History

of the

U.S. Food and Drug Administration

Interviewee:	**Robert E. Dickinson** **Gary L. Beard**
Interviewer:	**Mr. Robert A. Tucker** **Mr. Ron T. Ottes**
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RT: This is another in the series of FDA Oral History tape interviews. This morning, November 19, 1997, in the Office of Federal-State Relations in the Parklawn Building at Rockville, we're interviewing Robert E. Dickinson and Gary L. Beard, recently retired Consumer Safety Officers in the State Contracts Program. The interview is being conducted by Robert Tucker and Ron Ottes.

We'd like to begin the interview with a brief autobiographical sketch of each of you as to where you were educated, how you came into the Food and Drug Administration, and, of course, how you came to this program that we're addressing today.

GB: Well, can we just say for the record that we have some documents here which list that information, and it can be incorporated in the record about where we attended college, degrees earned, et cetera, when and where we entered into FDA? Is that okay?

RT: That's fine.

GB: We will then provide you with copies of our biographical sketches.

RT: Well, I think it might be helpful to just briefly mention here, if it isn't in those documents, how this program came about within the Food and Drug Administration, because this was a new venture for the agency with regard to paying for state assistance. Heretofore, maybe you want to briefly mention what kinds of cooperation there were.

GB: Before the contracts you mean.

RD: Well, I can talk just a little bit about what there was prior to the contracts with the states. The main contracts started in, were actually awarded in '73, and

perhaps when we get to that part you can pick up the supplemental appropriation.

GB: You're not talking about FPLA (Fair Packaging and Labeling Act) now. Weren't you involved in FPLA contracts with the states before 1973?

RD: Yes, I was going to back up before that and talk just a little bit about the agency's first experience with contracting with the states. It was in about 1970, when the Bureau of Foods at that time had contracts for Fair Packaging and Labeling Act enforcement with a series of nine states. That seemed effective; Federal-State Relations was involved in the project advisory group level on those; and in the oversight of the contracts. They were actually operated by the FPLA Branch; and they had, I believe, probably three or four series of eight or nine states at a time.

That set the precedent for a couple of things that governed the program that ultimately came about, the most notable of which was that there was an opinion rendered by the general counsel on the business side of the house that FDA shouldn't reimburse the states for state enforcement of state law. That meant, and was subsequently interpreted, that the states could embargo products, they could write warning letters, and those kind of things, but if there was any formal enforcement actions such as hearings, court actions, or those kind of things, they would be excluded from reimbursement. That precedent carried over into all of the subsequent contracts based on that interpretation.

RT: Bob, maybe we should clarify what the states were doing in the Fair Packaging and Labeling Act area for the agency.

RD: Well, the FPLA required significant labeling changes such as placing the quantity of contents statement on a principal display panel, and several other requirements. The states were going into firms, collecting labels, coming back to

their offices, reviewing those labels and, if there were problems with them, getting back to the firm in the form of correspondence in trying to get those labels fixed. And if there were subsequent problems, they would have come back to FDA. So the principal responsibility rested with the states.

RT: Well, even before that point, the agency was working in cooperation with the states in other areas. Do you want to mention a little bit about the agreements and so on?

RO: Before we leave the Fair Packaging and Labeling Act, did FDA encounter where the states had different labeling requirements than the federal government?

RD: There were some of those, although the part of the requirements as to whether or not they got a contract, I believe, was that they had requirements in effect that were parallel to FDA's. The law itself said that the states' requirements could not be different from the federal requirements. Those kinds of issues were worked through, I believe, in the contracting process working with the states.

RO: How long did that contract on FPLA last?

RD: I believe it lasted a total of three rounds of something like one and a half to two-year contracts. There were twenty-some-odd states involved in FPLA, and they were done in groups of eight or nine at a time. The initial awards were for eighteen months or something like that.

In the food program particularly and in the medicated feed program, or for that matter, all of the agency's responsibilities were the subject of some work-

sharing agreements between the agencies and the states. My recollection is that Dr. Goddard at that time had come out and indicated that he wanted some agreements with the states. Those agreements provided for things very similar to what a partnership agreement would cover now. No funds were involved. They talked about the exchange of information, joint planning so you wouldn't trip over each other going into a plant at the same time, cooperative training efforts, and an exchange of reports.

Of interest at that point was that there were agreements with the majority of the states--maybe fifty or sixty agreements. They covered a lot of food inspections, and at one time, there were probably 15,000-18,000 reports of state inspections that were put into the FDA data system.

The states voluntarily reported significant summary data on the firm when they inspected it and probably a compliance classification. That information for all practical purposes was never used by FDA. It was deemed to be information that wasn't solid in that the FDA had no control over the state inspections. "We didn't know the quality of the inspections," was the comment at that time from the FDAers, and that it was interesting that in the very recent past some thoughts were given to resurrecting the same kind of data acquisition that was done in the late sixties and early seventies. That's what the situation was at the time the contract programs came about.

RO: Did FDA share their inspectional results with the states that were cooperating under that program?

RD: Not in a very formal way. There was limited exchange of information. There would be planning conferences in which summary information would be exchanged by both parties, and in many cases a work plan might be exchanged.

Of course, the work plans varied an awful lot, and I would say the information was more from the states to FDA than any other direction.

RO: Under that program, were there joint inspections?

RD: There were some joint inspections for training. There were efforts to upgrade the states, a continuation of the food inspection techniques courses from the mid to late sixties. They were all district based so that they varied in quantity and quality based on the relationship between the district and states and the desires and interests of the particular field management.

RT: Well, I think that perhaps one of the first really serious joint planning of inspectional work may have occurred with regard to the tomato canning industry in the Midwest, and that dates back into the fifties. I wanted to ask you, Bob, or Gary, I think it would be helpful if we could address what brought about the initiation of this program. Now what were the circumstances that led the agency to decide to contract with states? That isn't really covered in the attachment.

GB: Well, FPLA was a new act. I do not know exactly how FPLA became a funded activity. Maybe you know, Bob, the terms of why that particular activity was funded? As opposed to seeking voluntary effort with the states, a decision was made to obtain state involvement through contracts. Because FPLA was a federal mandate, I suspect the thought process was that if FDA didn't fund it, the states probably would not be interested in doing it. The key issue was that if you're not giving the states any financial resource support, what's the incentive for them to do something for FDA other than cooperation, which, of course, there was much of that prior to the contracts? So I believe it was finally decided that if you want the states to do a specific task and do it our way, the only logical way

you're going to get it done was to do it through a contract where you pay them to do a specific task for enforcement of federal laws.

RT: With regard to the larger contracting effort, were there circumstances that led to expanding the program?

GB: That's right. When the GAO (Government Accounting Office) report came out about insanitary food conditions they found in processing plants in the country.

RT: Was there also a congressional interest apart from the GAO or was the GAO report the genesis of the Oversight Committee interest in compliance or violation rates?

GB: My suspicion is that the GAO report created a congressional interest in doing something about it; that seems to be the way things usually work. Something gets the attention of the public, and suddenly Congress is interested in seeing that something is done to fix a problem or a perceived problem.

RT: What was the problem specifically?

GB: Well, as I understand it . . . I don't have a good recollection of the report itself; maybe you do, Bob. But basically, the GAO went out and surveyed a number of food industries and came back with a report indicating that the sanitary conditions in some plants were not of the best quality and there were shortcomings in the coverage of these firms both by FDA and the states.

RT: At that time, what was the frequency of routine coverage of food industries?

GB: It dropped off considerably. I know that with more and more emphasis on drugs and devices, that FDA's traditional habit of inspecting a food firm once every year was the norm when I started with FDA in the sixties. Every year a firm came up for inspection regardless of its status, and maybe more often than that if it was having compliance problems. I'm sure we have slipped considerably from that. Maybe you remember, Bob.

RD: I'm not sure what congressman or committee was involved in requesting the GAO report. This was after thalidomide and those kinds of episodes that divested resources into the drug area. I think there more of a perception that insufficient attention was being paid to the food industry, and the GAO audit went out and looked at a lot of different plants. It was focused only on food plants. It included big manufacturers for which FDA had assumed the traditional inspectional responsibility and many small plants such as small bakeries, and it included interstate travel facilities. A number of different aspects of the food industry were covered. When they came out with that report it used the word *deplorable,* if I remember correctly. And that resulted in the authorization for FDA's expansion of personnel to the tune of eight hundred and some-odd positions.

RT: Was that the Project Hire then?

RD: That led to Project Hire.

RT: Then in addition to that, a decision was made to look to the states. What was the source of resources for that effort?

GB: You probably have a better recollection of this. Bob, why don't you explain what happened.

RD: Well, my recollection of what occurred--I think I'm pretty clear on this--was that the agency, as a part of the second supplemental appropriation of '72, got something like $8 million for the purpose of supporting training and equipping those additional positions which were being brought on board.

And this was no-year money. During the latter part of '72, it became apparent that the FDA would not use all those funds for training and equipment and went back to the Congress with proposals for the use of the roughly $4.5 million available from the $8 million.

One proposal was for a modest contract effort with the states to the tune of $1 million over two or three years for work primarily in the food programs. Some medicated feed work was included, because there had been a tacit understanding when the cooperative medicated feed program was developed for the states to look at drugs, which had not been their focus. The understanding was if contract money became available medicated feeds would be included.

That $1 million proposal was part of the dealings between the agency and the committee, which was chaired by representative Jamie Whitten from Mississippi. And that was in '72 or early '73.

GB: Seventy-three. I think it was early '73.

RT: OK.

RO: Let's see. Now there was a figure that I recall, $4.3 million. When did that come into . . . ?

RD: That was the $4.4, $4.5 (million), something like that. Thus, the agency at that time proposed a relatively small incremental increase in inspections over what FDA was going to be able to do with those new eight hundred positions for food work, and the committee's instructions were to use the entire $4.4 million for contracts with states. At that time the funds were no-year money. The contracts were awarded in June of '73.

GB: So it started in . . ?

RD: In the spring of '72, plans were to go for a $4.4 million effort spread over three years to include food sanitation, interstate travel in the food area, some medicated feed work, and the sample analysis program. Subsequent to that we were asked what would happen if this is converted to base money for one year. Can you spend it was really the question at that point, which was sometime in '73, I think.

RT: Now is part of the rationale for looking to the states the fact that there would be a certain period of training of these new Project Hire federal employees, whereas the states were already there and qualified for some of these inspections?

RD: That's probably a part of it. Based on the agreements that were in effect with the states, there was a resource there, and the initial sanitation contracts were very limited. They were limited to inspections of the bakeries, warehouses, bottling plants, and a little bit of grain elevators work, because those were the areas where it was felt the states had program expertise and were trained.

RO: Bob, you mentioned no-year money, and for the record, would you explain that?

RD: Yes. In essence, the no-year money could be spent over a series of fiscal years and was not tied to the base appropriation, whereas most of the funds had to be spent by the end of a particular fiscal year. During 1973, we learned that the congressional committee was going to recommend the funds be converted to one year money, which would mean rather than $4.4 million over three years, it was going to be $4.4 million a year. By that time, we were far enough along, and had expressions of interest and some feedback from the states, and we had concluded the $4.4 million could be used. In fact, that's what occurred.

RT: Gary, we have kind of transitioned on into these other programs. You two gentleman were designated as project officers. What was the division of effort between the two of you with regard to the overall contract operations?

GB: The contracts we're talking about were initiated in '72 and '73. Bob Tucker was the project officer for the initial start of the process, but then Bob Dickinson became the project officer for the food, feed, interstate travel, and sample analysis contracts. Those were the four projects that were in effect at the beginning.

RD: Since I'd been involved with FPLA and food work, I was more involved in some of the initial efforts to put some of it together.

There was a letter sent to all of the states and all of the departments that could have any of these responsibilities; it was called the Letter of Interest. It was sent out in June of '72, and indicated FDA had money--didn't say how much--but outlines the possibility of contracting with state agencies for several

programs as Gary just described. The letter included a few paragraphs that they would be cost-reimbursement contracts, which I think is a very important principle, and that they would be put into effect in the following year.

The letter went out, and I think we were both involved in formulating that. When the rest of the package was put together--it was about three-quarters of an inch thick. This Request for Proposal issued by the Contracts Office included Statements of Work detailing what needs to be done.

That September was the round of pre-proposal conferences, which we both participated in. You might just mention those.

GB: Yes, we set up conferences in six cities. Bob did three and I did three. This was a new concept to the states. It was a broad undertaking much larger in scope than anything we'd done before with the states, especially in contracting. The states were not familiar with contracting procedures, so the Contracts Office and DFSR (Division of Federal-State Relations) decided it would be good to go out and actually hold conferences with state representatives at selected FDA regional offices. We invited state program directors to these conferences to learn about the contracts we were contemplating awarding, as well as to ask questions about program and contracting procedures.

Bob and I each went with a representative from the Contracts Office. I went with Wayne Slaughter and you went with Bob Cowell.

GB: As I remember, you took the western part of the country and I took the eastern part. Conference locations included Atlanta, Buffalo, Dallas, Denver, Kansas City, and San Francisco.

There was also one here in Washington. They were one-day sessions. We would hit one city one day and then travel the next day and set up our next conference. In one week, we did all of them. It was a real roadshow. The participation was tremendous. I was amazed about how many state people

attended. We presented the program aspects, and the Contracts Office discussed the contracting procedures.

RT: How were the field offices involved other than scheduling the meetings? Were they involved in these discussions at all?

GB: Well, speaking for the cities we visited, those FDA field offices that had personnel that were routinely involved in dealing with the states in cooperative matters made sure they were present. They showed support for the program, and made sure the right state people were there. They sent out the invitations, as I recall, and did a very good job of getting the people there that needed to be there, like the state food and drug program directors. There were large numbers of people at all the conferences.

RD: One point is that the preproposal conferences were held after the Request for Proposals went out. So the state had the documents in-hand, but prior to the time that they had to submit proposals.

GB: We figured that with such a huge workload, if we got a lot of proposals back that were improperly done, unusable, or which required a tremendous amount of work in the negotiation process to make them into acceptable contracts, the workload would be tremendous. You've got to keep in mind the Division of Federal-State Relations did not have a large staff to deal with contracts. All of us were new to the contracting game. The Contracts Office at that time was quite small; their staff was limited. This enormous workload of trying to contract with fifty states many with limited contracting experience. We tried to do whatever we could to make the states more knowledgeable and capable of submitting acceptable proposals.

RT: Once the proposals were received and were being evaluated, what, if any, role did the regional or district offices have in either supporting or not supporting the award of particular state contracts?

RD: Well, I would say that at the time the program was formulated, it was understood from the start that the districts would have a significant role and would be participating in every stage. They wouldn't have a veto authority, but their expertise was going to be necessary in evaluating the proposals. Their emphasis and expertise was to focus on program matters, rather than . . . (Interruption)

RD: . . . on the financial aspects, because we were going to try to view costs from a national perspective. I just mentioned briefly, and I'm going to mention once more, the cost reimbursements notion. That basically said that we went into the contract program with the idea of reimbursing the states for all of their legitimate costs for doing the job that we were asking them to do. The legitimacy of costs would be determined by the Contracts Office. In practice, the costs included not only the direct labor for the inspectors, investigators, sanitarians, whatever they were called at that time, but also some supervisory administrative time, clerical support, and laboratory support.

Those were the big chunks of costs that were involved, and in addition to that, you could end up with quite different reimbursement rates for substantially the same kind of a job. New York State and Florida, for example, had very, very low labor rates, and they came in fairly cheap for, let's say, an 8-hour inspection; whereas California, as usual, and some of the state health departments, like New Jersey, would come in with not only higher salary rates, they would have higher indirect costs. And so you could end up with very, very different costs for the

same job. And so we tried to deal with that nationally rather than having the field involved.

You asked about the field's role in the contracts. I remember being escorted into Irv Berch's office in San Francisco, and he was not necessarily a real big fan of contracts. And, of course, he was dealing with California as well, which was, and always has been, the nation of California versus the nation of FDA on the West Coast or however you want to term it. He wanted to know what we were going to be ramming down their throats. We assured him that he and his people would have a say in it, and we weren't going to be ramming anything down their throats. We described the process that we would go through, and what they'd would be involved in. And he said basically, "OK. Bye." And that was it.

RO: In that process, the initial recommendation for which states would participate in the contract program that came from the Division of Federal-State Relations. Is that right?

GB: There was no recommendation on which states should participate. It was made available to all states.

RO: No, no. I mean, after you've gotten all the proposals in, you probably got more proposals than you were going to be able to fund. Then you had to make a selection as far as the states that you felt were going to be able to make the inspections and the kinds of things that you wanted them to do. So the initial selection was made in the division and then did it go back to the field for their concurrence or comment?

RD: It didn't really turn that way, and that's one of the reasons why the going from $1 million to about $8 million in three years made a big difference. As long

as any of the states had an acceptable proposal, and the field felt that they could do the job, they were awarded contracts.

There were a few states initially that the proposals looked like somebody just sat down and scribbled something out in a very short period of time, and we really didn't have anything to work with. In some states there wasn't much regulated industry. The Request for Proposal listed the amount of industry, the count of firms of the various classifications and various programs in each state for which contracts would be considered. In some cases, the district believed any contract would be too small. I think there were a couple of states that submitted very small proposals. So you had a Wyoming or a Vermont or similar states that we didn't award contracts.

But I think the rest of them we, together with the districts, tried to see if there was at least some basis for trying to improve the proposals during negotiations. For the most part, any state that wanted a contract was accepted where there was enough work and the state had the people resources.

GB: And these reviews were work done in concurrence with the districts. In other words, the district reviewed the proposals along with the DFSR. If the district saw a fatal flaw or a serious shortcoming, they would bring it our attention, we would discuss it, and decide if it could be overcome. As Bob said, if there was enough work and the state had submitted a workable proposal and had the resources, a contract could be considered. For FDA, money was not necessarily the issue, since $4 million a year was now available for contracts.

RT: As I recall from some of the headquarters' discussions of this program, expressions of disdain were made by some of the field managers. Apparently they preferred that those monies go into FDA's own coffers rather than share it with the states. Do you want to speak to that a moment?

GB: Well, as Bob pointed out, FDA presented a list of options to Congress on the use of the entire $8 million of the supplemental appropriation back in ‘72. Congress looked at the list of things and said, “You’ve already done as much as you can do for your agency to get work done. There’s only one other thing here that appears to create more inspections, and that is if you go out and contract with the states.” Congress thus made a decision to let FDA use some of these funds for state contracts. Yes, that was an unpopular decision, because many people in FDA, at that time and probably to this day, feel that the agency could have spent those resources better amongst ourselves rather than sharing them with the states through the contract mechanism. It was congressional decision; there was no choice in the matter as far as the agency was concerned. FDA received congressional direction to use that money to contract with the states.
RT: Well, as I recall, Paul Hile, who was the Executive Director of Regional Operations or EDRO, pointed out to the field managers that was the situation. And afterwards, as I recall, the troops then kind of fell in line.

GB: Somewhat reluctantly. Not all fell in line completely.

RD: That varied quite a bit. One of the challenges that we had over the years was where you have a we/they situation, that is, FDA versus the states. FDA’s use of the funds was not a choice, which was a perpetual song that we had to reiterate over the years.

As new managers came in, who weren’t aware of the contracting history, they always were saying, “Well, we can do it cheaper, and we can do it better.” On the issue of costs, there were from time to time a number of efforts made to look at how much it cost to do a state inspection versus an FDA inspection. Initially it was about $150 or less for a state inspection. The field would think we

can do it a lot cheaper than that, because we're paying a GS-9 or -11 let's say ten bucks an hour. If an FDA investigator spent six or eight hours on one inspection, that's sixty or seventy bucks versus spending $150 for a states inspection. That's the kind of comparison the people always wanted to make, but it ignored indirect costs, supervision, laboratory costs, travel, et cetera.

RT: Well, in terms of the time spent for inspection and reporting of those investigations, what kind of comparisons were made? There were some studies in-house and by GAO and so on. How did it actually shape out?

RD: Let me speak to the food program first, which was the biggest one. I think that there's big distinctions in some of the later programs, certainly x-ray and then devices, in terms of what we were having the states do.

There was another decision point on the food inspections initially, and that was to what extent do states have to do an FDA inspection. That involved how they approached the inspection, the level of detail, their documentation of the evidence, their collection of samples, and in particular the kind of report. At that time, FDA, with the exception of some specialist journeymen, was still writing detailed, narrative reports, and most of the states were not. The states had traditionally used check lists.

There was a discussion that involved a number of people, including Dr. Angelotti who represented CFSAN (Center for Food Safety and Applied Nutrition), and someone from General Counsel, et cetera. The issue was, do the states conduct an FDA-like inspection and is it done under federal authority, i.e., a commission, or should it be done under an applicable state law, if they had a comparable statute? (The commission grants FDA authority to designated state officials.)

Regardless of under which authority the inspection was made, the question also existed as to the procedure for conducting and reporting the inspection. Should a notice of inspection be issued together with a notice of observations and a full narrative report be prepared?

These issues were viewed in the context of what we wanted the state to do. It was concluded we wanted the states to do an FDA-like inspection in terms of covering the same areas in the plant and seeing those kinds of things an FDA inspector would see. If there were problems in the firm, the same violation should be found regardless of the individual's organization.

In terms of sanitation, which was the focus of the GAO report, that was the goal. It was a little different when you got into some of the food and color additives, but initially the emphasis was sanitation in those basic industries.

The conclusion was not to commission. FDA could use state information in court if necessary, based on precedent cases. A reinspection would need to be done anyway, and FDA could be involved at that point if necessary.

Thus, the choice was to cover a lot more firms without all the red tape. Commissioning and the detailed, narrative inspection was not included. The FDA cover sheet and summary of findings were required, and checklist exception reports were developed for the original group of industries. This allowed the states to have a uniform inspectional approach and to record only the details where they found problems. FDA's responsibility was to review inspection reports and see if the states plan for any necessary follow-up was adequate. If it wasn't, the district had the option to work with the state or come back in on a joint inspection.

RO: Did the FDA ever take any action based solely on the inspectional results of the states?

RD: I don't believe there were any solely on a state inspection without an associated FDA inspection.

GB: Didn't we have a commissioned state inspector in one of the southern districts that worked almost like an agent of FDA?

RD: Yes, you're right.

GB: I'm trying to think of that state.

RD: It was Mississippi. The Department of Agriculture which did not have an adequate food law. They were one of, I believe, two states that were commissioned in the food program. The Mississippi Department of Agriculture had some of the law, but didn't really have a law covering warehouses. The department was commissioned; they hired somebody to do those inspections. New Orleans District had this individual operating as an FDA investigator under *almost direct* supervision, making the assignments, reviewing the reports, and everything.

And there was a place called Bill's Warehouse, I believe, which had a series of problems. The inspection was done by this commissioned individual, and samples were collected. Mississippi didn't have a laboratory capability to do some of those sanitation samples, if I recall correctly, and the samples were analyzed by Atlanta. New Orleans District recommended, and I believe, there was an action taken on that without an FDA inspection. Shortly after that, Mississippi decided they didn't like that anymore and pulled out of the contract program entirely. (Laughter)

RT: Were there any states that declined participation in the program, perhaps on the premise that we don't want your federal dollars telling us what to do?

GB: Yes, there were states that never did have a contract. I think the highest number of food contract states was in the high thirties.

RD: Forties.

RD: Yes. It's typical of just about every state contract program we've ever had over the years. Not all states are interested. It's not just, "We don't want Uncle Sam's nose under our tent." Some just don't have a program. They literally just do not have a program in that area. There's no interest within the state to do that type of activity. There could be a number of reasons, but, yes, you rarely have a . . . In fact, I don't think we've ever had a state contract program where funds have been sufficient to award contracts for all fifty states where every state has participated. But the reasons are myriad in why they don't want to.

GB: Save MQSA (Mammography Quality Standards Act).

RD: Well, MQSA is still that way. New Mexico is not doing a whole lot in the MQSA, I believe, right now.

GB: And Alabama was an example of that kind of a state, Bob. They said, "No, we don't want anything to do with you for a long time," for that reason.

RT: I think Kansas might have also had a little reluctance at one point.

RD: Many states just didn't see any justifiable reason to get involved with the federal government in a program, so they'd stay away, right.

RO: When you issued a contract to a state, was that based on the fact that they had sufficient personnel to do that contract work, or did they have to hire additional people?

RD: For the most part, it was based on them having sufficient personnel. However, one of the things that the agency tried to point out to the states, and we tried to emphasize in the early going, was don't get yourself in a box. You can't count on federal money. If you elect to hire people and add people to your staff, there is a possibility that at some point those funds could not be there. And we didn't know whether they were going to be there beyond three years initially. And so we said, "Have the contracts be a benefit to you, and so that we could say you were doing something better or additional or whatever." And many of them did that.

There were some new hires, however, most notably in the food area. The one that comes to mind was California, which set up a mini food staff. They took some of their best field people, plus a couple of supervisors and a program manager for a total of eight or nine people in the unit which was funded by the contract. Then they hired to backfill into some of those other positions. Two or three years into the program, we found there were between forty or fifty positions directly supported by the contracts.

GB: It was always hard to determine exactly how many state positions were directly funded by the contract, because they had a lot of partial positions funded.

RT: What kind of quality control or quality assurance was initiated with regard to state work to assure that states were doing acceptable quality to FDA standards?

GB: Well, early in the contract program, we recognized that there would have to be some quality control of the state work. There would have to be FDA oversight and assurance to make sure that the government was getting its money's worth. That led to the development of a Field Management Directive or FMD '76 which was developed by DFSR, and it set forth procedures to make sure that we could give with a reasonable assurance to anyone who asked if the state work was acceptable. The goal was for the state contract inspection have the same results of an FDA inspection. They didn't have to look exactly alike in content or format, but the end goal was that the state inspector saw the same conditions when you went into a plant as an FDA inspector.

RT: How was that actually accomplished then through the FMD?

GB: It was decided that there would be independent reinspections by FDA following a state inspection. I think they were to be done within thirty days of the state inspection.

RD: In the case of food, yes.

GB: Right, food. There were different parameters, but they were pretty much the same for contracts. I remember for feed and even x-ray at the beginning, that within thirty days of a state inspection, an FDA inspector would go in to make an audit inspection. Now this was not after every state contract inspection. They were randomly selected and we tried to do some statistical sampling of the state inspections based on the size of the contract and how many inspections

the state did under the contract. We would look at X number of those inspections.

The FDA inspector was hopefully going to be there in a time frame that would allow him or her to see exactly the same conditions the state inspector saw and to corroborate that the state report was accurate, or inaccurate, as the case may be. There was also to be review of the state report. Again, keeping in mind, they didn't have to look like FDA inspections reports, but they had to have the sufficient information for the district to make a compliance decision on the status of that firm.

RT: Who had that responsibility in the field office?

GB: Well, it was given to different folks in the field. Sometimes it was first-line supervisors that looked at these reports and maybe was held responsible for it. Some districts had federal-state coordinators who were given the duties of working with their states on various program matters, including the contracts. They might be the individual. It could have been a resident inspector in a major resident office where the resident was either a supervisor or the lead resident, and therefore would be more knowledgeable than maybe some of the other staff.

RD: There were some compliance officers as well.

GB: There were compliance officers given this assignment. It varied. The districts were given latitude on how they assigned this responsibility, but the FMD directed that there would be someone doing this and that the states were aware of the audits being performed. The states were given copies of the FMD; they understood the requirements. The contracts specifically mentioned that there

would be audits of the state work, and that this work would be reviewed, and if any shortcomings were found, the states would be notified.

RO: What would happen if there were shortcomings?

RD: Let me jump in for just a second here with one anecdote that just came to mind. I remember we were trying to figure out how would you approach the evaluation. We said we could review reports, have joint inspections for training, evaluation or audit.

I remember a conversation we had with Glenn Kilpatrick, DFSR Director. At that time, Glenn was in favor of having joint inspections for evaluation, because that's the way FDA looked at our own people. We argued that in order for the contracts to have any credibility, externally in particular--but also internally--you need to have some kind of a solid basis for audit, and that required independent FDA audits. One day, after another discussion on whether there would be independent audits or not, Glenn threw up his hands and said, "Oh, all right, I reluctantly agree. I don't like it, but, I can see your point."

GB: Glenn had such a close working relationship with the FDA when he was in Utah that he felt that every state and every FDA office operated the same way. We knew differently, of course, coming from district offices . . . I came from that San Francisco District office that Bob mentioned earlier, and I remember the admonitions I received from my district director when I was a green inspector. When I went out and made a joint inspection with the states, I was told to watch them very carefully to make sure they were doing the job right, and, Lord, don't let them mess up the job that we are trying to do out there. There was always suspicion that the states were somewhat less of a qualified workforce than the

FDA folks. And while there's something to be said about holding your head high, many times the FDA offices looked down on the state inspectors.

Therefore, Bob and I knew to have credibility these things had to have some pretty strict requirements for accountability or they just wouldn't fly in the districts.

RO: Were the states ever removed for inadequacies?

RD: Yes. The FMD that Gary mentioned included procedures for what happens if you find bad work. Now "bad work," of course, had to be defined. Carl Blozan, who at that time was a statistician in ACPE (Associate Commissioner for Planning and Evaluation), developed a statistical plan based on state and FDA inspectional findings. We were trying to find out where a state finds a firm good and FDA finds it bad in terms of sanitary conditions. If the state already said it's bad, you don't really have to go back and look at that. And that if they say it's getting bad, by the time you do an audit it may be bad, so you don't really want to look at that either. So the audits were restricted to firms that the state said were good, i.e., concluded No Action Indicated (NAI). A bad inspection occurred when FDA went back within thirty days and found Official Action Indicated (OAI), conditions the state should have reported, i.e., a black and white situation.

The FMD includes the number of audits required, which depends upon the number of inspections done by the state. For a big contract, twenty-some-odd audits were necessary, and agreement in the classification of twenty-two out of twenty-three, or whatever the numbers were, would be required. Initially, in some states audits showed unsatisfactory inspections.

The FMD included follow-up procedures. Districts were required to get back to the state, inform them of the results in a timely way, provide them a copy

of the FDA report, and ask the state what they planned to do to improve performance. There were probably two or three states on probation initially. We never terminated a contract in the middle of it for unsatisfactory performance. Usually by the time the evaluation process was completed, the contract had expired and was not renewed. I believe the Missouri contract was one of them not continued in the food program.

RT: Pennsylvania in the feeds program?

RD: Well, that may be. I know Missouri was dropped from the feed program. There was another one not continued--I think it was Tennessee--in the feed program. There were at least a couple in the food program that were on probation. In some instances, it was found that a single investigator had performed the unsatisfactory inspections, and the state terminated that investigator. That fixed the problem on a retest. In other cases, it was agreed that training was needed. Some states, particularly in the feed program, decided not to contract any longer and that removed the problem.

GB: Yes, we had one x-ray contract terminated because the sole inspector that the organization had was incompetent or unwilling to do the job properly--we never did determine which it was.

(Interruption)

GB: When we identified the problem with the inspector, we alerted the contractor--in this case, the District of Columbia--and they had no one else to do the inspections. We entered into lengthy exchange of correspondence and

telephone conversations, and by the time the process was completed, the contract was up for renewal. We elected not to renew it.

RT: I mentioned Pennsylvania. I think Bob Dickinson was correct. I think that was the case there. It was an individual, and the individual was separated from the state program.

GB: Well, sometimes we had individuals taken off contract work. I had another contract I was involved in that was similar to the District of Columbia situation. We convinced the state that this person was unacceptable to us for contract purposes. That individual remained a state employee, and continued to do state work, and years later was allowed to come back into the contract work after doing a certain amount of time finding himself.

RT: Well, over the years there were some draws on contract money. I seem to recall that we had a GSA (Government Services Administration) billing that we were about $1.8 million short of funds, and so the opportunity was taken to channel some of the contract funds into that need. In order to keep the program ongoing, some adjustments were necessary in the length of contract time. Would you like to speak a little bit about some of those ups and downs that required some good management?

GB: Let's see, the GSA was SLUC, wasn't it?

RT: Standard Level User Charges (SLUC).

GB: Yes. That was probably the first big hit I think we took. I mean, as we all know, there were several events like this over the course of years, but this was the first one, and, yes, that was a particularly difficult situation. Up until then

we'd probably been rolling along pretty smoothly with sufficient funds and no problems until that came along, and they took about $2 million, wasn't it?

RT: One point eight million or something like that.

RD: Yes, and that was close to the end of the fiscal year when most of the contracts were renewed in May and June.

GB: Yes. This was not anticipated. The agency didn't find out obviously until well into the fiscal year that suddenly we're going to lose that money, and like Bob said, we'd already awarded some contracts. We were down the road a piece when this came along and caused an immediate reaction. Obviously something would have to be done or we were going to run out of money before we got to the end of the year, and contracts would not be renewed. One of the things we were trying to do to keep the states interested in the program was to avoid that kind of disruption of the contracting process. One thing we learned over the years was they didn't want to have the door opened and closed continually on them when they'd have a contract.

So we had to figure out a way to keep all of the contracts alive with about $2 million less than we had planned at the beginning of the year. We had to keep the contracts going until we could carry them into the next year, because we had the understanding that this was a one-time event, and that next year we would be made whole again, and we would have money for all the full complement of contracts the following year. So we had to do some gerrymandering of the contracts and the monies to keep them all going into the next fiscal year.

RO: Excuse me. I want to clarify something, because I'm not clear now. You mentioned earlier that the contract money was a no-year money and available for

three years. But now you're saying that the money used for contracting was in FDA's base. Is that right?

GB: Right.

RD: Yes.

RO: But how long did you issue the contracts for? Did you contract for multiple years with the states?

RD: My recollection was they were one-year contracts, but the idea was that it would not be a one-year program. Initially, we were in the position of telling the states that we have the money for three years, and we would plan a three-year effort. Contracts would be funded annually, but we had the money in hand, which was significant to the states. Prior to the time the contracts were ever awarded the funds were converted to base money which is appropriated annually. Beyond the second or third year, however, we were not so sure the funds would be available. As it turned out, they were. But it was in '76 or thereabouts--it wasn't very long after the contracts were in effect when this significant cut of almost 50 percent was made for SLUC.

I recall one thing that occurred at that point. There was a gentleman who was in the "Get It" Branch of Division of Financial Management who informed us of the cuts. They have two offices in DFM. One is the "Get It" Branch and the other's the "Spend It" Branch. The gentleman's name was--let me see--Ronald G. Chesemore; that's it.

He told us we were SLUCed, and he wanted a list of the contracts that we were going to drop to save the $1.8 million. That's when we sat down with the Ouija board and, together with the Contracts Office, figured out that what we

could fund was forty contracts for three months, rather than ten one-year contracts. This permitted continuation of the full program into the next fiscal year when the new appropriation was expected. I think extensions were made and the contracts were incrementally funded.

GB: I think they were, yes.

RD: Meaning that you negotiated for the year, but you put only the first portion of the money into the contract from the funds that you had for that fiscal year. When you got into the next fiscal year, you put next fiscal year's money in it for the contract year, which then got it over to the following year. So there were a lot of those kinds of things that from time to time had to be done.

GB: The assumption was we would have to terminate contracts, and as we indicated earlier, we knew that was unacceptable to the states to terminate contracts and then come back to them next year and said, "Oh, by the way, we have money now. Would you like to come back into the contract program?" So, as Bob said, we got the Ouija board out and looked at ways to keep those contracts alive. So with the assistance of the contracts office giving us some alternative things we could do with the contracts just to keep them running until they carried over the next fiscal year, and we kept all the contracts going.

RT: Now during the course of the contract program, there were several sort of introspective looks at the program, one of which I think was called for by EDRO, Paul Hile. I don't believe that ever came to fruition as a final report; but a draft was done, and there were some interesting observations or findings. Care to go into that a little bit?

GB: Well, I think there were a number of look-sees at the contract program. Since it had its supporters and detractors in the agency, everyone had their own perspective of the contracts, regarding how good or how bad they were.

As Bob said earlier, some people were trying to approach it from the standpoint of is it cost effective to contract with the states? Early on, the states had an edge on us. In terms of cost, they probably could do inspections cheaper since at that time state salaries were quite low. The states were not as interested, I guess, at that time in getting their hands too deep into the federal money bag, and I would say many states were doing it for a bargain price. They were just coming along for the ride. They wanted to do this, and they didn't really care about cost. There were a number of factors at the beginning that probably would show clearly that the states were doing it for less, whatever that meant. I think that situation has changed drastically with some of the new programs we have in the contracts now.

But other people were looking at it for quality, and I think that's what Mr. Hile was interested in. He was the one who, you know, decided this study should be done. It was to look at the overall quality and the effectiveness of the contracts. Were they really doing what they were supposed to do? And I don't remember the charge to look at the cost effectiveness, because that was in the eyes of the beholder really, you know, whether or not they were cost effective.

So, yes, we were charged with doing a full-blown study of the program. As I remember three of the people in this room here spent the better part of a year thrashing around in that thicket trying to sort out all the pieces and come up with some kind of logical presentation in what had been accomplished. We didn't look at all the contract programs, the entire contract history. I think we chose a five-year period or something like that to look at. At that time, we had a mixture of programs in the contracts system. That study report was finally prepared, reviewed, and somehow it just became forgotten.

RT: Well, I was wondering if you recall in terms of half-life or compliance achievement, how did the state inspections seem to compare with federal FDA inspections in terms of corrections or findings of violations and so on?

GB: Well, I think what we found was that every review showed the states compared favorably with FDA inspections. And other reviews were done on the contract programs later. In fact, we had specific reviews of individual programs, the food program, the feed program, the x-ray program. What every review or study showed is that the states were doing the inspections, and through the evaluations and the audits being done under FMD '76 and review of the state work, we learned that generally speaking, the work was acceptable, and it met the requirements of the contract.

What was more difficult to judge was what does all that mean? What are we accomplishing in terms of bringing the industry into compliance? Are we better off in terms of compliance nature of the industry now with the contracts than we were before without the contracts? We could demonstrate that states brought about a lot of voluntary corrections of firms they inspected. Certainly we found in some programs that you could demonstrate that compliance rates were improving, but to demonstrate that this was clearly the result of a contract was a very hard thing to assess.

But what we found in every study that was done, as far as I can remember is, that there were no major shortcomings in what we were trying to achieve through the contracts in terms of state work. We were getting the work, we were getting the inspections, firms were being inspected, and we were getting the data, and the data seemed to be very reliable.

RD: OPE (Office of Planning and Evaluation) during some of those periods of time had done a number of studies as well. They had looked at compliance rates in the food area in particular. Let me mention one thing about expansion of the work available. While the initial food inspection contracts were limited to four industries where the states had the expertise, about three years into the program--I believe it was in 1976--the contracts were expanded to include all industries, depending upon the district's assessment of the need for the work in other than the basic industries and the states' capabilities. After that, state inspections could include microbiologically-oriented inspections or any other type, as long as the state had some lab capability.

The kind of industries inspected by the states were expanded so that when OPE looked at food inspections, they reviewed FDA and state data. The OPE conclusion was that the FDA and state compliance rates were comparable. States were finding approximately the same extent of problems. Regarding average times, the data showed that FDA spent a lot more time making inspections. Over the years, though, that began to change, and the data showed the difference was attributable to the FDA documentation of violations and the write up of the report. And if you looked at inspections classified No Action Indicated (NAI) and then compared FDA and state time for that classification, the times were pretty close. Thus, when there were no problems, the inspections were taking about the same time. FDA took a little bit longer, but not an awful lot.

RT: How about the states now that may not have had a contract? As I recall, an annual, at least, inspection under contract was indicated or more if there were problems. But how about states that had no contract? Were the states with contracts inspecting the inventory more frequently? Was there an imbalance, in

other words, that was being created by coverage of contracts versus no contracts? If you follow what I mean?

RD: I think I follow what you mean.

RT: In other words, I seem to recall that there was a suggestion that with contracts you're over-inspecting compared to what were getting covered where we're not contracting for it.

GB: The idea was FDA would take its resources, its own people and do work in non-contract states to equal out the coverage of an industry, say, within a given district. In reality we know that it doesn't always work out that way, because of distances we travel, staff, or, you know, whatever. That was supposed to occur, and it probably did occur in a number of cases, but didn't always occur, and, yes, could result in overinspecting in some states. And this would apply to any program. If you have a district with five states and there's contracts in three of them, in three states you know a firm is being inspected at whatever frequency we mandated through the contract. That means FDA would have to take up the slack in the states that don't have the contracts; or if they continue doing their same level of work in those three states that have contracts, suddenly now you are "over inspecting" in those states. That was a district management problem.

RO: The inspection results then from the state contracts went into FDA's database.

RD: Yes.

RO: Was it designated as a state inspection?

RD: Yes. That question that you had, Bob, about the disparity in coverage of the industry was probably most apparent in the medicated feed program. Initially, the big states were under contract, and some FDA's inspection efforts had been centered in the other states. As the FDA resources declined, routine biennial coverage of the registered medicated feed mills dropped. The result was more frequent coverage of the mills in those states with contracts, and very little coverage elsewhere. This trend was exacerbated when the medicated feed program was basically changed, in terms of the kinds of firms that had to have a medicated feed application and register. During this period, the inventory went from 12,000 down to 2,000 to 2,500 firms where inspections were required.

RT: I think it may be helpful for anyone pursuing this transcript to get a little clearer idea of really what were some of the outreaches of this program. We've mentioned sanitation, medicated feeds, and so on. But as the program matured, we got into a number of new programs, and I think we might mention some of those, if you would.

GB: Well, what happened was, as you mentioned earlier, that there were contractions and then expansions of the contract budget over the years. I mean, these came about frequently for various reasons.

RT: Gary, could you give some highs and lows, just roughly?

GB: Well, let's see. We talked about SLUC in the late seventies, where they took the almost $2 million to pay the agency's housing bill to GSA. That was a one-time reduction, and you can deal with that. The ones that were more difficult were various things that came along during the late seventies and the eighties and even occurred in some of the nineties, where either Congress or the

administration, the White House, made decisions about federal budgets in general which affected the state contract budget.

RT: How about the Gramm-Rudman-Hollings Budget Reduction Act?

GB: Gramm-Rudman was certainly one such case, where it was not a one-time cut. It was a situation where they came in and said, "The government spending will be reduced by 5 or 10 percent or whatever." The early years when President Reagan was in office, he came in with an agenda to reduce the size of the federal government and reduce government spending. All of those things, Gramm-Rudman, all these things, tied in. We went through periods where the contract budget as the agency's budget was whittled back every year or held in a "running-in-place" literally. Reductions had to be made throughout the agency, and, of course, that affected the contracts.

Those were much more difficult, because then you were faced with a long-term spending reduction, which means that you couldn't carry contracts into the next fiscal year where everything would be made whole again. You suddenly now had to face a continued loss of funds over the succeeding fiscal years.

RO: Well, I think you mentioned, we started out with $4.4 or $4.5 million, and I believe, Bob, in passing you said it got to be a high of $12 million or something.

RD: Well, let's . . .

GB: Yes, we need to be careful there, because a lot of other things come into play.

RT: It was about $8 million, as I recall.

RD: Yes, I think it was closer to $7 million, $6.8 or $7 something like that, when you look at comparable programs. MQSA, mammography added a lot of money to the total, but that was a special effort which was not directly comparable.

RO: I was just trying to get a picture here of $4-$4.5 million and a low of $1 million or whatever.

GB: No, we never got to $1 million. I think we got down to around $2 or $3 million as the lowest levels.

RD: Two something.

GB: Two something. We were between $2 and $3 million. That was probably the lowest point we ever reached where we were trying to keep the existing programs going, and it was at that point we had to start jettisoning some programs.

GB: We started out, as I said in the early seventies with food, feed, and sample analysis, and interstate travel. Those were the programs that came to EDRO at that time. There was another program going on over in BRH, the Bureau of Radiological Health contract program, the x-ray program, that they started on their own separate from the contracts we've been discussing up to now.

RT: And that was to do what?

GB: In 1974, the Radiation Control for Safety and Health Act or something of that sort was passed which mandated federal performance standards for

diagnostic x-ray equipment, and the then Bureau of Rad Health was given responsibility for enforcing those standards. And like the rest of FDA, they were faced with a lot of inspections with inadequate federal personnel to do the work. Not surprisingly, they took the same track the agency took in food and feed, they elected to contract with the state radiation control agencies to do this work. That contract was run out of BRH until the agency made a decision in 1976, I think it was, to centralize all of the state contract programs in DFSR. And at that time, the program was transferred from the Bureau of Rad Health over to DFSR and became an ORO, ORA, EDRO, whatever you want to call it, kind of function, and has remained here ever since.

There were other programs added along that time, too. Methadone came along. The inspection of methadone treatment programs. That was added to the mix of state contracts. I think methadone, x-ray, food, feed were the basic programs when that first big hit came, and the decision was made then that we could no longer keep all of the balls in the air at one time with less than $3 million. We'd gone from $4.5, $5 million down to $2.5 to $3 million, and we had to make some tough decisions. I remember sitting in Gerry Meyer's office and deciding what was going to stay and what was going to go. Gerry was then running the . . . What did they call it then? He was the agency's chief administrative officer.

RD: ACA (Associate Commissioner for Administration).

GB: And at that time, in company with the rest of us in the organization, it was decided that we would have to throw something overboard, because you could no longer keep everything on the ship. The decision was made to end the methadone program, contract program, and the interstate travel program. I think

we managed to figure out a way to keep food, feed, x-ray alive; those were the basic three.

RT: Now the interstate travel program, what was that about? Just briefly.

GB: Briefly, it was tied in with food and sanitation on interstate conveyances, trains, airplanes, and the states were looking at the caterers and the food service in conjunction with that, and the watering points.

RD: And restaurants along state highways. (Laughter)

GB: Yes. We had a bit of a stretch there.

RT: Well, somewhere along the line, we got into some shellfish work too, didn't we?

RD: Well, there was one time where there was a congressional increase, and it was subsequent to the time that methadone and ITS (Interstate Travel Sanitation) were dropped, and it was after some of the basic contracts had been cut back. Under the behest of the NASDA organization, the National Association of State Departments of Agriculture, there was a request to the agriculture appropriations committee or subcommittee from that NASDA organization to make the FDA contract program whole again, so to speak. I think it was at about that point that it was running roughly maybe $5.5 million. Does that sound about right? In the congressional appropriation, the agency was given another $800,000 or so.

GB: Actually it was $1.8 million.

RD: Was it $1.8 million?

GB: Yes, we were down around $3 million something, and it was a substantial increase. I think I know where you're going with this discussion about why we changed, yes. Go ahead.
RD: No, take it.

GB: Well, it was a substantial increase. Congress looked back, as Bob said, and looked at where our high watermark, and it was about $5.5 million, and we were about I think it was $1.875 (million) if I'm not mistaken, under that high watermark. It was not a law. It was congressional intent, I believe. Wasn't that the language in the committee report? They said, "FDA will restore the state contract program to its former level high point, and we are going to appropriate the funds this year to do it," and the assumption was that the funds would be there every year thereafter.

So we suddenly went from this much constrained budget to a much larger one. We had pulled back and pulled back and pulled back . . . The existing contracts were quite small by then, with the few that survived, and suddenly we're hit with this influx of new money. Well, what we did is we took a hard look at the existing programs and said, "Can we use wisely all of that money that we're going to get now on those programs alone?" Each program was looked at very carefully, the food program, the feed program, the x-ray program, and we decided what we could use for beneficial good, and we wanted to restore the contracts to the extent that we could, but we also didn't want to just dump money into it for no reason.

And lo and behold, we found out that once we restored the contracts back to what we perceived to be the workload and the priorities that existed at that

time, full coverage of industries, we had money left over. I mean, suddenly we now looked at money that was not needed for the basic core of programs.

RD: And I think it's important at this juncture to recall the role of the field in that process, because they were what really triggered a change. We went back to the field and said, "What do you need done that is not being done in these contract programs?" And the answer universally was, "Not much." Over time there had been a change in philosophy on FDA's part as to what was necessary or what the states should do. The notion of an inspection every year of a food establishment had long since gone out the window, and one inspection every five years became the norm for food establishments.

Then that norm for FDA planning purposes, which was driven by available field resources, was made the basis for how big the state contracts ought to be, rather irrespective of whether or not, the inspections did any good. Of course, during that time there were a lot of discussions about inspection frequency, the need for periodic inspections, or a cop on the beat. But the FDA planned coverage was the driving force behind the conclusion that Gary just recited.

(Interruption)

RD: There were additional funds available which clearly had to go to contracts with the states by the direction of Congress. The EDRO and others hands seemed to be fairly well tied on the use of the funds. The center was then asked if they had needs that could be fulfilled by the states. That started a whole other process which leads to some of the things that you were kind of heading towards, Bob. Didn't the states do some other things for us in the interim? And the answer to that is yes, a whole bunch.

GB: Yes. That was in the mid-eighties, in the early to mid-eighties that occurred, and suddenly now the program became a much different program. It continued the basic inspections, food, feed, and x-ray, but now suddenly we could entertain new ideas. We should point out that food, feed, and x-ray still took a lion's share of the contract budget, but didn't take the entire contract budget. So now for the first time, we had money to do other things.

RT: So what were some of those programs?

GB: When that realization hit home that we now had the opportunity to do different things, the decision was made in the organization that we ought to find out what needs to be done. What are some of the good things we can do with this money? As Bob pointed out, it was given to us as a state contract increase. We went through that same reaction from some field managers at that time that we had when the contract program was first started, "Well, why don't you just give us the money, and we'll do the work. We can spend it more wisely." Well, we didn't have those druthers. Congress said, "This will increase the state contract budget back to this level," and that's why we had to use it for state contracts.

RO: So that money is not discretionary money with the agency. That was . . .

GB: No, no, no. That was money that had to be spent on state contracts, and we had to demonstrate at the end of each year how much of that money we had spent.

RO: And that is still the case?

GB: I'm sure it's a lot less . . . I think the state contract budget lost its identity some time ago in terms of what is the ORA funded portion of the state contract budget.

RO: Oh. So it's not discretionary money? Congress intended that FDA spend the appropriated money on state contracts.

GB: It was never totally protected, we found out later. We knew over the years that the amount of money transferred to the ORA, EDRO, whatever you want to call it, organization was greater than the actual amount that we operated with here in this division. Administrative overhead, whatever you want to call it, was taken by the parent organization to cover costs of managing the state contract program, both in headquarters and the field.

RD: It was a significant . . .

GB: It was probably pretty significant.

RO: When you're talking about what was given to the ORA organization as far as state contract, was there any effort on the part of the bureaus to retain some state contract money for their own? Or were they always happy to have Federal-State Relations manage that program?

RD: Not that I can recall. The only thing that I can really think of is the time when there were going to be significant cuts in the medicated feed program. That center and the field advisory committee both came in and said, "We don't want you to do that," and ultimately prevailed on the ORA organization to not take the magnitude of cuts that the ORA front office was originally planning.

Over all this period, we had to walk a fine line and do a tap dance to explain funding changes. We would talk to the states on the one hand. "Oh, gee, our budget's getting cut. We're going to have to cut back your contracts." Other parts of FDA, ORA, regional specialists for example, would come into those same state offices, said, "Oh, yes. We'll be out here four times this year. We've got all the budget and travel money we need." The contracts were not the only dealings the agency had with the states, and sometimes we were almost in competition with ourselves within the agency, when you look at it more broadly. Did FDA want a state to put their resources into shellfish, or want to push them to do more food work, or to do something else? In the case of a state like California that has a broad food and drug program, well, do you want them to also do drug work or devices or do it all?

GB: I think probably the hardest part of--the trickiest part, I guess you'd say--of the job that Bob and I have as project officers, you had three interested groups you're dealing with. You're dealing with the agency itself, the internal organization--I mean, the ORA or EDRO organization--the field, and the headquarters organization, trying to make sure we were matching up with the mandates of our own management. You had the states, of course, that we're trying to deal with. As Bob said, maybe we're trying to push the states over in this direction, then we're trying to push them over here, but we also had the centers, or bureaus or whatever they were called, who were watching us very closely how we were spending *their* money.

And so Bob and I felt like we had to keep all three parties reasonably happy and content or there would be a revolution, you know, or a palace coup. I think that over the years we were fairly successful in doing that, but it was definitely that you had three masters to serve at all times. I think the reason why--not to take credit for this--but I think by making sure that we were trying to

represent the agency's priorities and program needs, and try to match that up with the states. I thought that was really the role of DFSR was to try to assess the states' programs, their abilities, and try to pair those up with the agency's needs. We did the same thing through the contracts; we tried to match those, and at the same time provide the centers with the information, work, whatever it is they needed at the same time.

RT: We kind of veered off. I want to reiterate this question. We've mentioned a number of the programs that we've included. Let's make sure that we define any others. There were some new programs in devices and some other areas.

GB: Have you got the laundry list there?

RD: Yes, I've got it right here. Just glancing here at some of the information in this report. When those discretionary funds became available, suggestions for new projects were solicited from the centers, from the field managers, and from the associations of state officials. So all parties were given an opportunity to say what they thought should be done with the new resources. Between '83 and '85, there were about twenty different projects done by the states under contract.

RD: A good part of the projects were for data collection and there were others for surveillance or cooperative efforts. There was an economic adulteration of food project where states collected and analyzed samples for particular adulterants that the center had determined, and they varied over the two or three years of these contracts. There were shellfish pilot projects started in Massachusetts and New York to track shellfish in commerce back to their source, to the growing waters. FOODCONTAM, the pesticide residue data

system, was developed. Other food efforts included bacterial methods for raw milk, and a number of other shellfish projects.

There were several in the veterinary medicine area that provided data for the center, such as the contaminants in feed and feed products contracts. In another, the states followed up illegal distribution of vet _ (veterinary prescription) drugs and did investigations as follow up to complaints. In addition, there were a number of projects that Gary was involved with in the devices and rad health area.

GB: The then Bureau of Rad Health had a long history of working with the states. They were very much an organization that was oriented toward working with states, and that's why when the x-ray program came along, that is, the standards for x-ray came along, and BRH's natural inclination was to go with the states.

Eventually BRH merged with Bureau of Medical Devices, and for a while, I think the BRH folks maintained that desire to work with the states. As a result, we had a number of contract programs with the states where we asked the states to go out and look at the user level of medical devices. We didn't ask the states to go out and make inspections of medical device manufacturers or to do investigations. We asked them to go out and assess how these devices were performing at the user level, which usually means hospitals, doctors' offices, and so on. We had a long series of this type of contract.

Really what the CDRH (Center for Devices and Radiological Health) did is they would look at their medical devices with the highest level of deficiency reports, complaints from users, whatever, and they would take that device and ask for contracts with some states. We would send the states out to hospitals where these devices are being used, assess what these problems are, write a report at the end on what they learned on the problems that existed with these

medical devices, and that was brought back to FDA through a final report they submitted. These contracts were usually twelve months long, sometimes eighteen months, depending on how long it would take to gather the data. The center would then take this information from the states and make a determination of what kind of corrective actions were needed to be taken to eliminate or reduce the number of problems being reported for these devices.

They went through defibrillators and infusion pumps and endoscopes. You name it. We went through a large number of medical devices and radiation omitting devices over a period of several years.

RT: How about drugs? Was there any adverse reaction of drugs?

GB: In drugs, the primary emphasis was again on user problems. The Bureau of Drugs decided that what they wanted to do was increase the reporting of adverse reactions to prescription drugs, not choosing a category of drugs or a specific drug. What we did is we tried to stimulate the reporting through contracts with the states where they would go out and promote to the medical community and pharmacy communities of the reporting of these adverse reactions. And those contracts were more of a long-term nature, like two, three, four years, because it took time to generate state interest in increased reporting.

RO: You weren't really buying a product in that case.

GB: In that case, we were just trying to stimulate the reporting. And what we could look at would be the reports coming into FDA from the specific states where we had generated this higher level of interest in reporting adverse reactions through the contracts. And we found that you could stimulate reporting, but it came at a pretty high price.

RD: Mammography is what it . . .

GB: Yes. Mammography is a relatively new, although now tobacco is the newest kid on the block. But in 1992, Congress passed a law called the Mammography Quality Standards Act, MQSA, which, was a women's health issue. The concern over breast cancer had reached a high level in all aspects of the United States. While there were voluntary programs in place through accrediting bodies and other organizations to try to make sure that women received adequate mammograms, Congress decided that a federal law was necessary, and they passed that law, and that ultimately became a substantial state contract program.

RT: Another thing that we might mention, and this is kind of a retreat back to what we mentioned before in quality assurance, the General Accounting Office, I think the Philadelphia Regional GAO office, became interested in the state contract program, primarily I think because a state official up there had raised some questions about the program. So that team came down here and, as I recall, among other things, asked why don't we try not contracting with the states for a year and see what happens, and then, you know, pick it up again. Well, we've already covered the fact that you don't play yo-yo with the states. Was there anything else about that that you recall?

RD: I never did hear exactly where that complaint came from. I would not automatically assume that it was from someone in a state. The State of Pennsylvania ultimately dropped out of the contracts because they said they weren't really getting any benefit out of the funds, and that was very much in line with the thinking of their regional director at that time, Dick Davis.

One other thing just came to mind, and that was California dropping the food contract. That was another instance where something came along and the contract that was in effect with California for a long time was no longer possible. The thing that made that change was California's enactment of a law that required, in effect, user fees. There were some states that had a form of fee structure in place all along. Some of them had registration or licensing fees. Those were viewed to be basically taxes. Some of them in the feed program had tonnage fees, but they didn't have anything to do with drug enforcement. The tonnage fees predated any drug efforts in feeds, and were based on monitoring fat, fiber, and protein content. Maybe even North Dakota or some of those states had things like that. (Laughter)

But in some cases states instituted inspection fees, where a state would charge for doing a certain type of inspection. That raised the question, "Do these fees duplicate what FDA would be paying the state for under a contract?" It was discussed with the contracts office, and a number of others in the agency. The conclusion was, yes, that if it was a fee that was paying the state for an inspection--as opposed to a more broader-based fee for taxes or program support--that we would have to take that into consideration in negotiations. We had done that in one state, Kentucky, where they had a small inspection fee. That fee amount was deducted from the amount of their reimbursement under the contract.

In the case of California they put a rather broad-based inspection fee in place that covered all foods. That action was interpreted under the Government Performance and Accountability Act, whatever the name of that, as having the inspection costs reimbursed by the industry which meant FDA could not continue the contract under those circumstances. The regional director at that time, Don Healton, recommended, and we concurred that the contract with California in the

food program be discontinued. California officials argued rather vociferously but to no avail.

RT: Well, you gentleman have both been active in management of this program up to within the past year, and at this juncture, do you have any particular insights as to what the future directions of the program may be based on at this time?

GB: Well, since I got here earlier this morning and had an opportunity to talk with some of the current members of the Division of Federal-State Relations, I would say the future looks rather bleak indeed. My personal opinion is because of constraints on federal spending, which translates to tighter budgets for FDA, the future of the program, while there may be strong merits in it and reasons to continue contracting with the states, the real question is will there be any money to fund these contracts?

Now, we have to be careful here, because some programs will persist regardless of what happens to federal budgets because they are funded through inspection fees and whatever. MQSA is a good example of that. Every time a facility is inspected, whether it be by a state or an FDA inspector, the firm pays an inspection fee unless they are a government entity, and we won't get into that. But most facilities will pay an inspection fee to Uncle Sam. The money comes into a trust fund that the agency can spend from, and that's how the contracts are in large part funded. A user fee supported program will persist; that's what MQSA is.

We have another new contract program now called tobacco, and as long as Congress appropriates funds to continue the surveillance of retail establishments selling tobacco products, and trying to discourage the sale of those products to young people, that program will persist. But right now with the

constraints on spending in the federal government and the extremely tight budgets FDA is experiencing, I think that the future of the state contracts where you have discretionary money to go out and, you know, do things that we described that have been done in the past, is no longer probably going to be there. They're not going to have that money.

RD: I find it ironic that we were in the position of having to walk a fine line. We were in the ORA organization that determined how much money was going to go for contracts, and how much would be spent for FDA/field operations. Sometimes it was a we/they situation.

There were times when it might have been--we never seriously considered it--but might have been very tempting to try and stir up political support from the states or their associations for increased contract funding. But we didn't feel that that was appropriate, even though the agency's budget kept getting bigger, the percentage of contracts had always gotten smaller. I think the agency's budget was perhaps $75 million to $80 million at the time of the first contracts. So contracts were 4 or 5 percent of the agency budget.

So they engendered an interest in the Congress, the administration, the commissioner's office, and Mr. Hile, because they were a significant chunk of resources. The contract funds never kept pace with inflation. When cuts were made, they seemed to be based upon the need to equip, train, and operate our own folks; therefore, we'll take a chunk out of the state contract work.

There was never a real consideration, along the lines that you suggested, of the costs and benefits of contracting out. My personal opinion is that in order to do that assessment, you would appear to be unfaithful to your own organization, to your field folks, and you would have a rather difficult time to hoe with them if you did not try to advance the cause of your own organization. For those reasons, it was always a difficult position.

There was a time, particularly during the eighties, when FDA could make some arguments to the Congress and get dollars for functions where you couldn't get additional people. When that was the case, contracts were beneficial. ORA could propose all the things you wanted for the field and add on a proposal for additional state contracts. Sometimes additional funds were obtained and the contracts were advantageous at that point.

The inspection philosophy has changed a lot over the last several years, in the food contract in particular. Under the contracts still the original intent was to get frequent inspections and obtain compliance, i.e., to maximize the number of inspections made. That philosophy has gone by the wayside, of necessity, in the food program. If contracts continue, the focus will need to change.

And I view that as a possibility. Perhaps, the transition to HAACP-based (Hazard Analysis and Critical Control Point) and an audit-based inspection programs will provide the basis for a revised contract effort. But as it stands now, and as Gary indicated, the numbers of inspections and the bang for the buck have been continually decreasing.

GB: What you need now is a federal mandate that makes it a national cause almost, to get the states involved in these things now. Again, we mentioned tobacco. Congress has decided we are going to decrease the level of smoking by the youth in this country, and FDA obviously doesn't have the resources or people to do it, so you contract with the states.

Mammography was another one. Congress mandated that every mammography facility in the United States will be inspected annually. And there again, there's over ten thousand mammography facilities. Again, FDA did not have the resources to do it, so we contracted the states. I think those kinds of programs might continue. HAACP would be a good one. If someone finally decides there's going to be a uniform approach to doing this and again FDA's

given the responsibility and doesn't have enough horses, you might contract. It's those kinds of programs, I think, that will survive, or persist, or continue to occur; but discretionary type of contracts around the fringes I think are going.

RO: Well, of course, food safety right now is a high priority with the administration.

GB: Well, it depends if money comes with that priority.

RO: Often times it doesn't.

GB: Often times it doesn't. (Laughter).

RD: Understatement.

RT: Well, I think we've probably covered the subject rather broadly. Are there any closing thoughts or comments you'd care to conclude with?

RD: From my perspective, when we started contracting with states, it was something new that had not been done before. It lined up directly with what the agency was doing, expanding the food work.

(Interruption)

RD: (Laughter) Anyway, it was a good and righteous thing to do. There were enough things over the years that were new and different that had not been done before. The contracts were experimenting with different ways to get various jobs done.

In the later years, however, when all you were faced with was budget cuts and those kinds of things, the contract world had changed significantly. Contracts for inspections and coverage became less and less significant, and the contracts were much less important to the field and states. If things were to start anew, there would have to be a fresh look with a different kind of programmatic approach. That would really be necessary if there was going to be some significant change or if the contracts are to be reinvigorated.

RT: Thank you.