biggest user of the data in terms of any single organization is and always will be ORA, principally Division of Planning Evaluation and Management. The field has been using the data system more and more and more in the last few years. Foods and devices are the two biggest users outside of ACRA. I'd say drugs is probably still the smallest user. CVM is in between there. Biologics ditto.

There's more and more interest from outside the agency in information. And you might think if you have opposing parties in the White House and in Congress, wouldn't that have something to do with an increase or decrease in information requests? Well, when the Republicans got into power a couple of years ago, their first six months or so, they were just driving everybody crazy with the information requests. But when you think back, the Democrats, Dingell and others like him, were driving us nuts with information requests all the time, too. The thing that I see that is different about the Republicans is that some of their requests have a belligerent attitude in the way that they ask for things. It's almost like they are expecting you not to want to reply, or if you do reply, it probably won't be accurate or complete or believable anyway.

GAO, of course, has always been a big user. It's unbelievable to me how long they've been around dealing with this agency. My first contact with them was about 1969 or '70, and they are still here.

RP: Do they still have a permanent office around here?

RD: Oh, yes. You might say offices.

RO: They used to be in Parklawn Building. Then they moved across the street to the Park Building.

RD: One of the unfortunate things for us with dealing with them is that the auditors keep shifting from one area to another, and we have to sit and spend valuable time training each new GAO person in the basics of what FDA is and does. And then, every once in while, you'll find that they're asking for the same pieces of information as somebody that started a study six months ago. I used to say, "Why don't you go see so-and-so and get that information so we don't have to recreate it again for you?" Their responses invariably were, "Oh, well once they use it they throw it away."

RO: Keith, the field has been reorganized recently with a new regional reconfiguration and some laboratory consolidation. What was your involvement, your office involvement in restructuring the field?

RD: Well we had kind of a minor forced landing requirement when we went to ten regions way back. I think that's when Nixon was . . . In the seventies. That caused some heart palpitations for the agency trying to change the system and so forth for that. No, the big reorganization that I was heavily involved in, and Bob was on the same committee, was the one that was accomplished in the mid-eighties, where the field structure was changed from ten regions to six. That study was a massive undertaking of every aspect of the organization, DPEM developed detailed information, compilations primarily by Sterk's office on workload data by various

industry codes and districts, even down to the point I believe it was by zip code. Did it go down that far?

RP: Well, not in my time or to my knowledge.

RD: County, I guess.

RP: County, yes, county.

RD: Well, that was refined and made even more detailed. That's been used several times. But those data compilations took thousands of hours to put together. We took all of that information and prepared maps of various types that showed where the workload was in foods, and drugs, and devices, and the like by state and county, and then developed numerous alternative plans ranging from six or more regions. There had to be at least fifteen or twenty different options. I'd say--what do you think?--there was about a dozen people or more that was on that committee?

RP: Well, I'd have to guess at least that, because the committee divided into subcommittees, and each subcommittee had a minimum, I think, of three people. I would say there were probably fifteen or so.

RD: Yes. The committee was chaired by Ron Chesemore. Because of my position, I was stuck with putting the numerous alternatives together for the review committee. Some people on the committee did an incredible amount of work on the study, and then there were others that were more of an impediment than they were a help. I wasn't looking at Bob for that reason. (Laughter) But not that they necessarily were doing it intentionally, but they knew that somewhere along the lines, their regions were going to get hit in some adverse way and didn't want to be considered the cause of the changes.

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Overall, most people put in a healthy amount of work. But frankly, I got hit with the lion's share of not only having to put the report together, but having to rewrite large segments of the document so it would have a single sound to it, instead of sounding like it was written by a committee. As I look back and think about the amount of work that I personally put into that, God, it was awful. I swear. (Laughter) I wouldn't want to have to go through that again.

RP: That occurred, after all, some time ago, that six district configuration. Haven't there been developments since?

RD: Not in the number of . . . In terms of regions, it's still the same.

RP: How about laboratories?

RD: Well, there was a laboratory study in the early nineties, or late eighties in which the agency decided to consolidate or close a considerable number of laboratories. That got blown out of the water and nothing really happened, principally because there were considerable complaints from some of the field. I believe Minneapolis was one of the heaviest complaint areas. Anyway, their complaints got to Congress, and then we had a GAO review of it. In effect, GAO's findings said that we should not go forward with it because the study wasn't carried out in a proper way, that we had already made our conclusions and then wrote the report. (Laughter) So virtually nothing was done relative to that document; it just kind of died. GAO and Congress were really upset about it.

RO: Was putting a field laboratory at NCTR (National Center for Toxicological Research) a part of that nineties study or is that another study?

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RD: I frankly don't remember that. That business about NCTR, that came up in the preliminary stages, is my recollection, of the current study.

RO: Is the current study still viable?

RD: When I left it was viable within constraints of getting resources. There were some congressmen that were saying no resources could be used for consolidating laboratories. Now you heard a while ago, when we took a break, we were talking briefly with them in there about the laboratory study. I don't know what's happened in the last four or five months or more.

(Interruption)

RP: I reported the idea, years and years and years ago, when I first really got in this business, that what we should do is have three laboratories, like the Department of Agricultural regional labs. Communications, way back then were crude compared to now, but even then I felt that communications were such, and transportation of samples was such that we could operate with three regional laboratories.

RD: Those would be huge laboratories.

RP: Huge laboratories.

RP: The first germ of this was when I visited the agricultural laboratory somewhere in Illinois. This would give you flexibility in the distribution of your inspection force.

Incidentally, historically when they first started the inspection force back in 1906, they all worked for a chief inspector in Washington, and all the laboratories did was give them a little office space. They were not otherwise related.

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RD: Well, there have been a lot of things that have occurred . . .

RP: Maybe someday that's what they'll end up with.

RD: Regardless of whether we in the past, as a result of that first study I was talking about, have closed any laboratories or not, it really doesn't make any difference. Some consolidations were being accomplished anyway by making certain laboratories specialists in, say, drugs or sterility or things like that, so that every lab wasn't doing everything.

The idea of trying to buy equipment for seventeen to twenty laboratories in which everybody has the same training and capability of doing analyses across the board on all types of products just isn't realistic. There's too many different products on the market, too many different special pieces of equipment of a very expensive nature that would be needed. It would increase the space that would be required for each of these laboratories by having all of that. And the training of all of the people to do all of these things and maintaining that expertise would be outrageous in today's climate.

Thirty years ago things were much simpler than today. Food work was primarily analyses for the filth, pesticides, or aflatoxin. But today, the products are growing by thousands every year, and the kinds of things you have to look for and so forth, the various pathogens, chemicals, drug and device sterility, etc., it's just much too complicated, and it just wouldn't work in the environment today to try to have everybody be able to do everything.

RO: You were talking about laboratory equipment. Now, from a data standpoint, haven't you changed over the years as far as the equipment that the field has and what you have in headquarters here?

RD: Yes. At one time the only place you'd find any kind of computerized equipment in the field would be in the DPUs (Data Processing Units). Then the laboratories got some, particularly because of the drug analyses and the like that they were doing that they needed them to make rapid high level calculations. To sit there with a paper and pencil and then a calculator just wasn't a realistic thing to do. Then we've gradually added some computers in the investigational area. And I guess you could say that the compliance people probably are the last ones that got into the use of computers.

ORA is trying to get to the point where everybody out there in one form or another will have a computer available to them, so that instead of an investigator or analyst filling out a paper form, turning it into a single location, which was then called the DPU, and then entering the data in the computer and being sent, in the old days sent by tape to headquarters or before tape on magnetic cards, I'm sure you'll remember . . . Now it's all electronic. And gradually they believe--I'm not sure I believe it totally, but I can understand how they believe it--that people, if an investigator inputs the data, or a compliance officer does it, they'll have a greater proclivity to put in complete and accurate information.

RO: And accurate?

RD: Yes, that's the belief. By making them responsible for their own information. It's always been difficult to figure out who made the errors in the past. All you knew was the data was not right, but you didn't know whether the error was made by a DPU clerk, a supervisor, or by the person who filled out the original cover sheet, or sample collection report, or green data sheet.

RP: I'm a little surprised that we haven't by this time reached the point when an inspector or an analyst creates a report document, that that data isn't automatically sent into the central computer. It seems like that's a technique that's long overdue.

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In a grocery store, when you buy a bottle of ketchup, hell, their computer tells the guy that orders it, you know, when you get down to one hundred bottles you reorder, and the computer generates the order. All of this is done, and it has been for years. How come we haven't been able to move ahead with that kind of thing applied, of course, to our work?

RD: Well, of course, you're not doing inventory control. Inventory control is a pretty simple thing compared to what you're going for.

RP: Oh, I understand that. No, I'm talking . . . Well, it might be, but we've gone a long way in this country in terms of being able to do that kind of thing. It seems to me that it's time. The time has come.

RD: Well, the time is here, and if that new system . . . If they get the money and get it done and off the ground, everything will be done electronically.

RO: You said "new system." What are you . . .

RD: New data system. I guess it's still called FACTS. I think it's called Field Accomplishment and Compliance Tracking System.

RO: Because there was another system. What was the import system? Were you involved? I thought there was an import system that was supposed to be up and running.

RD: You're talking about ISIS?

RO: I don't know. I'm asking you.

RD: Our office didn't have anything materially to do with the development of that system, either programmatically or electronically.

RO: What does ISIS stand for?

RD: (Laughter) Well, let's see. Import Support and Information System.

RO: But you had nothing to do with that. And what is it supposed to do?

RD: I didn't have anything to do with the development of the system. ISIS was generated programmatically using people from the field, primarily two compliance officers in determining what it was that they wanted to be able to track and control. The system was developed between a contractor--in fact, there have been several contractors over the years--and ORA's information division. My division, DPEM, worked them, in terms of whenever and whatever they asked us. We would be involved in the discussions relative to the OEI, PODS data reporting requirements, and so on, but DPEM personnel did not work on the program requirements of ISIS.

When they got around to certain aspects of what kind of data would be required in that system to be able to transfer the data into PODS, we would be involved to be able to tell them what they had to have in addition to the basic information that they wanted to retrieve. Certain things had to be there. The hours spent doing the import operations, the central file number for the establishments, the employee numbers, and such things had to be in ISIS to be able to transfer the data to the PODS system or in the future the fact data system.

RO: Was it supposed to give an inventory of the import entries?

RD: Well it's supposed to do a lot of different things. One of the things it is supposed to do is building an inventory of the various kinds of products--not just

industry codes, but specific products that are entering the country. Secondly, who's handling those products; what countries they're coming from. It was supposed to aid the field in identifying what products to collect and when to collect it.

ISIS also, part of it, was to have information available on the history of those products. Were they products that had problems? And if so, what kind of problem had it been? If there had been problems and the field knew what kind of problems there had been, are there certain importers that were causing that product to be entered into the country? And of course, the country of origin as well, to the point of where you are actually computerizing lists of those products so that when they bring up the product for entry, the field can take a look at it and then compare it with other information and decide, "Do I want to collect that product, or do I just want to pass it?"

And, of course, ISIS also aids them in identifying whether maybe somebody's attempting to bypass given ports and come in at a location where allegedly in the past, because of lower staff available or whatever, they might not have looked at the products with the same interest as in some of the larger ports such as San Francisco or L.A. or New York. There are a lot of things built into that import system.

RO: Is that up and running?

RD: When I left, pieces of it were up and running in several districts, but the entire system was only up and running in Seattle. I don't know where it is now. They were wanting to have the complete system operational I believe by August of this year, '96 . . . I think it's August of this year. But Jerry (Henderson) could tell you specifically. It could have all changed. It all depends on the money they have available . . .

RO: Yes, there's always been a criticism of the amount of time that FDA spends on imports. *We're spending too much time on imports; we're not spending enough time on imports.*

RD: Well, there's been criticism on that. Domestic producers criticize us for not covering imports more. Importers claim we're covering them more than we do domestic. It's a different kind of coverage. Generally speaking, you can't inspect foreign plants except in drugs and devices and some LACF (Low Acid Canned Foods). But FDA does have inspectional information on domestic plants and products. You not only have the products available on the market to sample; you also have the producing plants and warehouses and so forth available to inspect. Basically, you get only one shot at the imported product. That's when it hits U.S. shores.

RP: Well, I wanted to go back to this, did you call it FATS?

RD: FACTS. Field Accomplishment and Compliance Tracking System I believe is the term.

RP: Can you tell us what you know about that?

RD: Well, that data system has been under development for about, it seems to me, four or five years. When I retired, nothing was off the ground yet. It's had a change in contractors a couple of times. So has ISIS. One of the primary problems I understand, is that money just has not been available, for a variety of things, contracting purposes and for equipment to really get it totally moving.

RP: Is it a new system maybe in terms of equipment and systems analysis?

RD: It's a totally new, different type of operating system.

RP: OK, but is it just the mechanics of it, of getting in the information that's now on PODS, or does it have a whole new kind of basis, philosophical basis?

RD: Everything is different, operating system language, file structure, data access, programming, and so on. Philosophically it's . . . The first thing you would hear is that it's a system that the field could get much more out of than what they can get out of PODS, that they have more control. The system not only covers PODS, it will be the ORA umbrella FIS. It will have assignment control, OEI, compliance actions, etc.. It's also supposed to include some of the new things that have been coming up on the ORA 21 (Office of Regulatory Affairs 21) that I haven't had any real involvement in whatsoever in terms of voluntary agreements, sharing of data with states, and so forth.

RP: So this is supposed to be a unifying all . . .

RD: And development of new things that they've not had before, which is primarily the compliance and assignment tracking system. The assignment tracking system, for example, is such that if the Center for Foods wants to send an assignment to one of the districts, they would merely enter that assignment from their location, and it would electronically be available at the district where they want the assignment done. And when the field has completed the assignment, and they put the information in the assignment control system, and it becomes electronically available to the center and electronically available in FACTS.

RO: How is that squared with the overall field plan?

RD: Those assignments?

RO: Yes, the assignment. Is there some . . .

RD: Well . . . It doesn't necessarily totally relate. Within the field workplan, a compliance program like the, well, the human drug program, the center has always had the opportunity to send out assignments to the field. But the assignments, even though they might be identified by a PAC (Program Assignment Code), a set of numbers and alphabetic symbols that identify what compliance program the assignment relates to, those assignments can be coming from various locations within a center. One might come from the Office of Compliance; one might come from New Drugs; another one might come from, who knows? But there isn't any one location in the center that puts out all assignments; so therefore, you could have many more assignments issued around to the various districts that we don't know anything about here. And by the time all that work is done collectively and turned in, you could burn far more resources than what's in the program.

RO: I thought that those had to be coordinated through headquarters here to make sure that . . .

RD: Any assignment that does not involve more than three days' work or more than one district doesn't have to clear anywhere. They can just send it out.

RO: Sometimes that assignment, even though initially you wouldn't think would consume more than three days, might end up consuming a lot of time.

RD: Oh, well, I am sure they know damn well when they start out that the assignment's going to involve a half a dozen districts. So instead of sending one assignment to the half a dozen districts, I've been told they'll send one assignment each to six different districts. Therefore, they don't have to clear it.

RP: Even though they know it will probably take a week, they can just estimate three days.

RD: Oh, and it can, but there's no way that we can prove that that happened. There's no paperwork for it, and all that shows up in the computer is work done against that Program Assignment Code. No, you don't have total control over anything. I mean, we don't have data in the system on every hour expended by an employee, any employee. They get paid for 2,087 hours a year, but out of that 2,087 hours, you'll be lucky if you get a little over 1,200 for an investigator, because you don't retrieve data on annual leave, and sick leave, and court leave, and travel, and many other activities.

RO: Training? You said . . .

RD: Well, training now is . . .

RO: . . . is back in again?

RD: Yes, it's back in. It has been for a few years. But there's a lot of things that inspectors and analysts do, and unfortunately, every year something new seems to be happening because of various governmental requirements, like OSHA in the laboratory on safety of hazardous substances and those types of things. There's no PODS operations covering those things. There are literally hundreds of things that are going on by field personnel that we may know about in the whole, but we have no idea what it's taking to do them.

And one of the reasons you don't have that kind of data is that nobody is willing to pay the price to retrieve it. As long as you don't have to provide that information on a routine nature, it will never be available, and nobody's going to be willing to pay the price.

We said years ago that we would do total time studies periodically. We did one in 1979 and '80 in my division. Several Bureaus were involved in the study and all bureaus agreed with the study recommendations which the commissioner approved. . Subsequently, we made modifications in the various ways that we plan the information and the resources available for an investigator and an analyst. The plan was that every five years we would update that study. Every time we got ready to update the study, nobody wanted to spend the time to do it, and it has not been done since 1980.

This lack of updated operational and position class resource information came to a head when Congress passed the bill for new drug approval. The agency was required to have specific information available, computerized, of what it cost to do everything connected with that program. They wanted to know what it cost to do an inspection, and an investigation, how long it took to process the paperwork in the center, who did it, and what their salaries were. All of these things. This information was required to demonstrate that FDA was using the "User Fee" Resources only on legitimate new drug approval activities.

RO: You mean Congress wanted to know.

RD: Congress wanted to see it. And GAO was required to check to make sure that we developed the resource usage information from valid sources and methods. FDA had a contractor review ORA, center, and Office of the Commissioner's New Drug Approval Procedures to assure the agency would meet GAO/congressional requirements. When we were asked to show how we plan work for an investigator for new drug purposes they were surprised to see that only 930 hours out of a 2,087-hour workplan was specifically planned and asked, "What happened to the rest of their time?" So we described what makes up a full work year for a typical investigator and analyst . . . So much time for inspections, sample collection and analysis, annual leave, training, sick leave, and so on.

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And they said, "All right. Can you show us the most recent proof that you have?" Well, when I showed them it was 1979 data, I thought they were going to choke. "You mean we're in 1994, and you're using data that's fifteen years old?" Well, when we explained to them what had happened over the years, they said we needed to update the information ASAP. I said, "Well, fine, but you're talking about probably a year's effort." They didn't seem to believe me, and after they talked with some others in the agency and with some of their own statisticians, they came to realize, they were not going to get updated information in time to satisfy Congress.

But they put a statement in their report to the agency that ORA needed to update its operational position modules as soon as possible.

Well, I brought this to the attention of ORA management, and they asked me how much I thought it would cost. I told them I didn't know. I also told them that I didn't have personnel available to do a study, and that OPE had told me they couldn't do it either. I said, "Nobody's going to give us resources to do this. It ought to be contracted." I was asked, "What do you think it will cost?" I said, "Anything I tell you is a guess." "Well, give me a guess." I said, "Half a million." I thought they were going to die. We never got it.

So I talked with various people in the agency like Frank Clounts, who at that time was the head of the budgeting division, and asked him, "Isn't there some way that we could use "user fees" funds for new drug approval process to do this study, because the end result is it will be used for that development of that information anyway?" He said he didn't know whether that would be legitimate. So I guess it took about six months with various people, talking with GAO, and they came to the conclusion, "Yes, I guess it would be legitimate." But . . . we never got the necessary funds to do the study because there were always some more important needs.

Then along came another new "user fee" legislation, mammography. Similar information was required to demonstrate appropriate use of resources on this program. Again, we had to use our old modules to plan the program, and I think it was Arthur D. Little Co., asked the same questions, etc., as for new drug approval.

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I told them the same thing I discussed previously,and we used our historical data to plan the program. I advised Jerry Henderson and Ron Chesemore that again we were told that we should update our modules. The upshot was that even with all the money that was coming in for the new drug approval process, they couldn't let loose with some money to do the study.

So when I left the agency the study still hadn't been done, and they were trying to figure a way to be able to do a shorter study with fewer people involved, albeit a statistically-based study. So I don't know. I haven't talked with John (Lechus) about it. I've been gone about four months now. I know they don't want to try to do it with their staff, because their already snowed in with what they have on a routine basis. But it needs to be done.

(Interruption)

RO: Well Keith, we've talked a lot about the data system over the years and the progress or lack of progress that has been made on that. You mentioned several times about the involvement of OPE in certain things, Office of Planning and Evaluation. I imagine you made reference then to the agency's Office of Planning and Evaluation. I'm wondering what their role was in all of the planning and evaluation that went on as far as the field activities were concerned. Were they limited to the overall agency, or did they take a look also at some of the field accomplishments in some of these areas?

RD: Actually, OPE did both. One of their primary functions was always a coordinating office for agency planning activities. They would put out assignments for long- and short-range planning, and in many cases, specialized studies that they wanted to put together or they'd ask for information on, such things as research, or maybe imports. It varied year to year what subject matter they were dealing with. But they put those assignments out to the centers, previously known as the bureaus,

to ORA, to various assistant commissioners and coordinated the responses into an agency-wide report for the commissioner, department, OMB (Office of Management and Budget), etc.

(Interruption)

RD: Another primary function of OPE was the crosswalking of plans and budgets with Division of Finance Management. OPE asked for guidance from each of the organizations on their plans relative to the budget each year. For example, they would ask, say, around November of last year, 1995, to begin development of the 1998 budget on a long-range basis. They would have you take a look at what your 1996 current plan would be in terms of resources and programs, and with what the agency guidance, taking into account some of the things happening in Congress, what they anticipate will be the case for '97 and '98.

They would say such things as, "If you had a 5 percent cut in personnel and/or dollars, in your program area, where would you take the cuts?" Other times they would say things like, "Name the top ten highest priority programs and the bottom ten programs in your foods, drugs . . ." In our case, ORA, that would cut across all of them: foods, drugs, CVM, devices, biologics. And they would ask for us to provide guidance on where we would have either increases or decreases depending on what the guidance was for that particular year.

Then they would take that information from each organizational element, put it all together, and come up with an agency picture of how much resources were either needed to meet a particular strategic plan, or how much resources as a whole could be cut and what programs would be affected, or whatever it might be in that particular reason for having put out the assignment.

The important thing there was that they would put the agency picture together. Secondly, if they got contrasting points of view from ORA and, say, foods, they'd say, "Wait a minute. Aren't you guys talking? Foods says that low acid

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canned on foods is their highest priority program, and here you are in ORA saying sanitation is. They both can't be right. How did you come to these conclusions?" So we would then sit down at a table and discuss them.

The first time that happened, the question came back kind of like, "Hey, you need to talk before you put these documents together." Frankly, we usually had a problem getting the centers to sit down. They would wait until the last minute to put their documents together, and there were times when we didn't know what they were going to do at all when it was turned in.

It got to be a very difficult situation to deal with, even to the point of--I'll use foods as an example--where the director of foods might want to go a certain direction, I recall years ago Virgil Wodicka wanted to have the center examine foods for all kinds of quality attributes in terms of: Was the quantity of fill proper? Were they using the proper type of fruit or vegetable, whatever it might be? Did it have any contaminants in it in terms of chemical, microbiologic, heavy metal, whatever it might be? He wanted to have a picture of, say, green beans across the entire manufacturing spectrum, and then he wanted to publish the results in newspapers and in effect say to the American public, "This is the quality of canned green beans in this country."

Well that hit the fan. Nobody above Virgil Wodicka in the administration wanted to be doing that kind of thing. It never got off the ground. Personally, I could see how the public might like something like that. Of course, you can imagine the political fall out. It would be a firestorm over there once you started doing that type of thing.

We got to the point with OPE, in the coordination job, that as soon as they put out their basic guidance, we would contact all of the centers and say, "Look, we got this information. This is what our cut or recommended increase is from the agency. We're going to take a look at it in terms of our views from a compliance standpoint in the field, where we think the resources ought to go. Take a look at it

from your point of view and let's get back together." Well, when that wasn't working, we tried to go around the corner to OPE and ask them to talk to the center.

OPE would not do that. Their position was, "It's up to you and them to get together. If they refuse to get together let us know, but we don't feel like we should have to be a referee." I had an ongoing disagreement with OPE on that one point for at least the last five years. And every time they'd come around on an annual basis and ask us to critique that prior year's planning, I hit them with that, and Jerry would hit them with it, and I was sitting there one time when Chesemore hit them with it, and all three of us got the same answer: "We don't feel that's an appropriate role for this office." I think they're wrong. I do believe, regardless of that, that there is a role for an overall agency planning organization.

RO: Were they concerned more long-term then, or long-term I say at least . . .

RD: Well, it was originally they used to be, way back when you were here, Bob, and they had five-year plans.

RP: And ten-year plans at one time.

RD: But it was ridiculous. We were putting together these discrete five-year plans, etc., of the number of inspections, number of samples, and then once it was done, it was forgotten. It was a useless exercise, and that's what we and others told them, and after a few years it was stopped. So basically it was changed to about a one and a half to a two year long-range plan.

RO: They never felt that they were supposed to broker any disputes that you had with . . .

RD: No. However, over a period of time from the seventies on up, there were several instances when the centers complained that, as a third party, feeling like they weren't getting their share of the resources out of ORA, regarding our modules, for example. OPE was asked and conducted several different studies. Copies of them are all down in our files. In every instance, those studies indicated ORA was handling its resources properly and that they were getting the most they could.

RO: Well, Bob, anything else we should cover.

RP: No, I don't have any more questions.

RO: Keith, anything that you want to go on the record here that we haven't covered?

RD: Offhand I can't think of anything. I believe in the long run, it will be a number of years before he retires, but certainly John Lechus will have considerable to be able to say about the evaluation and providing guidance to the field and various systems, particularly PODS and the data codes manual and that type of thing.

I think that the division that I used to head up did a very credible job of providing information throughout the administration, and to GAO and Congress, and as well as providing guidance to the field and to be able to properly record data and interpret data and so forth. Unfortunately, it's a thankless job. It's something that people just don't like to do. It's almost like asking people to submit income tax. They just don't want to do it. They don't see that they're getting anything out of it. But as I said earlier, it's a necessary evil, particularly in this day where Congress has such exquisite oversight and looking at every little detail that you can think of, how you're using resources and so forth, that it's necessary that we be able to provide a credible picture of the use of that resource.

RO: From where you sat, did you see a big swing in the agency's priorities from commissioner to commissioner? You've served under a number of commissioners.

RD: Yes. I think the biggest swing that you'd probably see is where one commissioner will say, "I want to get things done, and there's no one way to do it. Whether it's voluntary compliance or cop on the beat, let's get it done." And others will say, "Cite, seize, pros(ecute), and enjoin them. To hell with that voluntary compliance stuff."

Through each one of these changes in administration, we have voluntary compliance; we need to collect data. And then another one would come in, and voluntary compliance would die for a while. We've instituted in my lifetime at least three different systems of voluntary compliance. Stop collecting. Collect. Stop collecting. Collect. And now it's on the biggest run that I've ever seen, in combination with other efforts, trying to get the states to do more and more with, as they say, less and less resources.

RO: You're saying more with our compliance activities rather than emphasis on different products. There has been more of a swing from commissioner to commissioner on that rather than . . .

RD: Yes. Oh, I don't think that there's any doubt, Ron, that this commissioner has put his stamp on certain kinds of products, like blood, and on new drug approval, and device approval. Nobody has even come close to things like that. As you well know, in the old days, if it wasn't foods, it wasn't important.

RO: Well, but before I left, and that was ten years ago, there had been a big change in the resources that went to foods as compared to what had been allocated drugs and medical devices.

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RD: Well, going back thirty-some years, the big legislation that has transpired in all that time has been new drug and new device legislation. It's been in things associated with both of those. The Kennedy legislation back in the early seventies. Of course, device was around '76, '77. There hasn't been any real, new food legislation of any kind, except maybe a little something on seafood. They've talked for years about getting rid of the food additive problem with the Delaney Amendment. That is still here. And you hear less and less. When your wife was still here working, Bob, pesticides was a very big thing.

RP: Yes.

RD: Hell, it's gotten to the point now where foods is wanting to rename their project system, and the word pesticide doesn't even exist anymore. They don't feel downtown that pesticides is a problem. Microbiological contamination is the big thing. And you can't really argue against that very much. Pesticides, you might get a little sick, but microbes can kill you.

RO: OK. Well, Keith, unless there's something else, we want to thank you for participating in this interview.

(Interruption)