

History

of the

U. S. Food and Drug Administration

Interviewee: Richard A. Moats

Interviewer: Robert A. Tucker
Ronald T. Ottes

Date: July 20, 1994

Place: Rockville, MD

DEED OF GIFT

Agreement Pertaining to the Oral History Interview of

Richard A. Moats

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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.



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GENERAL TOPIC OF INTERVIEW: HISTORY of the FOOD and DRUG ADMINISTRATION

DATE: July 20, 1994 PLACE: Rockville, MD LENGTH: 140 Minutes

INTERVIEWEE

INTERVIEWER

NAME: Richard A. Moats

NAME: Robert A. Tucker

ADDRESS: [REDACTED]

ADDRESS: U.S. Food & Drug Admin.

[REDACTED]

Rockville, MD

FDA SERVICE DATES: FROM 6/26/73 TO August, 1988 RETIRED? Yes

TITLE: Director, State Services Branch, Division of Federal-State Relations
(If retired, title of last FDA position)

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Richard A. Moats
Interview

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RO: This is another in a series of interviews in our FDA Oral History Program. Today we are interviewing Richard A. Moats, former director of State Services Branch, Division of Federal-State Relations in the Food & Drug Administration. The interview is being held in the Parklawn Building in Rockville, Maryland, and the date is July 20, 1994. Present, in addition to Mr. Moats, is Robert Tucker and Ronald Ottes. This interview will be placed in the National Library of Medicine and become a part of FDA's oral history program.

Dick, to start these interviews, we like a bit of autobiography. So if you would start with some of your early years, where you were raised, educated, and any work experiences that you had prior to coming to FDA.

RM: I was born in Preston County, a little town called Aurora, West Virginia. That was on October 22, 1926. I went to elementary school in Aurora and a little town called Erwin, West Virginia. I went to Aurora High School. In my senior year in high school, I joined the U.S. Navy and took my boot camp at Great Lakes, Illinois. Upon completion of boot camp, I was shipped to Leyte in the Philippines and was assigned to the heavy cruiser U.S.S. New Orleans.

RO: What year was this, Dick?

RM: I went in the navy in 1943. I was discharged from the navy in July of 1945. I always really liked the navy, and I really thought I would like to make a career of it, but rank advancement was limited without a college degree. So I decided to leave active duty and join the U.S. Naval Reserves, which I did in 1945. During World War II, they had the G.I. Bill of Rights. I went to Fairmont State College under the G.I. Bill and got an A.B. degree, bachelor of arts degree in environmental sciences and secondary education to teach school. I obtained the degree in May 1949. As I proceeded through the studies, I never really thought I'd make a good teacher, because if, for no other reason, I just didn't like to stay inside all the time.

During my senior year, the chief engineer for the West Virginia State Health Department was holding job interviews at the college for environmental health inspectors. I scheduled an interview with him. The position involved milk and food control and general environmental health responsibilities. He made it sound so good, and I thought, well, there's the end of my teaching career. On June 20, 1949, I was hired as a milk and food sanitarian for the Tyler County Health Department.

The position of sanitarian in Tyler County included eighty percent of the work being milk and food control; the other twenty percent was general sanitation, including private water supplies, private sewage disposal systems, refuse control, et cetera.

RT: Did the state give you special training since your degree had been in another area?

RM: Yes. West Virginia at that time required everyone that was employed as a sanitarian to satisfactorily complete a twelve-week orientation training program. It was a complex training program. If you didn't satisfactorily complete the training center to their satisfaction, your employment ended after the end of those few weeks. Upon completion of the training program, you were then assigned on your own to a local county or district health department. You remained a state employee assigned to a specific local health department.

RO: Really your direct supervision, then, came from the state, not from the county health department.

RM: That's right. There was a good reason for that. The policy maintained a uniform standard throughout the state. For example, during World War II, there was a shortage of milk. Dairy farmers were allowed to ship a Grade A supply of milk by foregoing certain sanitation requirements during the shortage. There were about a

hundred dairy farms allowed to ship milk under these conditions in the county I was assigned to. Some of the dairy farms did not have approved water supplies, sewage disposal systems, and other major state sanitation requirements.

Unfortunately, the county commissioners were also dairy farmers, and they refused to sign the county health department budget if I continued to enforce the state requirements. Since I was a state employee, they had no control over my activities, so they were required to comply with the standards like every other dairy farmer.

RT: Did you have any support or guidance from I guess what would then have been the Public Health Service people in the milk program?

RM: Well, as milk production expanded in West Virginia, some of the dairy processing plants, like in Parkersburg, Clarksburg, Wheeling, were shipping products interstate. At that point in time, these processing plants had to be listed on an interstate milk shippers list in order to ship products interstate. The interstate milk program was supervised by the Public Health Service. The state would conduct interstate milk sanitation ratings according to the Public Health Service standards. The states used these sanitation rating results as a guide to allow milk products to be shipped into the state. The Public Health Service trained and certified state officials to conduct official ratings. Their milk and food consultants, which are similar to the ones the FDA have now, would check rate the states to see whether or not the states were applying the standard adequately.

The most important feature of that program was that there was one standard that every state used and that was the United States Milk Ordinance and Code. That ruled out all the little local requirements that were used mainly as trade barriers. It didn't matter what the local requirements were; if you wanted to sell milk outside of the state, then you did it by complying with a uniform national code.

I worked three years in Tyler County. In 1952, I was assigned to a three-county district as a supervising sanitarian.

During 1952, the sanitarians were required to become efficient in performing basic laboratory tests, e.g., plate counts, phosphatase, tests, et cetera, in the laboratory. Each county or district had a laboratory. We were trained by the state laboratory to conduct these tests. We did a lot of what we called rim counts on restaurant utensils, glasses, et cetera. We would take swab counts of glasses, dishes, eating utensils, et cetera, in the field and conduct a laboratory bacterial count in the county or district laboratory.

One particular day, in a little town called Sistersville, West Virginia, I was collecting rim counts on food establishments. Probably the best known pharmacy in town had a soda fountain, and right around the corner was a real rough beer dispensing establishment. I did a rim count on the pharmacy, and the test results were too numerous to count. The beer establishment came up with practically a zero count. Now the reason for that was the pharmacy was using a quaternary ammonium compound, and they were using it light, and the beer establishment was using chlorine as a disinfectant. The beer establishment was just picking up a Clorox jug and pouring it in the rinse solution. The chlorine level was too great for much bacterial growth.

But, anyway, my health officer at that time was an M.D. called Dr. Viggano.

RT: How do you spell that, Dick?

RM: V-I-G-G-A-N-O. And he was a tough cookie, too. We had decided that we were going to publish all of these rim count results in the newspaper. Well, we published just one series of counts in the newspaper. When I attempted to get rim counts at the pharmacy after publishing the first results in the newspaper, they first refused entry, but they finally let me in. We used to carry an insulated box with our sample vials and ice. I started to make an inspection before I picked up the samples,

but I wanted to check something out back, and when I went out the door, they locked the door. They wouldn't let me in, and all of my day's work and the rim counts were inside. The pharmacy manager was upset because his establishment was published having a real high bacterial count and the beer establishment having zero. So I had to get the sheriff to retrieve my sample case.

RT: And you recovered your samples then, did you?

RM: Yes, I recovered my samples and went back to the laboratory and ran them.

RT: In your food work, you spoke about retail establishments. I guess you got into restaurant sanitation some, too, did you?

RM: Yes. We did inspections of restaurants and all other food service operations, including food manufacturers. The inspections had to be made four times a year. Once a year, the West Virginia State Health Department supervisors conducted an evaluation of all inspectional activities that you were required to accomplish during the year. They knew the establishment inventory, the various kinds of establishments, and they reviewed inspection reports on each establishment. If you had 250 establishments, you had to have on record 1,000 inspections. The same thing was true for the milk programs. There were other areas of general environmental health, e.g., water supplies, sewage disposal, solid waste, et cetera, that you were responsible to supervise. The evaluation was a numerical system with a minimal acceptable rating.

I did fairly well on the ratings, because in October, 1955, they transferred me to the State Health Department in Charleston as assistant-to-the-director for the Food and Milk Control Program. During my tenure in this position, I applied for educational leave in '62. I went to the University of Minnesota and got my Master's

Degree in Public Health in '63. When I was discharged from the navy, I joined the Active Naval Reserve for three 4-year terms.

The Public Health Service Region III office in Charlottesville, Virginia, kept calling me about going to work as a milk and food consultant for the Indian Health Service. I decided to go on active duty in the commissioned corps of the Public Health Service. It was easy for me, because I transferred my naval reserve into active duty time in the commissioned corps of the Public Health Service.

My first assignment with the Public Health Service was Region I in Boston, Massachusetts, as a milk and food consultant. I did not accept the Indian Health Service Assignment. Region I served the six New England states. The individual that arranged for me to become an active duty officer of the U.S. Public Health Service was located in Washington, D.C.

RT: This fellow was the personnel director for the Public Health Service?

RM: Yes. His name is William Miller. We called him "Dusty" Miller.

RT: I've heard of him.

RM: Yes. He's now basking in the sun in Myrtle Beach, South Carolina. I became a milk and food consultant in New England on April 1, 1966. In 1968, the program responsibilities were reorganized, where the milk and food program was transferred from HEW to the FDA. The new organization, as I remember it, became the CPEHS, Consumer Protection and Environmental Health Service, and ECA, the Environmental Control Administration, under CPEHS. I was not transferred to FDA as a milk and food consultant. I became the regional representative for the Environmental Control Administration, which included duties involving environmental problems in the urban setting. I set up the first Environmental Housing Control Administration in the state of Massachusetts that was accepted by the governor.

RO: Well, what agency was this in?

RM: It was in CPEHS, Consumer Protection and Environmental Health Service.

RO: Yes, Consumer Protection and Environmental Health Service.

RM: As I recall, the milk and food program and maybe some other programs went to FDA under this reorganization. Programs such as solid waste, radiation, et cetera, went to the newly created Environmental Protection Agency (EPA) from the Department of Health, Education and Welfare (HEW).

So what was left was the general environmental programs, which made up the program structure of ECA. I was assigned to ECA. Of course, I made a lot of state contacts in New England working in the milk and food program. I met Don Heaton (FDA) for the first time during the reorganization transfer of these programs.

RT: Was he district director there?

RM: Yes. Richard Davis was his assistant.

RO: District director?

RM: Yes. During this particular time, the FDA office in Boston was a district. After President Kennedy was elected, the Boston offices of HEW were designated as a regional office. I was not happy working in the ECA program areas. I still preferred the FDA-type programs. In 1970, I was transferred to Washington in a program that was called the Bureau of Community Environmental Management (BCEM) in ECA.

RT: Bureau of Community . . .

RM: . . . Environmental Management. My job there was writing policy issues concerning community environmental management problems. We developed a program called NESS, a system to evaluate the environmental status of a community, including its housing.

RT: What was that acronym?

RM: N-E-S-S.

RT: Yes, but what did that stand for? Do you recall?

RM: The National Environmental Surveillance System.

RO: Well, now was this a part of PHS or . . . ?

RM: Yes. The Consumer Protection and Environmental Health Service (CPEHS), ECA, and FDA was in the U.S. Public Health Service.

RO: You were still a part of PHS.

RM: Yes. The biggest problem with the program for me was that there was no way that you could immediately see the results of your efforts.

RO: You never knew whether they were implemented?

RM: Yes, that was one thing, and they didn't really have a really good defined measuring strategy. However, efforts of this type may take years to accomplish so they are difficult to measure.

RO: Were they supposed to be implemented by the states?

RM: They were supposed to be implemented by the states, cities, towns, and the federal environmental health agencies concerned with community development. Community environmental management is a very complex process. A successful environmental management program depends on responsible community leaders implementing the environmental safeguards in their overall management plan for the community.

RO: Were there grants connected with the program?

RM: There were some grants. The grant programs were not adequate to remedy the environmental hazards being detected in the communities.

RT: Was this at all related to the so-called Model Cities Program?

RM: The Model Cities Program was a Housing and Urban Development program. This environmental management program was the environmental aspect of what let's say a model city would be. Provide an adequate and safe water supply, safe housing, adequate solid waste collection and disposal, proper sewage disposal, et cetera.

RO: Probably if they had implemented that we wouldn't be in the problem we're in now.

RM: Yes, probably if the environmental recommendations were implemented, the problem wouldn't be so high today. In 1973, Mr. Charles Pogue from FDA called concerning a position with FDA.

RO: Of the Division of Federal-State Relations.

RM: Yes, the Division of Federal-State Relations. Mr. Pogue arranged for me to have an interview with Glenn Kilpatrick, himself, and Bob Tucker. Mr. Kilpatrick offered me a job in the State Services Branch of the Division of Federal-State Relations. So I came to work for FDA on June 26, 1973.

RT: When you first came in, Dick, you were in the State Services Branch. What was some of the work that you initially did with the Division of Federal-State Relations?

RM: Providing information to state food and drug officials on policy and positions of FDA. Soliciting information from the states on matters of interest to FDA. Mr. Kilpatrick had given me an initial assignment to explore the feasibility of developing an electronic communication system, whereby, FDA could rapidly communicate directly with each of the state's food and drug agencies, and they in turn could communicate directly to FDA headquarters and each regional and district office.

RT: What was the system being used then at that point? Do you remember?

RM: The U.S. mail. We made copies of news releases, talk papers, et cetera, and sent them via U.S. mail. If the news release or talk paper concerned a problem with a product, the information did not reach the states until several days later, and states could not respond to public inquiries or take action to remove the problem product from the market.

RT: Do you recall when those mailings were made? Were they made during the week or was there as a special time when they seemed to go out?

RM: Well, it seemed to me like--but I haven't any scientific evidence to back this up--that most news releases of product recalls always happened on Friday afternoons.

RT: That was what my question was.

RM: There were times when releases were issued during other times of the week. I think late Friday was always the ones that we remembered most.

RT: Having worked in that office with you, I seem to recall that one of the problems the states had was that the news media had the stories in the paper, and some of the states were being asked about things that they didn't have any information on Monday morning.

RM: That's correct. Mr. Kilpatrick's challenge to try to improve the speed of communication with the states. About this time, Western Union had perfected a capability of communicating via teletype. We explored the possibility of using teletype machines by putting them in the state agencies that had the larger part of their program responsibilities in the FDA-related programs. We developed a draft concept of a system that we could use. We discussed the concept with Mr. Pogue and Harry Haverland. Mr. Haverland had been with the State of Ohio Department of Health, so we wanted a state perspective of the concept.

RT: And Harry at that time was . . . ?

RM: Harry at that time was the director of the state training branch for FDA.

RT: And was that . . . ?

RM: That was 1975.

RT: Yes, that was before that branch became a part of the Division of Federal-State Relations. Is that correct?

RM: As I remember, it was a part of DFSR at that time. The concept was finalized and submitted to Mr. Ottes, EDRO, and the associate commissioner for regulatory affairs for approval. The proposal involved FDA leasing the Western Union teletype machines and physically placing them in state agencies that had the uniform Food & Drug law. To provide basic coverage for these agencies, a total of fifty-seven machines would be required, costing approximately \$125,000 annually. An alternate proposal was also submitted to place a teletype machine in all state agencies that had a program responsibility related to FDA. This would have required leasing approximately 175 machines at an annual cost of approximately \$250,000 to implement.

RO: Dick, did FDA have that teletype capability at that time? Was that . . . ?

RM: FDA had the Western Union teletype at that time.

RO: So they were communicating then with their field offices through the teletype.

RM: Yes. FDA approved the proposal to place fifty-seven teletype machines in the state agencies having the basic uniform Food & Drug law. This was a unique program, whereby, a federal agency would tie itself directly via electronic communication nationally with state agencies for exchange of information.

RO: What did you call this system?

RM: NRSTEN, the acronym for National Regional State Telecommunications Exchange Network. The name is long, but we wanted it to be descriptive. The

network connected FDA headquarters, FDA regional and district offices with state agencies on a two-way communication capability. It was a national, regional, and state information exchange network. The acronym, N-R-S-T-E-N, became nationally known as an FDA telecommunication network with the states.

RO: Well, this was two-way now, not just from the FDA to the states. The states could also come back and . . .

RM: Two way. Yes.

RT: I think one of the limitations was that one state couldn't directly communicate with another state unless they went through the field office and had the field office transmit it back to the other state, the recipient state.

RM: The limitation was intentionally built into the system for two reasons. First, we did not have approval to use federal funds to support a state-to-state telecommunication network. Secondly, we anticipated several problems could arise if any of the FDA offices were by-passed on the system. The integrity of the system depends on information being exchanged with all of the parties having responsibility in the specific information area.

While we were determined to cover every agency on the network, we didn't want to overload the state agencies with information that was not pertinent to their program area. For example, sending drug information to a food control agency. So we developed a system where we coded every state agency unit by subject area. The headline on the message contained the codes so the recipient agency with the FDA machine would readily be able to determine what agency in the state should receive the message.

Since we did not have the resources to place a communication terminal in every state agency that FDA had a program relationship with, we required the agency

receiving the terminal to agree to dispense messages to the other agencies in the state according to the subject codes noted earlier. We accomplished this by requiring the state agencies in each state that had an FDA-related program to agree through a Memorandum of Understanding (MOU) of disseminating the messages within their state appropriately. Every state agreed to these requirements so the network covered every state.

The first real test for the communications system was the Goodpasture grain elevator explosion in Houston, Texas, where suspected contaminated grain was leaving the explosion site via barge and trucks before being cleared. We used the NRSTEN system to alert the states where we suspected the grain was being shipped. The states responded by confiscating the product or notified the FDA regional and district offices for enforcement actions. The system worked beautifully.

RT: I think some of the stuff even got up as far as Illinois.

RM: Yes, it did. In fact, Illinois was one of the states that placed embargoes on the grain until FDA cleared the shipments.

RT: As I remember, you and your group were recognized or given an award for the success of that effort.

RM: Yes. So then technology changed, and we went from the Western Union teletype to electronic mail via the computer.

RT: Well, before you go into that, were there any particular problems found in the operation of the NRSTEN system? I'm not thinking so much as problems from the point of FDA, but from the perhaps lack of initiative on the part of some of the states.

RO: Well, I can see in the states, you know, if the state agencies were housed in one building that, you know, they can have a runner. But if they're housed across the city or something, which a lot of them are, why, that could really cause a problem.

RM: We had some problems with the state agency that had the terminal of living up to its agreement in the Memorandum of Understanding of distributing messages to other state agencies where the messages were coded for other agencies. We were trying to cover over two hundred state agencies with fifty-seven agencies having the terminals. The problem was minimal, and the system worked much better than we expected. When we expected a problem of this nature we conducted spot-checks on specific messages and their distribution within the suspected state. As I remember, we had to relocate terminals from two state agencies and place them in other agencies.

The basic principles of the NRSTEN system has been approved and accepted as an important tool for cooperation between FDA and the states. The first major changes to the system was changing from the teletype machine to the computer for electronic mail.

RO: Do you remember what year that was, Dick?

RM: I believe that was late 1977 or early 1978. FDA had changed over to electronic mail, so the change in the NRSTEN was done to be compatible.

RT: Well, somewhere along the line, Dick, whether it was the initial system or the improved system later, I recall that some of the managers here at headquarters, FDA managers, were observing that the Division of Federal-State Relations was getting information more rapidly to the states than our own system was to our field office, and they wanted some kind of a cloning-in on that as I recall. Is that correct?

RM: Yes, especially when we went to into the electronic mail. You could do a lot more on electronic mail than you could on the teletype machine. On electronic mail, what we sent to a state automatically went to the regional office. We didn't send anything to the states that we didn't send to the regional or district office. They knew exactly what we were telling the states. I heard from the regional/district offices that they didn't get the talk papers and the news releases as fast as the states were getting them. The only thing I can say about that is as soon as the press release or talk paper was released by FDA, we immediately put the information on the NRSTEN system. Maybe FDA's information office took longer to issue the information. I don't know.

I think sometimes those complaints were not really accurate. I think they were getting them, but I think the district offices had the same problem we were experiencing with some of the states, in that the information would get through to the FDA's information unit in the district or the region but was not being disseminated out of that room. Like a state would not disseminate information over to another agency.

RO: When you went to electronic mail, did you then go to every state agency, or were you still limited by sending it to a key state agency?

RM: We expanded to a greater number of agencies. Many agencies had computers that were compatible with the system that we were using. We put those agencies on the system, so we wound up with more agencies on the system. On the other hand, there were some states that didn't have computer equipment. FDA actually purchased some small computer units and put them in those states that did not have electronic mail capability.

Electronic mail was a lot faster; we could send more information in less time. It was cheaper than teletype, but it had one big deficiency over the teletype. The teletype provided hard copy of the message at the machine, where on electronic mail

you had to go to an electronic mail box to get a message. Consequently, we had difficulty getting some states to access the mail box.

RT: Well, I seem to remember, Richard, that some of the other agencies became aware of this telecommunication initiative of FDA and were interested in either getting in on it or duplicating it. Wasn't EPA one of those? And I know USDA had some kind of a marketing thing.

RM: Yes, that's true. USDA would have meat and poultry product recalls, but had no way of disseminating the information to state officials. We sent the information over NRSTEN for them. We also sent radioactive fallout data to the states for EPA. One of the biggest things that we did for EPA was supplying radiation level data to all state and federal agencies over NRSTEN during the Chernoble accident in Russia. We sent information on NRSTEN to state consumer safety officials for the Consumer Product Safety Commission.

RT: Richard, you, of course, were in charge of the State Services Branch for a number of years before your retirement, and I know you got involved in a number of important other activities. One evidence of the contribution you made to the states, of course, was the fact that you did receive the Association of Food & Drug Officials (AFDO) Harvey W. Wiley award. I don't recall the year. Was that about 1990 or '91?

RM: 1990.

RT: Which is the organization's highest award in recognition of your contribution to uniformity and communications with the . . . I think it's . . . What is their thesis? Communication . . . Uniformity through communication and cooperation or

something like that. So you might share, if you would, some of the other kinds of things that you worked on, which were manifold, I know.

RM: In the State Services Branch, the programs there were pretty much related to trying to initiate actions with state agencies that would supplement the type of interests that FDA had.

RT: As I recall, you have talked about expedited communications. Is it correct to recall that your staff handled many written inquiries regarding all kinds of state concerns and channeled them through the agency for development of responses?

RM: That's correct. The states have a close interest with FDA, in the fact that they both have similar types of responsibility; the FDA being a federal agency with the federal statute, and states having a variety of state laws to administer in the same program areas. We tried to develop programs jointly with the states and associations, such as the Association of Food & Drug Officials, to accomplish as much as we could without the duplication of resources and services. One of the major objectives was to share laboratory data on pesticides residue samples, antibiotic and drug residues in animal feed, et cetera. We developed a program in the State Services Branch called Health Fraud Surveillance Action Team, where the FDA district office would serve as a catalyst to assemble the various interest groups in a community that had an interest in curbing fraudulent activities. Many of the health associations, e.g., the Arthritis Foundation and so on, would bring a team together to identify what health fraud problems existed in that state or in that area.

RO: What foundation was that?

RM: Well, one foundation was the Arthritis Foundation, but there were other similar foundations dealing with health fraud. Hopefully, the team would consist of enforcement personnel, as well as resource individuals. One of the first teams that was organized was in Philadelphia in Region III, which is now called Mid-Atlantic Region. This region was very instrumental in controlling a number of health fraud activities in the region.

RT: I think another state that was quite active in the fraud area was the State of California.

RM: That's right. By the way, all of these actions on the health fraud were being passed to all of the states through the NRSTEN system.

We developed a program called the State Action Information Letter (SAIL). The purpose of the program was to share with all states the enforcement actions taken by individual state agencies. The purpose of the program was to acquaint state agencies of the successful enforcement techniques being used by some agencies and to alert all states of some problem areas that they may wish to pursue. AFDO published the SAIL letter in their journal.

RT: Were you involved with laws and regulations for a time, too?

RM: Yes, we tracked state laws and regulations in the food and drug areas. We also directed the development of model uniform laws for state adoption.

RT: Well, in that regard, were you involved in your staff--what would I say?--modifying or reconciling some of the federal manuals and so on for use by state people?

RM: Yes. We kept a continuous update of the state inspector manual to be uniform with the FDA manual and a number of other operations-type manuals and guidelines. Two of the major efforts that come to mind were the development of a revision of the AFDO Uniform Food and Drug Law and the Model Veterinary Drug Code.

RT: What year was that? Do you recall?

RM: I think both were finalized in 1985.

RT: What was the purpose of that particular code?

RM: The purpose of the veterinary drug code was to get a standard in all the states that was uniform with our own standards for veterinary drugs, for dispensing and mixing drugs in feeds, et cetera.

RT: Was there a problem that the states had in kind of regulating bobcat-type sales of veterinary drugs to animal producers? Was this code intended to control this problem?

RM: Yes, with proper labeling and licensing all distributors of animal drugs. A dairy farmer, for example, could go out to any feed store, buy three dozen syringes of antibiotic penicillin, and treat his cows for mastitis. The drug residue would stay in the cow's body for the next three days, and in the meantime, shipping the milk would continue. A big problem for a number of years has been antibiotics in milk.

RT: And then in addition to feed stores . . .

RM: Drug firms.

RT: Weren't there peddlers, people who just kind of drove the farm roads, and those were a problem?

RM: Yes. They would be loaded on the back of a pickup truck like a peddler. I always figured like a Good Humor ice cream truck. It would be loaded down with drugs.

RT: Yes, it was a business, I think. It was very hard for the states to regulate them.

RM: Yes, for the states to handle.

RT: And FDA couldn't do it from federal level.

RM: No.

RO: How was this supposed to deal with the states, then, on extra label use, because that's really what you're talking about.

RM: Yes, right. And the states could adopt that as a standard. You know, they gave the state authority to handle those kinds of situations from an enforcement point of view. And the Model Veterinary Drug Code was also compatible with federal standards.

RO: How many states adopted that?

RM: Well, at the time I retired, there were probably about five. I don't think it was finally completed, officially adopted, and put into the Council of State Governments until about '85.

RT: Their *Suggested State Legislation* publication.

RM: I retired in '88, so I don't know how many have it now.

RT: Well, from your experience with the FDA over quite a number of years, do you have an impression as to the direction the agency is going in terms of accomplishing consumer protection? That's kind of an open-ended question I know. In other words, have you seen changes in your tenure that suggest that the cause of consumer protection is improving or advancing or going new directions?

RM: I developed a really high regard for FDA. From where I worked in FDA, I thought they were always fair with everybody we dealt with. FDA was committed to make a consumer product the best it could be under the statute that it had to do it with. And from reading the newspapers--I never miss an FDA clip--I would say the commitment of the agency to its overall goal and objective and responsibility, that it's doing what it's mandated to do statutorily. Now, you can always question organization and management techniques, but as long as the Federal Food, Drug and Cosmetic Act is being carried out to what it was intended to do then I think the FDA does a good job in trying to do that fairly.

I think one of the most disrupting things to occur that made it difficult for FDA and other federal agencies to accomplish effective management of their agencies was the Employee Performance Plan system adopted during the President Carter administration. I personally think it took away the freedom for managers to be innovative, flexible, and effective. In some cases, I think the managers became more interested in the financial rewards associated with the plan rather than giving attention to the most effective way to manage their respective program areas. You can have under this system a high performance rating and a lousy overall program accomplishment.

RO: Well, Dick, since you raised that personnel matter, you are not of the general schedule personnel system. You came into FDA under the commissioned corps, which is an entirely different personnel system than most of the FDAers. Did you ever find that there may have been a little difference in the handling of commissioned corps as opposed to the GS employees?

RM: Well, I think FDA was a little different than some of the other PHS agencies. There were some PHS agencies that if you were commissioned corps you didn't go through the performance plan.

RO: You didn't share in the financial rewards.

RM: Yes . . . Well, what I meant by that is that if you were in the commissioned corps, you were evaluated under the Commissioned Officers Efficiency Report (COER). The same people doing the "COER" evaluation would also be doing the performance plan review. FDA required the commissioned officer to undergo both evaluations.

RT: So one of the inequities perhaps for the commissioned corps vis-à-vis the career civil service was that the Public Health Service officer didn't get any reward or any bonus.

RM: That's correct.

RT: Yet his criteria were the same for expectations.

RM: Yes. Although the commissioned corps personnel did not share in the pool or were even recognized as effective managers when the recipients of the awards were announced in performance plan ceremonies.

RT: . . . pool of people.

RM: Yes, a pool. See, you know I didn't get a bonus because I don't even understand the pool. The commissioned corps did not share in that program. I was happy with my personnel system, and I never had any animosity against the bonus or reward program of the other personnel system.

RO: Well, I think part of that was when the Public Health Service employees started to come into FDA, we got the commissioned corps personnel system that was so vastly different from the general schedule that I know there were a lot of the old timers in FDA that didn't exactly know how in the world you were going to deal with these people with station leave and a few things like that. It was entirely different.

RM: Sure it was.

RO: And so I think one of the reasons that they decided that the commissioned corps was going to be a part of a performance evaluation system, even if they didn't share any reward from it, was that they wanted the other FDA employees not to feel or to hear they were entirely different again.

RM: Well, you know, I didn't have any problem with doing that. I mean, it never bothered me about doing that. I just thought the structure of the performance plan concept itself had a hell of a lot of deficiencies in it, and a lot of times I thought it was a federal bureaucratic mirage when it came out. Whenever you develop a system to evaluate someone, and you've agreed to it . . . If you're management and you agree to it with an employee in January, and all of a sudden you have to have the diversity of that individual to spend eighty percent of his time to track down Tylenol that's been contaminated, or some other emergency, and he doesn't have the time to do his plan, you can have some supervisor whose staff employee could say,

"I'm not doing that. I'm going to do my performance plan programs, because that is the source of the bonus and the awards." It was not easy to change a plan to deal with the diversity problem, because the plans were tied together up through the various levels in the chain of command.

RO: Some of the problem was that in developing those performance plans . . . And don't think that I was a supporter of the system.

RM: I'm not saying who's a supporter, I just knew I was not a supporter in the way it was designed and implemented.

RO: You know, a lot of the employees didn't want to have a qualitative evaluation of this, because they were right back again. This is your judgment against mine. So that in developing these things, they were asking for a quantitative measurement so that . . . Hey, I'm supposed to do ten of these. I did twelve of them. I get a, you know, an extra rating.

RM: Well, I know that evaluation has to be a part of the overall management of any program, and I'm not against evaluation.

RT: I think the genesis of the management by objective more or less was from the Department of Defense under Secretary McNamara, and then it spread government wide. As you pointed out, some government functions are sufficiently on track that that may be a very good system, but where priorities frequently shift by emergencies, as in this agency, it's more difficult.

RO: Dick, and another thing. You served under a number of different managers, not only the first level, but also at the commissioner levels. Did you see any difference in, at least at the commissioner level, in the attitude towards, you know,

federal-state relations in any of them? Were there some that seemed to be much more supportive of it than others?

RM: Well, I always thought that Commissioner Young was very vocal in support of federal-state relations, and a lot of the proposals that went to him that dealt with states, he acted favorably on them. Sherwin Gardner: I don't know that he was anti-federal-state relations; I don't think he was any great supporter of it. Dr. Kessler: my experience with him, he seems to have supported a lot of the programs that DFSR through EDRO presented to him.

RT: Dr. Schmidt?

RM: I thought Dr. Schmidt relied heavily on recommendations of the units under him, like a field office staff, and if they thought it was a good idea, I think Schmidt would have thought it would be a good idea.

RO: You came in when Glenn Kilpatrick was head of that division.

RM: Yes.

RO: And I always felt that Glenn thought that the federal-state relations should not have been organizationally placed where it was. It would have been much better off if it was placed up in the commissioner's office. Did you have any feeling that maybe there could have been, you know, you would have had much more success in doing some of these things if it hadn't been submerged down in the old EDRO organization under the ACRA?

RM: I would personally have some reservations about placing federal-state relations in the Office of the Commissioner. I don't think you can separate federal-state

relations activities from the activities of the FDA district and regional offices. Because the field offices, in fact, are the backbone of any communication that you're going to do with the state anyway. You can provide states with all the information that you could muster, but you have to have someone to help guide them to handle the information, and the FDA regional and district offices were working with the state people all the time. So, from that standpoint, I thought DFSR was appropriately located. I think Glenn was more concerned that the DFSR be given a prominent role and identity rather than be divided and placed down in the structure of an organization where it could not function effectively with the state. I think you are seeing the dissolve of DFSR currently, which points out that current management has very little interest or concern for the states or what they do in the field of food and drug protection.

RT: Well, picking up on Ron's question, when I joined the agency earlier, it was a part of the commissioner's staff, and supportive of what you've just said, at that time it was primarily a staff office; it was not an operations office. And in more recent years that your experience has documented in the interview here, there were many operational relationships with both the field offices and the states that have been quite productive.

RM: Without the complete assistance by the FDA field offices, laboratories, et cetera, many of the operational-type programs supported by federal-state relations could not have succeeded to the extent that they did.

RO: Did you find any difference in the acceptance by field offices of some of these things?

RM: There were differences among the field offices in the acceptance of the importance of cooperating with the states. Some were strong supporters and others

were very negative toward the states. Starting around 1979, many of the negative field offices became supporters, so the negative influence on federal-state relations has dwindled considerably. I think some of the change of attitude was due to the development of better operational-type programs by DFSR where there were clearly defined roles between the field offices and the states. One such program was FOODCONTAM, where the field offices and the states shared laboratory data on food and feed products.

The food contaminant program was engineered by Dr. Bill Cobb in DFSR.

RT: He was the director of the Division . . .

RM: He was director of the Division of Federal-State Relations.

RT: And when was that? Did he come in about 1980?

RM: Yes.

RT: So that was about the time that . . .

RM: Dr. Cobb's background was in microbiology. After the food contaminant program started generating information back and forth between FDA and the states and state-to-state for that matter, it was supported by state contract funds, too, right?

RT: That's correct.

RM: In Mr. Tucker's branch of DFSR.

RO: In some of these massive FDA recalls, we'd ask the states a lot of times to assist in those. Did that come under your State Services Branch?

RM: Not entirely. Some of these recalls involved several units within DFSR. The State Services Branch primarily developed the logistics, conveyed the information to the states and field offices, and monitored the state response to the FDA request.

RO: How were the states on doing some of those recalls and things? That would be manpower intensive.

RM: The states were very good on retail food and drug product recalls. They were not as effective on the wholesale level products. However, they had one enforcement tool that FDA did not have. That was embargo power. Many times the states would embargo products at the request of FDA, both during recalls and at other times when necessary.

RO: Since we contracted with the states for certain other types of work on effectiveness checks on recalls, did they expect to get paid for that?

RM: No, I don't think that was a problem during recalls. The states were very anxious to get recalled products out of the retail chain of commerce in their state. They wanted all of the state contract money they could possibly get, though.

I think another thing that says something good about the degree of relationships that FDA had with the state people was that it was very seldom that you would hear a state director, who's a trained professional himself in most cases, ever doubt or question the decision of FDA when it came to recalls. If FDA said there was salmonella in a dairy product, as far as he was concerned, there was salmonella in the product, and he would proceed to remove it from the market.

RO: Well, Dick, is there anything . . . We've covered a lot of things. Is there anything else that you want to add?

RM: No. I think that's about it.

RO: You retired then in 1988?

RM: I retired August of '88, and it's better than working. I enjoy it. But I still follow FDA in the newspaper.

RO: You can't help it, I guess. Bob, anything you want?

RT: No, I guess not. It was a pleasure working with Dick when we were in the same office. I always had a high respect for his professionalism, and it's nice that we could have this on record for the History Office.

RM: Well, the same goes for me, Robert.

RO: Well, Dick, thank you very much.

RM: Ron, thank you very much.