History

of the

U. S. Food and Drug Administration

Interviewee: Raymond D. Beaulieu

Interviewer: Ronald T. Ottes
and
Robert A. Tucker

Date: August 7, 2001

Place: Rockville, MD

DEED OF GIFT

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Raymond D. Beaulieu

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INTRODUCTION

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

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

CASSETTE NUMBERS: 1 & 2

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

DATE: August 7, 2001 PLACE: Rockville, MD LENGTH: 85 minutes

INTERVIEWEE:

NAME: Raymond D. Beaulieu

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INTERVIEWER(S):

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FDA SERVICE DATES: FROM: June 1966 TO: June 1996

TITLE: Food Safety Specialist, Retail Food & Interstate Travel Program
(Last FDA Position)

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RT: This is another in a series of interviews for the FDA Oral History Program. Today, August 7, 2001, the interview is being held with Ray Beaulieu, food safety specialist, Retail Food and Interstate Travel Program, FDA. The interview is being conducted in the Parklawn Building, Rockville, Maryland, by Ronald Ottes and Robert Tucker. Ray, we like to begin the interviews with asking you for a brief résumé of your birthplace, education, and early work experience, and so we'll go from there, if you will.

RB: Okay, thank you. Good to be here. I was born and raised on a dairy farm in Highgate Center, Vermont, which is right on the Canadian border. I went to high school in Highgate. After graduating, I headed off to the University of Vermont, and there I got my BS in vocational agricultural education. That led to a teaching position at the high school level, and that was teaching vocational agriculture and general science.

RT: When did you graduate from your university?

RB: '62. 1962 is when I graduated. I was teaching for a while and decided that was not something I wanted to do for the next forty years. It seemed like the schedule was just too tight. Every fifty minutes, a different class. And the other thing is, although it was easy teaching back then compared to today, I guess I could see looking ahead, it wasn't something I was going to want to do forever.

So I decided I'd go back to school. I went, again, back to the University of Vermont, and there I pursued the processing side of the dairy industry. As an undergraduate in the vocational agricultural program, I did a lot of studies relating to dairy production, animal husbandry, etc. When I went back, I got into the processing side, so that I was more involved in bacteriology, micro, ice cream, and cheese-

making, etc. I was able to dabble in dairy manufacturing a fair amount. That was under a research assistantship, so it went over a period of a couple of years, because I was doing some teaching, lab work, etc., at the same time while also doing research for my thesis.

At any rate, when time came to leave, it was at the time that we were pretty well involved with the Vietnam situation, and although I was probably at an age where I would not have been drafted, I decided I probably ought to get my military obligation over with. That way, employers won't have to ask or be concerned with whether or not I could be drafted. So I wrote to my local board in St. Albans, Vermont, and asked them, based on my education, what might be the best approach as far as getting into the service. They offered two options. One was a direct commission in the Army Medical Corps, and the other one was a commission in the Public Health Service, which I'd never heard of.

My advisor at the University of Vermont, Henry Atherton, said, "Why don't you contact Harry Haverland in the Boston office, Public Health Service regional milk and food specialist there," or consultant, as they were called back then.

So I contacted him and he sent forth application information on the Public Health Service. I submitted forms. You've got to jump through all the hoops and paperwork. Finally that was approved and in June of that year, I began my career in Washington.

RO: June what year?

RB: June of 1966. I ended up in Washington beginning my career in the Public Health Service.

RO: During the time you returned to the University of Vermont, did you then earn a master's degree?

RB: I did. I received my master's degree.

RT: And what was that in?

RB: It is a master of science, basically in dairy technology.

RT: So you came into headquarters in the milk program.

RB: That's correct. Strictly in the milk program. Back then, this was a program that was within the Public Health Service and it was in the Division of Environmental Engineering and Food Protection. The Division of Environmental Engineering and Food Protection contained a whole lot of pieces. It had probably all the precursors to the EPA and several other programs. Housing was involved among the several programs there. Of course, this continued that way for some time.

So I was in Washington getting my feet wet with a then fairly new document, the 1965 Pasteurized Milk Ordinance. I was learning about that and getting a few field trips to get some experience. Then that whole office, in probably August of 1967, moved to Cincinnati.

RT: At that time, was the unit that you were serving in under the Consumer Protection and Environmental Health Service [CEPHS]?

RB: Yes. It was under Public Health Service, but it was the National Center for Urban and Industrial Health, and it was involved with the Consumer Protection.

RT: Under C. C. Johnson.

RB: Right. C. C. Johnson was heading up the organization.

RT: At Cincinnati, were you involved in the training function?

RB: Not really. In fact, at that point, I was receiving training at the Taft Center. Or sometimes we'd get our training by CDC [Centers for Disease Control and Prevention] out of Emory University. We related well with programs at CDC.

RO: Was it only the milk program that was transferred to Cincinnati?

RB: No, it was a rather large segment, probably three or four hundred individuals. It included all the programs that made up the National Center for Urban and Industrial Health. That was the one I was trying to think of. NCUIH [National Center for Urban Industrial Health]. I was there for a relatively short while, probably six, eight months.

Then I finally received a regional assignment with the Public Health Service in, again, the milk program, and this was in Charlottesville, Virginia, at a time when we had nine regions in the country as opposed to the few regions that we have now. That region included, at the time, the states of North Carolina, Kentucky, Virginia, West Virginia, D.C. [District of Columbia], and Maryland. It was a nice region in which to work. From the standpoint of work in the dairy industry, it was really neat to work there. We had some really good state folks to work with. And so as it progressed, I started doing check ratings based on the Pasteurized Milk Ordinance.

RT: Did you mention the year you moved to Cincinnati?

RB: I believe it was August of '67 when we moved to Cincinnati. Probably in April of '68 I was in Charlottesville.

RO: You just mentioned check rating. What did that consist of? What were you checking?

RB: As the milk program is organized, the National Interstate Milk Shippers Program involves federal, state, and local jurisdictions. The states would do the surveys of milk sheds, which might be three or four hundred dairy farms that were associated with a processing plant. The states would submit the results of the survey for listing in the National Interstate Milk Shippers List, which is still being done.

RO: Is that a responsibility that the Public Health Service took the initiative for, or did the state need to request a check rating?

RB: As it worked out, the states would do their rating, and this was valid for two years, if I remember right. Then somewhere between those two years, we—the Public Health Service and later FDA—would go in and do the so-called check rating. This involved inspecting a smaller number of farms than for the state survey to determine if the survey was actually holding up. The Pasteurized Milk Ordinance was the standard for all these surveys and check ratings.

RO: This was primarily a review of the sanitary practices of the individual milk producer?

RB: That's correct. And the plants.

RO: At the farm level?

RB: At the farm level.

RO: And then the plants were also checked?

RB: Right.

RO: The processing plant.

RB: Actually, the program has three components: the plants, the farms, and an evaluation of the program that the states were conducting, including a review of their records to see if they are controlling shipment under certain circumstances, such as high bacterial counts.

RO: If they failed that, if the state program failed that check rating, they couldn't ship interstate then? Is that it, or what did happen?

RB: Well, what would happen is, that if the check rating revealed that the official rating that had been done was not maintained, a new rating could be requested. Under certain circumstances, for example, if a plant scored too low, it was delisted.

RO: So the new rating, was that then an initiative of the state? Then after that, they would be check rated at—

RB: Probably again, a year to a year and a half later, following the official state rating.

RT: That, in practice, involved a Public Health Service person accompanying the state milk control official on these reviews.

RB: Right. For example, in Virginia, the dairy farms were inspected or evaluated by the Department of Agriculture and Markets, and the plants were done by the State Health Department. When we did the farm check ratings, we had both individuals, two individuals from the state with us. If we did a check rating in Southwest Virginia, when we'd do the farms, we'd have the agriculture representative and also the health representative with us.

RT: Did that sometimes invoke resistance on the part of producers, having three persons involved?

RB: Not really. Most of the time, they were busy with something else. They were not necessarily aware we had come and gone. No, that sailed amazingly well. I probably was more concerned with the plants, because they were getting so many inspections. In the earlier years, sometimes folks from other states that were receiving milk would come in and check the plants.

RT: How about the Department of Agriculture? Did they go in?

RB: No, the Department of Agriculture didn't do Grade "A" plants, at least in Virginia. In some other states they might. West Virginia was strictly Health Department, so that was one agency that inspected both the processing plants and farms. USDA did not inspect Grade "A" plants.

RO: Wouldn't they have reciprocity? If they were on this shippers list, wouldn't that allow them to ship into other states, so wasn't there reciprocity between states? You said sometimes another state would come in and—

RB: Yes, the reciprocity came slowly at first. And again, it might be that a plant was making certain

ice cream products, Popsicles or whatever. I remember one department that would send somebody out to California, because Popsicles were coming into their jurisdiction. So I believe over a period of time, reciprocity did lead to eliminating a lot of the duplication of effort.

RT: The reciprocity was formalized in an interstate agreement?

RB: Yes, that's all part of the Interstate Milk Shippers Procedures and Practices.

RO: And that program is still in effect?

RB: That's correct. It is still a very viable program. In fact, the Interstate Milk Shippers Conference served as a basis for developing a similar conference for shellfish programs and for retail food programs. We now have the Interstate Shellfish Shippers Conference and the Conference for Food Protection. There are similar bylaws to deal with those conferences. The Interstate Milk Shippers Program goes back a long time, probably originating around 1950ish, and it has contributed much for uniformity among the states and in the industry.

RT: How long did you continue in that particular capacity?

RB: Well, in Charlottesville, once I got into the field, I also got into the retail food sanitation program, and also a bit of interstate travel. We were doing the airports up here, National Airport. At that time, National Airport, which is now Reagan National Airport, was considered a federal enclave, and it was hands off to states or localities. So the Public Health Service did the inspections and we'd come up every three to six months to inspect the food caterers and food operations within National Airport.

RO: You said you got into the food program, but then you mentioned interstate travel.

RB: With the food program, here we're dealing at that time with the Food Service Sanitation Ordinance and Code. That was the 1962 edition at that point.

RO: I wonder maybe in the progression here of our discussion, could we deal with the interstate travel program and then move to the retail food program as a separate area. Now, in the interstate travel sanitation program, you inspected the food preparation areas [caterers] that serviced aircraft, and you also would have presumably covered food service facilities along interstate routes. Is that correct?

RB: The interstate travel program is involved with food associated with planes, buses, trains. So, yes, there were bus stations that would be evaluated, train stations, as well as airports.

RO: As far as the conveyances themselves, were there inspections made when these planes or trains, primarily, were in transit somewhere?

RB: That was a possibility. Most of the time at National Airport, you could get on board a plane to check a galley. The primary concern, of course, was food coming from the caterer and how it's handled to get it into the plane so that it is properly maintaining a safe temperature. The same thing has occurred with trains over the years. Personnel have been on board and conducted inspections while the train was under way.

RO: As to food-handling practices.

RB: Of course, with trains or planes, it's not just food, but it's also water, sewage disposal, etc. Of course, that's true of all the facilities. For example, at the airports, inspectors are checking watering points, where water might be used to upload into an airplane.

RT: I think in recent years there was a program rather bluntly called "crap on the track." In other words, disposal of human waste off the bottom of the railroad car onto the tracks. Was there any particular result of that initiative to better, if you will, the discharge of human waste products in a more sanitary way?

RB: Yes, there was a big push in more recent times than it was back in the sixties. It probably really started in the eighties. I can still remember in the late eighties going to the train car bathroom and when the toilet was flushed, you'd see the cross ties through the opening. [Laughter] Somebody said, tongue in cheek, "So they flush. When you're doing around sixty, it just hits the cross ties, atomizes, you know, it's gone."

RT: Well, there was a problem at stations, unless they would lock the restroom doors at stations.

RB: They even put up a sign, "Don't flush when you're in a station." Yes, that did continue to be a problem for quite a while, but I haven't had too much contact with that area in recent years. I believe it's improved considerably.

RT: There's the possibility, like other conveyances such as aircraft, where there has been a container requirement for the waste.

RO: I thought it was interesting, you said that Reagan National was considered a federal enclave

and it was kind of hands-off.

RB: That was true back in the sixties. It was after I ceased being involved with interstate travel that some changes were made that resulted in local or state people having authority to inspect airport facilities.

Further, with that interstate travel program, it includes consideration of the construction of a ship, of a railroad car, of an airplane. There are people who are reviewing construction plans to make sure that at least all the food-related, water-related, and sewage items are considered. Right now we're short of people who can be really called specialists in specific areas. We have one person out west who is very good with airplane construction. Baltimore has a person very knowledgeable of trains. And down south we have one that's very good with ships. However, the knowledge base is improving at this time.

RO: Well, I was going say, it seems that in recent times, there have been some reports of food or waste problems on cruise ships. So personnel from the Public Health Service, or now the FDA, would be involved in those investigations.

RB: Right. They've been very active within the past six months, as there have been a few incidences of foodborne illnesses and some of those were out on the West Coast. The regional interstate travel personnel out there were very involved. Right now, at headquarters there is maybe somewhat over a person a year for that program, whereas there used to be six to eight.

RT: Is that Byrd Reddoch?

RB: Byrd Reddoch retired some years ago. Now Larry Edwards and Thomas Hill are working the

headquarters program. Thomas Hill just came on board within the past year.

RO: So, rather than having specialists distributed across the country in the field offices, this tends to be kind of a specialized assignment now, is it?

RB: Oh, no, it's still very much a field activity. That's where the action is.

RO: Are those personnel assigned at the regional office level or at a district?

RB: District.

RO: So you have, conceivably, someone in each of the districts.

RB: I'm not too sure, but I think there may be eighteen or twenty folks that are involved. They may not be full-time as they get called on to do other FDA regulatory activities.

RO: New ships that are just being commissioned, does someone go in and inspect those, that they're built satisfactory to—

RB: Yes. Depending on where the ships are going to be operating. The Centers for Disease Control and Prevention has jurisdiction over some cruise ships and international ships.

RO: I was wondering what if there was some joint responsibility, because I see every once in a while that CDC is involved. I was wondering under what authority that they're doing that.

RB: It's all under the Public Health Service Act.

RO: So that they just kind of split responsibility.

RB: Yes. FDA is involved with the ships that are operating interstate. For example, the ferry that crosses from Lewes, Delaware, to New Jersey, or cruise ships in Hawaii.

RO: On board ships, I'm sure at this point in engineering and so on, that waste is containerized, but historically I suppose that was also released to the stream or sea.

RB: Right. That was considered, again, probably in the early eighties to nineties. I've been on a ferry where you could hear a clunk and crash, and it was the trash being dumped over the side. That was some time ago.

RO: Yes, once in a while I read about some of these cruise ships, anyway, disposing of their waste food. Not human waste, but waste food overboard, which is also verboten.

RB: All of those things are being looked at more closely.

RO: Let's back up a little bit, because when you were transferred to the FDA, after being indirectly under the Public Health Service, there were considerable questions about a lot of the employees, such as how they were going to be handled in the FDA organization, when you'd been kind of a close-knit group in the PHS.

RB: That occurred while I was in Charlottesville. First of all, I need to say that with the interstate

travel program, I'm not the real expert on it. I have dabbled in it, and I can give some generalized comments like we've been through here. So I would suggest probably someone else to really delve into that program.

As far as the shift that occurred, this was when I was in Charlottesville. It occurred probably in '68, '69ish, due to a reorganization in government. FDA came in under the PHS umbrella. The question became, where did the PHS programs fit in best in this reorganization. Some of the programs that were in PHS at the time got spun off. EPA evolved at that time. When all was said and done, obviously with FDA you're dealing with food. So it seemed appropriate that was the best place to locate the milk, food, interstate travel, and shellfish programs.

RT: One of the differences—and I'm sure it came to many persons' minds in these programs before the transfer—was the fact that much of the work of the original state cooperative effort of the Public Health Service involved the development of ordinances and so on, whereas the traditional Food and Drug Administration was enforcement-oriented in terms of seeking prosecutions, seizures of goods, and so on. Perhaps that might have led to some feeling of possible estrangement from this move. Is that something you observed?

RB: Yes. I guess I was young enough when I got in, it probably didn't affect me as much, but yes, I think a difference of philosophy, as you say, the enforcement approach versus the way the Public Health Service programs operated through development of ordinances that states adopt. The states do the enforcement work, etc., and we provide assistance to the states. So it is more of a preventive program by working with the states in trying to prevent potential health problems. Whereas, obviously, with the FDA, its mandate was to go into establishments, conduct inspections, and carry out enforcement. There was a bit of a difference of philosophy.

As I look at it, I think probably both programs sort of changed a little bit. I think that

philosophy might have changed a little bit in FDA, resulting in a greater understanding of the cooperative programs.

RO: You were a commissioned officer in the Public Health Service and you have under a different system entirely than the general schedule of employees, and your leave policy and works habits and everything else was different. Wasn't there a little bit of resentment on the part of some of the old traditional people as far as the way the Public Health Service employees were evaluated?

RB: Well, I think that's because this was sort of new to the folks. All of a sudden, there is a reorganization, and now there are two different types of employee systems.

RO: Different personnel systems.

RB: Personnel systems, yes. And so, yes, that was probably creating some concern. I think that has all leveled out over the years, but, yes, early on it did result in misunderstandings. There is a different leave policy, a different pay system, and retirement system. Eventually, there was an acceptance of the two personnel systems.

RO: A different travel system.

RB: In terms of performance evaluations, I think the Public Health Service corps had a system that differed from what ultimately came in the Food and Drug Administration where you had the performance plan concept—

[Begin Tape 1, Side B]

RO: —let's say, under the agency's performance appraisal plan. So that probably was a little bit of a troublesome thing until the transition was truly completed.

RB: Yes. I was evaluated via a commission officer efficiency report. That was done by my supervisor and signed by the next step up.

RT: I may be in error, but Ron would know because he was very much involved in the performance appraisal plan of the FDA. Was there a double evaluation, or am I in error on that?

RB: Well, no. It was a double evaluation because a lot of the commissioned corps people felt that under their evaluation system, that they shouldn't be under the performance plan. But they thought in order to have uniformity for all FDA employees, that they should be under the general schedule of performance evaluations. So there was a kind of a double evaluation going on here.

[Tape recorder turned off.]

RT: While you were in the field, Ray, I understand that your primary assignment was in the milk and food programs. Maybe we should continue on that. Was there another relocation that you had in that part of your career?

RB: Yes. As you say, I was working primarily in the milk and food areas, out of Charlottesville. I was in Charlottesville for probably two years before there were some shifts in the regional boundaries and the Charlottesville office was closed and the whole regional office moved up to Philadelphia. Now, if we had stayed in Charlottesville, I'd probably still be there. That was such a nice area to work.

You're talking a small city, get around easily, you want to go visit somebody across town after work, it's ten minutes instead of two hours. [Laughter] Anyway, we did our work out of Charlottesville, which included the states of Kentucky, West Virginia, North Carolina, Maryland, and D.C. I was conducting check ratings and doing some food work in all those states.

Then we moved to Philadelphia. That shifted our boundaries a bit, so we now had the state of Pennsylvania. North Carolina and Kentucky were shifted to another region. So the region changed a bit, but the work continued as it had been. I was still very much involved in milk and food.

Philadelphia, I guess, wasn't—how can I say this nicely? It wasn't my favorite place, although I got married there. Anyway, I stayed there for probably eight months, and then there was an opening for a regional milk and food specialist in Boston. I headed up there, and there we had all the states of New England to work with, and again continuing the milk and food work in those various states, doing check ratings, evaluations, and assisting the states and locals in food and milk activities. At that point I was not involved with interstate travel. That was handled by the regional interstate travel specialists.

I stayed there for a couple of years, and then was contacted about coming to the retail food program headquarters unit in Washington. I gave that a little bit of consideration and then decided, okay. I'll take the option. So I came to the retail food program in Washington. Harry Haverland was involved with that program, along with Bill Bower and several other individuals.

RT: Was he director of that particular activity?

RB: I believe, yes, Harry was director of what was called Milk, Food, and Interstate Travel Programs.

RT: That was prior to his going as director of training to Cincinnati.

RB: Exactly. Right. When he went there, Bill Bower headed up the organization, the retail food piece of it.

RT: How was that different from your assignment in Boston?

RB: Coming into headquarters, having had the field experience, we worked with our regional people, and I was traveling around the country and doing standardizations of the regional people. Standardization is an effort where we go out with the FDA regional specialists who are working with the states, and work somewhat side by side with them, doing inspections, and then comparing notes after completing inspections. It's a test of sorts. Early on, we didn't work very closely together; we were in different parts of an establishment and then compared notes. It's become more of a training experience, but you can also assess the knowledge base of the individual you're standardizing. This was a process that we'd been doing for quite some time. We were doing it in the field, obviously, when we were standardizing state and sometimes local folks. Other functions of the headquarters unit include code development, issuance of interpretations, developing opinions, equipment standards development, training, etc.

RO: How much variance in observations and findings were permitted for standardization to occur?

RB: Well, as I remember it, in the food program, we had a forty-four-item inspection sheet. You had to be in 80 percent agreement on all items. You were allowed to be less than 80 percent on two of them. Going back to when I was at the regional level, doing the standardizations of state individuals in milk, it was a similar approach. You had to be in agreement a certain percentage on all items. You might be allowed one or two that would be an outlier.

RO: Once the field representative that you standardized had completed the process, did that individual, in turn, then work with state rating officers for standardization?

RB: Right. It's sort of a pyramid effect where we did the standardizations of our regional people. The regional specialists then go out and standardize in the states in their regions. Hopefully, the states conduct standardizations of their local people, the county sanitarians. So it was sort of a pyramid effect that we tried to work out, to try to bring along some good standard uniformity. That was very much a priority. We'd hear that from states and we'd hear it from industry, that they want uniform inspections. Standardization was one way to contribute towards uniform inspections. That worked well. I really enjoyed being able to do standardizations, because that brought me back out from headquarters and out on the firing line, working with state and locals when we're standardizing our regional people.

And also the regional seminars that are held in each region on a yearly basis for milk programs or for food programs, again gets you out there where you're seeing and hearing from the folks who are on the firing lines. It keeps you attuned to what is going on. Of course, the third aspect of maintaining contact with local issues involves training. We'd do some training at various places assisting the State Training Branch. That was another good arena for receiving information from the folks in the field. A lot of those folks, states and locals, were very hungry for information, so it was good to have an exchange like occurred in training sessions.

Now, at that earliest point of my career, we were working with the 1962 Code. In the early seventies, we started to develop a revision of the '62 Food Code, and by 1976 we had a Food Service Sanitation Ordinance and Code. That code was easier to work with than the previous edition. Of course, it brought a lot of information up to date. So the 1976 code was in effect for a good number of years. In fact, it still is being used in several states.

A sister document was developed in '82 and that was the Retail Food Store Code. Of course,

there was a third document, the Vending Ordinance and Code. That was applicable to vending machines that dispense beverages or food.

What was interesting is that as we worked those three documents and then standardize the regional specialists, we tried from year to year to use a different approach. Some years, we would go in and do strictly retail markets. This was a fairly new approach in the 1980s. We even got into some states that never had inspected markets, because a few states didn't have a retail program.

RT: Going back in the earlier history, I seem to recall that the U.S. Department of Agriculture had some kind of an involvement with retail food markets, perhaps as related to meat products. Does it have any correlation with the work of this agency, and is it still operative?

RB: It's still operative to some extent. I think it depends how much a retail operation is involved with the meat and poultry processing, etc. I don't know what the figures are. There are some cutoffs.

RT: Was the Department of Agriculture, federal, looking at sanitary practices in these establishments?

RB: Yes.

RT: Or more source of meat?

RB: They were looking at the meat and poultry operations. In some cases they probably even had, earlier on, resident inspectors in some of these larger establishments, and I think that's kind of gone by the wayside. I know that they still keep a hand in it, depending on what is going on in any particular market relating to meat and poultry.

RT: As far as the federal presence in retail food markets, it's somewhat indirect as you've described this standardization and uniformity initiative, is it not?

RB: Yes. As far as we, the FDA, are concerned with the retail food programs, the states have the authority to regulate. We really don't. We probably could, I think, through a stretch, because obviously, food is going interstate. But when you consider the million-plus establishments, there's no way FDA could possibly do it, so it's left up to states and locals.

RO: I suppose with regard to food recalls, there may be a greater FDA interest. Again, though, would you say that the states primarily are involved in recall of products at the retail level, or is it done in consort with FDA?

RB: FDA and states work together on recalls. The states have the authority to conduct recalls and generally are the ones conducting the recalls.

RT: They have embargo authority, which is more amenable to quick seizure of goods or collection of goods.

RB: Exactly. Going off the line a little bit here, we also have regional people and sometimes our headquarters people getting involved with disasters. If there's a major flood like there was in Missouri some years back, our regional people were out there pretty hard and heavy, and at that point they can be making the decisions.

RO: You mentioned these codes. Who develops those codes?

RB: FDA has been the primary organization in code development. I mentioned three of them: Food Service, Retail Markets, and Vending. Those codes were pretty well developed by FDA. They were sent out, I know, for comments to regulators, academia, industry, etc., but it was pretty well resolved in-house as far as finalization of the document. In 1992, there was an initiative to combine those three codes into one code, the Food Code. There were four of us—Betty Harden, Arthur Banks, Steve James, and myself—that starting in the second half of 1992, were sequestered from our office and all we did was pound away at developing, combining those three codes, coming up with the latest information, including all the research articles we could find relative to food safety, to make it the most scientifically sound code that we could possibly develop. I think we succeeded.

RO: When that consolidated code was finally produced, did that result in the readoption in many states of the consolidated code to replace those earlier ones, perhaps independent ones, that had earlier been used?

RB: Yes. Adoption is a slow process. When the '76 Code was done and available, it was several years before most of the states had adopted it. Of course, we knew that would happen with a new Food Code. The first edition came out in 1993. That was presented to the Conference for Food Protection. The Conference for Food Protection is similar to the Interstate Milk Shippers Conference. The Conference for Food Protection is made up of industry, academia, and government, so all levels can provide input relating to retail food.

Once we finished that first edition—when I say "we," there were four of us primarily—but we were getting lots of help from lots of folks. It's just that the four were sort of funneling it all together. When that edition was finished and presented to the conference, there was a lot of discussion, because it was a new document, and so it took a couple of years before more input was obtained and some

revisions made to the Food Code.

The first state to adopt was Rhode Island. Before then, actually, the Air Force had adopted the Food Code. Adoption is a slow process. It's ongoing right now, as I recall, this being early August, there are some twenty-six state agencies that have adopted the Food Code. It might be the '97 version or the '99 version. Right now we're just about to issue the 2001 version, so it continues to be revised every two years.

RT: You mentioned state agencies. Now, within a state, there's more than one agency that—

RB: Right.

RT: You might get one agency in a state and not another.

RB: That's correct. For example, in one state we might have the Department of Agriculture adopting it. In another state, you might have three agencies adopting it. It depends. I think Florida is still operating with three agencies. Georgia has two, with agriculture and health. So it depends on the states.

RT: You've given a number of adoptions. Are there any or several states that really haven't adopted any of these codes that you're aware of?

RB: When considering the '62, '76 Codes, etc., most of the states have adopted one of those versions. I mentioned a number of states that have adopted the recent code. There is an equal number of agencies that are looking to update their codes. It's a very different code, because we have some major interventions in here. Now, we mentioned this was the most scientific-based code to date, and

all the references to the scientific papers are listed in the code, in the annex at the back of the code. So when addressing cooking temperatures, a time and a temperature are specified specifically to kill a certain level of organisms. The cooking criteria are based on the anticipated micro load that you might expect in a particular food, and a time and temperature regimen is identified that will destroy the organisms of concern.

RO: The so-called HAACP [Hazard Analysis and Critical Control Point] concept is—

[Begin Tape 2, Side A]

RO: We were speaking of the HAACP concept.

RB: The Food Code is HAACP-friendly. If you look at it as a document, it's pretty much a command and control approach. This approach works well with what's called mom-and-pop operations. I guess the proper name now is a small independent business. They'd probably rather see the criteria spelled out. "I'll cook my hamburgers to 160 degrees and don't have to worry about time," etc. Whereas a large operation could use an HAACP approach and provide documentation of a different time and temperature scenario that would do the equivalent destruction of organisms that are of concern. So, yes, the HACCP approach and Food Code can go very well together.

RO: Based on your statement, can one infer that HACCP really has greater applicability to large food operations than the small?

RB: It can work both ways. If we're talking about certain food processing approaches, the large operation can afford a scientific evaluation to make a determination of the lethality of their proposed

approach, versus a smaller operation where they may not have that capability.

RT: The HACCP, by its definition, what does that acronym stand for?

RB: Hazard Analysis and Critical Control Point.

RT: As the title suggests, it gives special attention to temperatures and times and circumstances where the food is at the greatest peril of organisms and so on. Is that correct?

RB: That's correct. You make a determination of your particular hazards, identify the hazards and then the controls that are needed to control the hazard to prevent any future problem. So using the HACCP principles, just about any operation could apply them somewhere along their processes. Again, it depends a lot on the type of operation. If it's a cook-serve operation where they just take food out of the refrigerator and cook it and serve it, their hazards are considerably lower. The cooking step obviously is the kill step. That's a critical step.

A more complex operation may haul out lots of food, prepare it a day in advance, then refrigerate it and hope to get it cooled down, and reheat it the next day for service; that gets a little more difficult. So depending on the type of operation, the HACCP plan can be very useful. We have several large chains that have HACCP plans in place, and when we're doing standardizations, we look at those HACCP plans.

RO: Were there any special circumstances that motivated development of the HACCP program, or was this just an advancing knowledge of food protection?

RB: Well, it has its roots back in, probably, 1970. You sort of hear that it was developed for the

space program.

RO: It was.

RB: Yes. Then you find some documents that go back to the thirties. It wasn't called HACCP, but it's the same approach. These approaches have been around for a long time. It is a process for refining operations as you go along so that you get greater safety.

I wanted to mention that with the Food Code, there were some major interventions brought in that were not in previous editions. Along with the scientific approach, the Food Code looked at employee health, and when compared to the previous codes, it moved the chapter on employees from somewhere in the back of the code to the very first part of the code.

That was because we were discovering that employees can have a major role in contaminating food. If an employee goes to the bathroom, does not wash his or her hands properly and gets some feces under the nails, it may get on the food. If you're dealing with an organism such as hepatitis A, you only need a very few organisms to cause an illness. We know of several such illnesses. E. coli 0157:H7 is another organism where a very low level can cause illness. The shigella organism is another where there's a considerable concern that if an employee is ill, they need to be either restricted or excluded from the facility.

Employee restrictions and exclusions are very well spelled out in the Food Code, and also which illnesses are of concern. There are four major organisms that are of concern: salmonella typhi, shigella spp., E. coli 0157:H7, and hepatitis A virus.

Employee health is one of the five major interventions. Another one is operator or manager knowledge. Who in the establishment has to know what is going on if you're going to have a safe operation? That falls in the lap of the operator, the manager. So, manager knowledge has become one of the interventions.

Another intervention is no bare-hand contact with ready-to-eat food. Again, in spite of how well you wash your hands, you're not removing all of the organisms from your hands. Based on what we were seeing as I get out into the field and as we review reports of illness outbreaks, we are finding that a lot of it involves food that we would consider non-potentially hazardous. In other words, it's not a food that will allow organisms to grow, but if the food has been contaminated via employee hands, with one of the organisms previously mentioned, it could cause an illness. The code is very specific. There will be no bare-hand contact of ready-to-eat food. Employees are to use spatulas, tongs, gloves.

RO: What was just coming to mind was lettuce. That might be an example of something that of itself wouldn't support bacterial growth, but could be contaminated. So what you're saying is that well-managed food operations with the food handler does need to have gloves?

RB: Yes. Again, with lettuce, it could come in contaminated. So the code says you wash fruits and vegetables. Once food is prepared and there is no further kill (cook) step, the food must not be manipulated with bare hands.

RO: Then you should worry. Is that the idea?

RB: When it comes to washing fruits and vegetables, the code is not as specific on the no bare-hand contact issue because of what's involved there. However, when preparing salads, etc., then contact by bare hands must be eliminated.

RT: Then this code requires that in a food service place, the manager of that establishment has had to go through a course and be certified.

RB: That's an issue that's been widely discussed, and certification is an acceptable means of demonstrating knowledge. When talking about the manager's knowledge, another way to determine it is to ask questions. And, of course, when we do an inspection, that's what we promote, a pre-inspection interview, so you can ask questions to get a feel for how well management knows their food safety.

A third way to determine knowledge is to look at the establishment and see how well they are doing in their establishment. Is everything pretty much shipshape, or is it kind of reckless? You can draw conclusions based on observations.

RO: Well, I see here the District of Columbia lists those food establishments that have been closed for one reason or another, and one of the reasons is that they have no knowledgeable or certified, I guess is the term they use, manager in there.

RB: On duty at the time.

RO: On duty at the time.

RB: Right. The code does specify that there will be a person in charge and on duty that is knowledgeable. Some states do mandate a manager certification program that requires training leading to certification. Others don't, so it's an issue that's going to be discussed for probably a few years yet as certification programs evolve. But right now there are those three options in the code: certification, demonstration of knowledge through question and answer, or by virtue of looking at that establishment and does it indicate that the person in charge knows food safety issues.

RO: What's the date the code was first issued?

RB: The Food Code was dated 1993 and issued in early 1994.

RO: And updated when—

RB: Every two years. The basis for changes in the code are the result of the Conference for Food Protection. The next conference meeting is in April of 2002, so right now the 2001 code is coming out. In a year or so after the conference, we'll get some comments back from all the folks that are involved, and that will probably drive updating to the 2003 code.

RT: So there is the Food Code now, and then the Milk Code, is that right?

RB: The Pasteurized Milk Ordinance, yes. I have not been directly involved with the milk program for some time.

RT: We were just wondering. They had a number of them and they combined them into the Food Code, but the milk—

RB: The Pasteurized Milk Ordinance is still a standalone document. Right.

RT: The Interstate Shellfish Program is separate as well.

RB: That is correct. I need to finish the five interventions. I mentioned manager knowledge, employee health, and the issue of no bare-hand contact. Another one includes the time-temperature scenarios. In the old codes we specified cooking to 140° Fahrenheit. Well, we began to find out, for

example, with the salmonella in eggs in the eighties, 140°F may not wipe out the organism. Research indicated 145°F did.

Previously we only spoke to a temperature without addressing the time factor. We were very aware from all the information we were gathering, that whenever you're talking about temperature, time is always involved. That's why the code, whenever it addresses a temperature, there's always a time involved. For example, cook to 145°F for fifteen seconds. The only time you get away from time is with, for example, hamburgers where it is specified, and the research information showed, that 158°F provides an instantaneous five-log reduction of E. coli 0157:H7. That's one cooking scenario identified in the code that is instantaneous. The others have a time-temperature approach. And that's intervention number four.

The fifth intervention relates to animal foods that are raw or undercooked. This is applicable to folks who may be immunocompromised to some extent because they're going through chemotherapy or what have you, and therefore are more subject to foodborne illness based on the food that they eat. The code specifies a consumer advisory that may be on the menu or provide information by some other means, such as table tents, that provides disclosure that certain foods are raw or undercooked—for example, "These oysters are raw." And elsewhere on the menu it should identify as a reminder that if you are immunocompromised, you may be more subject to illness if you eat food that's raw or undercooked.

If we go to Alexandria, Virginia, we can find the consumer advisory on menus, because they have adopted that part of the code. This has been one of the more difficult issues for full adoption of the code.

Again, when we talk about adoptions of the code, it could be a total adoption or it could be adopting only certain parts. Some states have not adopted the consumer advisory, because it's a difficult issue. I know early on some of the industry remarks were, "Well, you know what that means? We'd have to have a doctor on the premises." Well, that wasn't the point at all. It's aimed at the

person who knows that they are more subject to illness and therefore they should be advised that food is raw or undercooked. That summarizes the five major interventions in the Food Code.

RT: That's interesting. That's a big improvement over what it used to be.

RB: Yes, I think so. When I look back—you know, if you were to ask in my thirty years with the organization what documents or what led to the greatest change, I would say the Food Code by far. It is so much more loaded with information than previous codes. There are appendices for the references, public health reasons, and several other aids. If you want to know why the code specifies certain provisions, you turn to the back of the book to Annex Three and you can find the public health reasons for code provisions. So it's a very useful document. A large document, but I think very useful.

RO: Is there any dissemination of information on the number of states that have adopted any or all of this code? If I wanted to avoid some state that hasn't adopted the code just for my own health reasons, would I know that?

RB: That is made available on the FDA Web site. There is a listing of code adoptions at the Web site. The Association of Food and Drug Officials [AFDO] is also working at making a determination of those jurisdictions that have adopted and specifically what they have adopted, and that's also going to be coming forth. I don't know what the time frame is on that matter.

RO: This is updated every two years.

RB: Yes, the Food Code is updated every two years, but some states, because of what they have to go through to update a regulation, will probably hold with, say, the '97 Food Code for a number of

years, but could bring in some of the criteria through interpretation relating to the newer version of the food code. That's another thing that I've been involved with over the years: writing interpretations or opinions relating to the codes. That goes back to the early seventies and it's a continuous process.

RT: This is very interesting. It certainly is covering activities of the agency that have not been in the oral history record heretofore.

You retired, and you're still active in counseling program managers in retail foods, is that correct?

RB: That's correct. I retired in '96. Being in the Commissioned Corps, my thirty years were accomplished and I decided to retire. There were some requests: could I come back? They even said full-time civil service. I said, "I can't come back full-time. "Well, we can do part-time civil service." I said, "You know, I'm retired." But anyway, there was a little more discussion. It's like a family, I mean that whole group that I worked with, just so fantastic. It's like a big family.

So I spoke to Tom Schwarz, who was heading up the Division of Cooperative Programs at the time. Cooperative Programs includes retail food and interstate travel, milk, and the shellfish programs. I decided, well, probably the best approach is that I come back under contract. That way, I'm not tying up an FTE, and it gives me more latitude. So that worked out and I came back and still do many of the things I did before retirement.

I'm very involved with developing interpretations, working on the Food Code. In fact, I've been involved with the revision of the '99 Food Code to the 2001 Food Code.

I was going to continue under contract to the end of the year, but the retail food program is involved in many issues, including the Olympics that are coming up in Utah in January, February of next year. They were short one slot and asked if I would stick around until February, go to the Olympics, and work there for a while. I thought, "How else am I going to get to the Olympics?" So I

said, "Okay, I'll do that."

The division director right now, since Tom is retired, is Betty Harden. An admirable person. She said, "Well, right after the Olympics is the Conference for Food Protection. Would you stay around for that?" So it looks like I have to go until the end of next April before I can say I've retired. And when I say retire, I think I will retire. But if the state training team requested me to do a training course or assist them occasionally, I could be agreeable to that.

RT: In that regard, you are participating in some training sessions with the training group under Gary German now, is that correct?

RB: That is correct. Right now I work mainly with Jim Fear and George Dawson, two individuals in Gary's shop. There was a whole lot of work done there in developing what's called a Food Code "Train a Trainer" course, where Food Code training information was put on a CD-ROM, so it's readily available. It's sort of like a road show. We go out, using one day for trainers [Train the Trainer], and then we follow up with information relating to the Food Code for three days or so. We provide the information to the participants from states and industry. We've done courses for the Indian Health Service. We've had many requests for Food Code courses since 1994.

This is not all about me, although I have been speaking in the first person. I have had the opportunity to work with some of the finest people one could know throughout the agency, but especially with the small group that I've been associated with for so long.

A lot of the recent direction of the retail food program began with Art Banks, who was very instrumental in getting us where we are with the Food Code and the retail food program. Also, Betty Harden, when she came on board, and has since moved up to division director, continued and enhanced the retail initiatives. I am thankful that I've had the opportunity to work with the many folks who staff the offices in the Division of Cooperative Programs and State Training Team.

RT: Mr. Art Banks is not in the immediate group, is that correct?

RB: That is correct. He's with the Office of Field Programs, with Office of Plant and Dairy Beverages. He's still very active and works very closely with issues that relate in their shop to the Food Code.

RO: If that covers the areas of your work, Ray, we would want to thank you for participating in the oral history program. This interview has added some new information in this oral history.

RT: It sure has.

RB: Well, I certainly appreciate the opportunity. I'm sure when I walk out of here, I'll think of many things I forgot. [Laughter]

RT: You're going to have a chance to edit this, and so then we can always incorporate more.

RB: Yes. Because then I'll see how accurate my statements were.

RO: Thank you, Ray.

RB: You're very welcome.

[End of interview]