

History

of the

U. S. Food and Drug Administration

Interviewee: Robert A. Tucker

Interviewer: Robert G. Porter
Ronald T. Ottes

Date: November 6, 1992

Place: Rockville, Md.

INTRODUCTION

This is a transcript of a taped oral history interview, one of a series conducted by Robert G. Porter, Fred L. Lofsvold and Ronald T. Ottes, retired employees of the U.S. Food and Drug Administration. 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 will become a part of the collection of the National Library of Medicine.

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Food and Drug Administration
Rockville MD 20857TAPE INDEX SHEETCASSETTE NUMBER(S) 1,2,3GENERAL TOPIC OF INTERVIEW: History of the Food and Drug AdministrationDATE: November 6, 1992 PLACE: Rockville, Md. LENGTH: 140 minutesINTERVIEWEENAME: Robert A. TuckerADDRESS: [REDACTED][REDACTED]INTERVIEWERNAME: Robert G. Porter
NAME: Ronald T. OttesADDRESS: Food and Drug AdministrationFDA SERVICE DATES: FROM 1962 TO 1992 RETIRED? YesTITLE: Director, State Program Coordination Branch, DFSR, ORO, ORA
(If retired, title of last FDA position)

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RO: This interview is one of a series of oral interviews on the history of the Food and Drug Administration. Today we're interviewing Robert Tucker, retired director of the State Program Coordination Branch of the Division of Federal State Relations. The interview is being conducted in the Parklawn Building, Rockville, Maryland. Mr. Tucker is being interviewed by Robert Porter and Ronald Ottes. The date is November 6, 1992. This interview will be placed in the National Library of Medicine and become a part of the Food and Drug Administration's Oral History Program.

Bob, to start this interview, would you give a brief resume of where you born, when you were born, your education, and really what brought you into the Food and Drug Administration?

RT: I was born in Centerville, Iowa, on March 20, 1926. My father, as an aside, also worked for the federal government from 1929 until his death in 1950 as an employee of the Bureau of Reclamation, Department of Interior, which took us from Iowa to South Dakota where my elementary education occurred at Newell, South Dakota. My first two years of high school were attended at that location. Then after my father's transfer to Denver, I attended both North and West High Schools in the junior and senior years, graduating in 1944. Thereafter I spent a little time in the navy.

I entered college as a part-time student in the fall of 1947 at the University of Colorado extension in Denver while simultaneously serving an apprenticeship as a funeral director/embalmer at one of the Denver mortuaries, believing that to be my career choice. Colorado's requirements for that profession at the time were the highest in the country, requiring a four-year program, two years in college devoted to a pre-med type curriculum. In the last quarter of that college time I took an elective course, Introduction to Public Health, and got interested in that field instead. Thus I got into a more "lively" career in public health.

RP: You sort of did that backwards, didn't you? You went from death to health.

RT: Well, that's right, and it was a very interesting course. I don't think you're interested in my employment that didn't relate to my original career track, so I won't go into that unless you ask about it. I graduated from the University of Denver in 1951 with a Bachelor of Science in Sanitary Science, which was a public health degree. After sending employment applications to twenty-six states and two territories and receiving a number of job offers I elected to go to Indiana rather than pursuing several West Coast opportunities. I started working as a public health sanitarian on July 9, 1951 with the Division of Food and Drugs, Indiana State Board of Health, and spent the following eleven years as an employee of that state agency.

RO: Who was the director of that agency at that time?

RT: When I was first employed, Tim Sullivan was the director. Tim always had a good rapport with the Food and Drug Administration, and he arranged for me to be interviewed at the Food and Drug Administration office in Denver by Frank Clark, who was then chief inspector and about ready to transfer, I guess, to Buffalo. So I had never been in Indiana until I reported to work.

RO: That was an early federal/state relation arrangement then.

RT: Yes it was. While working in Indiana during the 1950s I was able to observe and participate in a number of work planning conferences. These took place in Indiana with FDA district office staff from Chicago, Cincinnati, and then later Detroit when it was set up. With regard to the tomato canning industry, joint planning and priority selection were made as to whether joint federal-state or independent agency inspections would be made of that industry.

RO: Were you an inspector, then, for the state of Indiana or were you in the laboratory?

RT: I served the first few years at Fort Wayne, Indiana, a branch office of the State Board of Health, as a food and drug sanitarian. Milk Control was a separate division, but we covered all manufactured and other kinds of food processing establishments. In 1956 I was transferred to the La Porte, Indiana, branch office, which covered the northwest part of the state.

In August of 1957 I was selected as a headquarters branch chief assigned to implementing and developing administration of the Indiana Household Poison Registration Act, which was enacted that year, being one of five pioneer laws in the country in that field. The Indiana law was somewhat unique and distressed the industry, because we required formula registration as well as precautionary labeling. The formulation data were used for a poison control center reference in emergencies. Much of those data were shared later with the Food and Drug Administration's National Clearinghouse for Poison Control Centers.

RO: Did this registration of the formula, did that also include a submission of a sample for analysis?

RT: No, we didn't analyze samples, but the chemical specialty firms did have to reveal their formula, and a lot of that industry had never before experienced that kind of a requirement. The only similar experience they had was with a New York City fire code which required combustible labeling. The Indiana law really got the ire of industry. It was passed at the end of the state legislative session under sponsorship of the Indiana State Medical Society before an industry lobby against its enactment could be marshalled. So as a result, many of these firms were supportive later of the Federal Hazardous Substances Act at the federal level, primarily I think to blunt other enactments like Indiana's.

I had the privilege of speaking at several national conferences of chemical specialties manufacturers. At a national conference of the Chemical Specialty Manufacturers Association in New York City, I was introduced by a representative

from Dow Chemical as a young man from Indiana, here to talk about the Indiana bastard law. So it did stir up something, and we enforced it vigorously. And I guess that's one of my early accomplishments that I kind of treasure recollection of in field work.

RO: You know, a number of states had what they called an Economic Poisons Law. I suppose this was similar to the Indiana law?

RT: Well, this was more extensive. The old Caustic Poisons Act, the federal act, was I think the kind of law already found in many of the states. But this new legislation reached all kinds of household chemical specialties that were becoming involved in episodes of childhood poisoning. It was really a pioneer law, and it was a wonderful experience in dealing with an industry that wasn't used to being regulated in that way.

RO: Did that include cleaners and things . . .

RT: All kinds of household cleaners and other potentially harmful household products which if ingested or inhaled by infants or anyone, but particularly small children, could cause serious injury.

RO: Then it also included pesticides and . . .

RT: Well, pesticides were regulated under the Federal Insecticide, Fungicide, and Rodenticide Act, so our state law made provision to recognize that labeling but to require the filing of the formulation in a repository that all of the state medical and poison control folks had access to on a twenty-four hour, seven-day-a-week basis.

RO: Well, was there a fee connected with that registration?

RT: Yes, twenty dollars for each product registered. I remember Tim Sullivan coming in one day to ask "How many products are you going to register this year?" I picked a figure out of the air, and it turned out to be reasonably accurate, about two thousand, which I think we met that first year of the program.

RO: So you had a desk job then.

RT: I had an administrative desk job. For a while I didn't have an office, when I first came into Indianapolis, and there was just piles and piles of work to be done. I recall one visitor representing Sterno from New York City. He was quite adamant that their product shouldn't be subject to the Indiana law. I finally told him, "Well, you have a choice. You can either comply with it or we'll seize all of your product where we find it." When he left, Tim Sullivan said, "You know, if all your visitors are going to be as noisy as that guy, I've got to get you an office. I couldn't hear myself think." I was right outside his office in a little cubby hole, so then I shared an office with Frank Fisher, his deputy, who of course, upon Mr. Sullivan's death in 1961, succeeded him as director of the Indiana food and drug program.

When Jim Pearson, director of FDA's Office of Federal State Relations came along in 1962 to offer an opportunity to join his office, I approached Frank, who said, "Well, you've got to make the decision. I don't want to lose you, but you've got to decide whether you would rather be a big fish in a little pond here or a little fish in a big pond with FDA where you can move around and maybe get a lot more opportunities." So thus I elected to join FDA and reported for work at the end of April in 1962 along with Charles Pogue, who had been recruited from the Kentucky food and drug program about the same time.

When I came into the Office of Federal State Relations it was a relatively small office. Jim Pearson had come in from I think Seattle. He had been, I think, district director at both Atlanta and Seattle in his earlier career and chief inspector in a place or two. He was brought in to take charge of the agency's federal state

program that had been started originally by Bill Queen, a former North Carolina state official who in 1913 organized the Office of State Cooperation. It was a one professional person job with a secretary for all of those years until Mr. Pearson took over. He also operated alone for a year or two with a very competent lady, one of the most competent secretaries I've ever known, a Mrs. Cahill. Jim recognized he needed some state persons on board and obtained Commissioner George P. Larrick's permission to recruit some state officials.

He first recruited Bill McFarland from the state of Arkansas. He had earlier been a Missouri official. Mr. McFarland came in I think in 1958. The next two recruitees were Glenn Kilpatrick, Utah Department of Agriculture, and Charles Orr of the Missouri Health Department who came on board in 1960. The year I reported, a young man, Kenneth Poole, from Idaho was on board. I think he had been recruited in 1961. Oliver McKagen, who was an FDAer with earlier work in New Orleans and then in FDA's headquarters Press Office, also came over to Federal State Relations in 1961.

RO: Was this office then a part of the commissioner's office?

RT: Yes, it was called the Office of Federal State Relations and was a part of the Office of the Commissioner and remained so until Joseph P. Hile as the EDRO reorganized some of the agency. It then became a part of the EDRO organization. I don't want to jump around too much. I do want to comment on that, keeping a little bit on the same track, though, regarding the development of the Federal State Relations Office if that's OK.

RO: Yes. Were you still located in the Office of the Commissioner during Commissioner Goddard?

RT: Yes, we were, because during that period the office had been consolidated with two other units to form an Office of Legislative and Governmental Services, comprised of the Office of Legislative Affairs, the Office of International Affairs, and the Office of Federal State Relations. That organization was directed by Paul Pumpian, an ex-state official. He had been secretary of the Wisconsin State Board of Pharmacy and had joined the Bureau of Drug Abuse Control (BDAC), a couple of years before. Commissioner Goddard selected him to head this consolidated group. Later, although I don't recall the exact dates, the federal state relations staff was moved as a unit into the EDRO organization. The Legislative and International Affairs offices were also separated and again assigned elsewhere in the agency.

There were both advantages and disadvantages in my view to the EDRO acquisition of the federal-state relations function. Previously, while in the Office of Federal State Relations, as part of the commissioner's office, we were a very clear focal point for all in the agency for federal-state relations, issue resolution, policy development, clearance, and correspondence, etc. When the unit came into the EDRO organization we then lost that prime reference identification point in that there were other elements in the agency that either were then becoming more active or were created to handle federal state relations type matters. One of these existing groups was the intergovernmental staff under Dr. Jim Miller in the Bureau of Radiological Health. That group was reluctant to join the EDRO organization, resisted it successfully, and continued to function in the bureau, although one or two persons came over temporarily: e.g. Herbie Klein, who then kind of got into some other things such as EDRO's data information systems. Lois Miller also served in DFSR for a time before returning to BRH.

Another facet, though, of divisiveness in the federal state relations function occurred when Taylor Quinn in the Center for Foods--or perhaps Bureau of Foods, whatever it was at the time--developed a Division of Cooperative Programs, under which was placed the milk safety, shellfish sanitation, and retail food protection programs.

RO: Well, that happened after those Public Health Service programs were transferred to FDA.

RT: The transfer to FDA occurred in the reorganization of 1968, I think. In FDA these cooperative state program staffs did not really have an organization of their own in the bureau or the center, which they did after the Division of Cooperative Programs was formed. That fact kind of fueled the concept that, "The people in the field working these specialties are ours, and we can relate directly to them; we don't have to go through EDRO." The staff in the field in the respective disciplines were in fact EDRO and later ORO employees, not center employees. This created a little bit of competition with the Division of Federal State Relations which had then been formally assigned the headquarters coordination roles for these programs.

RO: Of course, prior to the transfer of those programs to FDA, the states would go directly to those units when they were in the Public Health Service for technical assistance. Isn't that right?

RT: That's correct, and that continued. We had the problem of a state official or FDA field representative writing in to one of the centers' food cooperative program staffs and getting a direct answer back that might have been of broad interest either across the state and local agencies or across the FDA field force. It was this one-on-one type communication that we had to muscle in to more or less get in the flow so that we could serve our assigned function of sharing information of common interest with all appropriate state and local officials and field FDA people.

RO: Well, maybe I missed it when you were telling about this before, but did each one of the districts and regional field offices of FDA have a milk and food representative?

RT: No, they really didn't initially for interagency cooperation, in general. When I first became aware of the Food and Drug Administration's organization, as a state employee, we worked pretty closely with Chicago district and Cincinnati district as Detroit district had not at that time been developed. There was good rapport, primarily because in the State of Indiana where I worked, Tim Sullivan was a very strong advocate of cooperation and was very prominent in the Association of Food and Drug Officials of the United States--AFDOUS, as it was called then--being president and active in all the committees. And he was very committed to interagency cooperation.

The state organization where I worked, we were trained to write the FDA-type comprehensive inspection reports--the only staff element in the branch offices that did that. And we irritated, I guess, the sanitarian engineer managers who were in charge of those offices by loading the secretaries down with all these voluminous reports on dictation spools. We also worked closely in joint activities with the FDA people and received a lot of training from those folks in milling and canning and other food industries. In turn, we trained some of the FDA's new folks. Jerry Bressler was a young plebe who came down with Charlie Curry from Chicago, and we helped Mr. Curry train Mr. Bressler in the canning industry in Indiana. So it was an exchange orientation.

However, when I came to FDA, I saw that that wasn't the picture across the country. Federal state relations in some locales, primarily attributable, I guess, to the FDA manager and perhaps corresponding state manager attitudes, it wasn't universally a strong kinship of working together. There was a lot of state and FDA staff attendance at meetings where good rapport was talked about; but as far as real program cooperative work, FDA kind of did its thing, and many of the states did theirs. FDA called on the states when they needed embargo assistance or in emergencies, but otherwise kept a little bit of distance. This was sometimes resented by some of the states, because it was kind of like the FDA was looking down their nose at state people and generally regarding them perhaps as more incompetent or

less elite. That was a problem in some districts more than others. However, I have observed that this issue has through the ensuing years largely been put aside by programs that have been developed for working together.

Jim Pearson was a committed communicator and spent a lot of his time traveling to meet with state officials. Often traveling by automobile, he would make various stops in his schedule trying to establish better rapport. However, the Second Citizens Advisory Committee Report--and I don't recall the year of that, whether it was 1962 or 1964--observed that the Food and Drug Administration's federal state relations program of that period was primarily one of seeking goodwill and not of working together. That concerned Mr. Pearson a great deal. He was both hurt and concerned about that feeling on the part of the state officials serving on the Advisory Committee.

One of the spin offs, I think, was the development in the mid 1960s of a voluntary work sharing, or MOU program, that eventually included about thirty-seven agreements over a broad variety of interagency cooperative activities in which the agency agreed to work with the states. As that program went on down line a little bit, EDRO Paul Hile at one of the RFDD meetings questioned the merit of all these MOUs, because some of them seemed to be paper exercises. He instructed the FDA field managers to look at these and rescind those that were not meaningful, and then develop other new working relationships that are operational, not just showpieces. That has occurred, and I think today there are about fifty-seven MOUs and five COPE, or Coordinated Operation Plans for Emergencies voluntary agreements. This expanded program has put the agency on the road of really working and planning work with our state counterparts.

The state contract program, which came along in 1972 . . .

RO: Before we get into that stage, could we back up a little bit, Bob, when you said that the units of the Office of Legislative and Governmental Services included Legislative Affairs, and International Affairs, and then the Federal State Relations.

When that split occurred, who headed up the various units? Paul Pumpian was the director of the whole group and then . . .

RT: He was, and Dr. Kenneth Taylor, a veterinarian, headed up the International Affairs. Glenn Kilpatrick was the director of the Division of Federal State Relations.

RO: And that's when that came to the EDRO organization then.

RT: That's right. The sequence of management of the Division of Federal State Relations, as earlier stated, kind of began in modern times with Jim Pearson, and Bill McFarland, his deputy, who headed the office when Jim retired in 1965. That was about the time Commissioner Goddard was setting up some regional associate commissioners, of which Ralph Bernstein of the New York Department of Agriculture and Markets became the RAC, as they were called, in New York City. George Sooe, Baltimore District Director, became the regional director down at Charlottesville. Bill McFarland became the regional director at Dallas. When Bill became interested in that pursuit, his interest somewhat waned in the Division of Federal State Relations and in the state organizations that we had worked with. At that time, he had some serious questions about the efficacy and usefulness of the Association of Food and Drug Officials, looking at that organization as one that met every year and never seemed to get very much done. I think he had a similar view of some of the other state organizations as well.

So after Bill's departure, Glenn Kilpatrick became the division director and helped further develop a number of new FDA-state cooperative programs.

(Interruption)

RT: Mr. Kilpatrick was an exemplary leader in this field, and he continued as division director until his death in 1980. Dr. William or "Bill" Cobb of North Carolina Department of Agriculture came in and served as director until he left the agency to become the state chemist in Texas. Heinz Wilms, who had earlier as an executive development fellow been in the division as chief of the State Services Branch, then came back from the Center for Drugs to become the Division of Federal State Relations director, which he is to this time.

RO: Well, I think when Glenn took over, he kind of reversed Bill McFarland's position on AFDO or AFDOUS, didn't he?

RT: Right. I'm glad you've prompted me to recall what I wanted to say. Glenn Kilpatrick was perhaps one of the most committed zealots for federal state relations the agency had seen up to that point. He really believed in it. And at many agency meetings he would ask the question, "Well, what about the states?" I believe there were a number of times when some of the other agency program managers would have liked to have pushed him down and said, "Quiet, Glenn, quiet. We want to think about FDA." Glenn was very gifted and influential in bringing the state perspective to many agency issues and decisions.

When Bill Cobb came in he brought a little bit different type of leadership. Bill was a little bit more of an introvert than Glenn, who was the eternal extrovert, optimist, and marvelous impromptu speaker. We used to have a lot of planning sessions where Glenn would have lead extensive discussions. As one of the grunts, I used to think, "Well, Glenn, this is great, but we're going to use all our time up talking about this before we get down to getting the work done." But we always somehow got it done anyway, and with the benefit of a strategy that Glenn had developed.

RP: You know, you talk about Glenn's enthusiasm for federal state relations. I like to take a little bit of credit for that, because he and I worked together in Salt Lake City when he was just a beginning inspector. We had not only close relations in terms of exchanging information, but we did a lot of operational work together. I even took him out and did some goat cheese inspections because I had some experience in that and other kinds of things.

RT: Bob Keating was another FDA person that used to work with Glenn a lot out of the Denver office. So Glenn had established, as had I in Indiana, a real admiration and respect for FDA's mission and people.

I might interject something else as I think about it. In the early times there were a very few of us in the federal state relations staff. A number of people were subsequently recruited. I think we got up to about twenty-six people in the original federal state relations staff; then we began to have specialty assignments, mine being hazardous substances because of my state experience; Bob Wetherell in medicated feeds; Ed Turner from the Ohio Board of Pharmacy was the drug person; and so on.

In the earlier years when Charles Pogue and I were there, before the office got larger, Jim Pearson's modus operandi was to have a lot of staff discussions. These usually involved Bill McFarland, his deputy, Charlie Orr, Glenn Kilpatrick--the original foursome. We had kind of a court jester in Oliver McKagen. He frequently became irritated because of delays in being able to get direction or counsel from somebody. Once he said, "You know, this whole outfit ought to be renamed. It ought to be called the Division of Closed Doors." We all thought that was kind of humorous.

When I came in our office was in HEW North, right inside the Independence Avenue entrance door. Two days later we moved to Tempo D, and then subsequently to several other locations. We were among the first occupants of FOB 8, and at lunch would check on the progress of the new building. In the first five years of my service with the Federal State Relations Division, that unit moved to different

locations ten times before finding a more permanent home in the Parklawn Building in Rockville.

When we were in Tempo D I believe our boss, Jim Pearson, a true southern gentleman with fine etiquette, believed he had to kind of season some of us rubes coming in from the states. He did this in a very gracious way. The office practice was that we all waited and went to lunch together. We would walk down Independence Avenue from Tempo D to the HEW North cafeteria. Oliver McKagen, who was one of the more assertive of our group at the time, was irritated because of the habit of waiting until about 12:10 or 12:15 to go to lunch. He said, "You know, I get tired of waiting around like this."

We used to kind of walk down Independence Avenue in file and in order of seniority. Jim Pearson and Bill McFarland, and Glenn Kilpatrick and Charlie Orr, Ken Poole and Oliver McKagen, and then at the end of the string would be Charlie Pogue and Bob Tucker. We'd interchangeably be the last one in line. The point is, there were seven of us and Jim. So McKagen came back one day and went in to see Jim as he often did after lunch. He said, "You know, Jim, I'm kind of embarrassed hearing other guys in FDA talking about Snow White and the Seven Dwarfs going to lunch." Immediately thereafter we had a divided lunch period, and the long wait for lunch was ended.

Jim Pearson was a courteous man and a man of etiquette. He usually got a bowl of bean soup and a salad for his lunch, although some of the rest of us were bigger eaters. But Jim, when he finished his meal, would sit with his arms crossed, as would the others, until the last person at the table had finished their main course and was ready to start the dessert. Being a person who liked a big lunch and usually quite hungry, I plowed right on into my dessert. Looking up, I saw all these folks sitting around the table, including Jim, Bill and the others, like Indian chiefs with crossed arms because somebody else was still on their main course. I put my fork down and folded my hands and waited my turn. Well, we discovered that as each new person came in, they had to be similarly coached in this subtle way. And we'd

always laugh. As it happened to several others, they would do as I had done, and then lay their fork down and wait. So he gave us some instruction on etiquette and social refinements that we'd missed in our earlier state careers.

When working at the state level, I always admired Shelby Grey, who was then district director at Chicago and later came in to headquarters to set up the first Office of Planning and Program Evaluation. I also admired Ken Milstead, who was director at Cincinnati, as well as Chet (Chester) Hubble who was Cincinnati District director too, before I left Indiana.

When I came in to work for FDA we were sent over to an FDA orientation class, and Shelby Grey was one of the speakers. He said, "Now, folks, you'll find one thing in the Food and Drug Administration. No one person completes anything alone." As ensuing experience and years have gone along I've seen the truth of that. It's really a teamwork organization, but somewhat of a frustration to some of us who came in from the states. We were used to smaller organizations; we were used to doing things without getting a lot of clearance. I was really kind of irritated with the FDA clearance process. I thought this was the most military organization to be a civilian outfit that I had ever come into contact with, because you couldn't do hardly anything without getting countersigns, even sending something to people in the field. It was really sort of a mother hen syndrome at work, and they didn't let any of us new state people go out on our own or do hardly anything independently until we had served our plebship and they were very sure we weren't going to go out and embarrass the agency. But in retrospect, I guess that was good.

Becoming a part of the mid-management-level group, I lost the awareness of that, but when I first came in here, I was impressed with the management team and was kind of awed by them and really respected them. I'm not sure that that same aura exists anymore. We said, "Mr. Commissioner," and treated with respect J. Kenneth Kirk, and Allen Rayfield, and Winton Rankin, Malcolm Stephens, and all the top level folks. Jim Pearson, after I had gotten so he thought I was ready to go out on the road, told me one time, "Well, you know, before taking a trip I always go

around and see Malcolm Stephens and Winton Rankin to find out what's going on." So I did that. I went into see Malcolm Stephens, who was a very gracious man, but I also learned in a courteous way that I shouldn't presume that I was Jim Pearson and come in on him without prearrangement. He gave me the information, but he asked if after that I would make prearrangements to see him. So I told Jim, "You know, we new people don't have quite the credentials you have as a long veteran and manager in the agency."

In those early days we, as a division, handled great volumes of correspondence. Very little inquiry processing was done at the regions or at the districts at that time. So we got all these voluminous letters, and we would be heavy user clients of the Division of Advisory Opinions.

RO: Was this inquiries coming in from the states?

RT: From the states, right. We would go over to the Division of Advisory Opinions and there are some people there that I remember with pleasure being associated with. Walter Moses was a man that always had a tremendous volume of work on his desk, but he always had time for you. You'd kind of know you were intruding on him, but he was very gracious. He'd lay his work down and talk to you. There was a fellow by the name of Abe Lederer, who was the key person on drugs, and Abe had two pens. He had a green pen and a red pen. We'd usually try to develop a draft as best we could and take it over and get it reviewed. Abe always had to wordsmith your draft. You had to say things his way or they weren't right. He would take out his green pen and edit your draft when it wasn't too bad, but when he took that red pen out, it was a sign that, boy, you really missed the mark altogether.

Harold O'Keefe was a pleasure to deal with, because Harold never worried too much about using a structured bureaucratic way of saying something as long as you were communicating the requested information, and he was a pleasure to work

with in that respect. Al Hoeting was a young and budding advisor in those days in the medicated feed program, an understudy of Ralph Kneeland, who was sort of the key person in that area. Ralph was always a helpful person to us. Chet Hubble, of course, had gotten to that office, and he was usually pretty helpful. He was a little more prone to change things than some of the others. Sidney Weisenberg was also a helpful individual. Morris Yakowitz was always a very thoughtful and helpful person. And then, of course, in hazardous substances, Dale Miller and Earl Burton were the persons that we related to in those programs, and they were both nice to deal with.

At that time the agency relied very greatly on PC (previous correspondence), and they had an extensive reference file. Two ladies who were very helpful and very organized in managing that function were Mrs. Pendleton and Gretchen Prohaska, whose husband was a scientist in the Bureau of Foods. Early in my FDA letter writing experience I learned we should only say that "we regret" something, not that "we were sorry" for something. I was told that the Food and Drug Administration is never sorry, but we regret whatever the delay or error had been.

One other experience that I thought was unusual. Guy Stevens, the director of the Utah program after Glenn Kilpatrick had left, wrote in to inquire about use of annatto in butter. That inquiry was taken to the desk of Mr. Kirk. When I pursued trying to get an answer, Mr. Kirk told me rather candidly, "We're not going to answer that letter." To me that was a surprise that the Food and Drug Administration wouldn't at least acknowledge or answer a state letter. So Guy Stevens went to his retirement and death, I guess, without ever knowing what FDA's position was on annatto in butter.

RP: Is that because of the question involved, or was it because of Guy Stevens?

RT: I'm not sure; I can't discern.

RP: Guy Stevens was a mighty peculiar man. (Laughter)

RT: That might be--I can't say. Well, I've rattled on a while. Is there any direction we want to go?

RO: I want to go back to when Legislative Affairs, Federal State Relations, and International Affairs were all together. When Federal State Relations was put into this group, you were moved in there as a body. Was there a previous body that had been designated as the Legislative Services group?

RT: Legislative Services was under Will Swain, who later retired and moved to Rome, Georgia. The Division of Federal State Relations, at least under Glenn's direction, sensed that they were kind of second or third string, not first string group, on that team. I always felt Glenn sometimes looked at things through rose-colored glasses as though the primary mission of the Food and Drug Administration was to work with, cooperate, help, and assist state governments. Now that's the attitude he should have, but sometimes it seemed a little unrealistic. As long as in the same mix you have Legislative Affairs and any other group . . . Well, Legislative Affairs is going to have to be the lead resource section, because the Congress has some very stringent requirements on responses and they are the source of our salaries and are our resource providers. But Glenn always kind of felt that the Federal State Relations staff were kind of at the far side of the consolidated office system.

I once got bawled out by Deputy Commissioner Winton Rankin without at the time knowing it until we got out of his office. Glenn had some chomping-at-the-bit concern about the states, and so I went into see Winton with Paul Pumpian, and I brought it up. Mr. Rankin didn't really say yes or no regarding the issue and I kind of kept going at it. Mr. Rankin, being another southern gentleman, never really told me outright to "shut up!" But after we left, Paul said to me, "You know, Rankin was getting irritated at you. He meant no." And I said, "Well, I guess I was just trying

to carry out a proxy representation for Glenn . . ." I then realized, and we agreed that we'd let Glenn speak for himself in the future.

RO: How did it happen that you were there with Pumpian rather than Glenn?

RT: Well, again, we were in there on a legislative matter, and I brought Glenn's issue up.

RO: I see. And you had taken on some legislative responsibilities rather than just federal state relations.

RT: That's right. The way both Robert Wetherell and I got over on the legislative side of that consolidated group was we used to spend a lot of extra time at the office. I've done that my whole career. When I was a state person I never watched the clock. That began before I was married, and when I got married I didn't change my style. My wife saw me when I got home. And I'm still that way. And so Paul Pumpian saw me there after hours, and he said, "You know, I like your work ethic. I'd like you to come over to legislation." And I did that. And then he said, "You know, there's another guy over there that I see around here a lot longer than anybody else, and he always seems to be busy, and that's Bob Wetherell. Do you think he'd want to come over?" And I said, "Well, why don't you talk to him." So that's how Wetherell got in the legislative track. And then I through a course of time got the head of the legislative staff that worked with the bill reports and testimony. As you know, because you were up there to help me find another location, I had begun to think, "That's not what I want to do for the rest of my career."

RO: Well, when was the period then--it was after Pumpian left apparently--that Merle Ryan came in?

RT: Merle Ryan. Right from Baltimore District.

RO: That was just on legislative affairs.

RT: That's correct. At that time it had been separated out, and Pat Ryan came in. I think Pat did a good job in many respects. He didn't genuflect quite as much as some of the people in the department would have appreciated and he operated as though he was still in the field office talking to other investigators when some of the department people contacted him. So there was a period there when things got a little turbulent. When Wetherell succeeded Pat, I think he smoothed those problems out. Bob was always a conscientious person and an accommodator, which may have ultimately led to his reassignment years later to the field, because he was helping the wrong committee staff, politickly speaking.

RO: Yes. You've been with FDA for a number of different commissioners, and has there been any difference in their attitude as far as federal state relations?

RT: Well, I think each commissioner has had an individual perspective. I think those persons that I remember best were perhaps more positively, overtly committed to federal state relations, e.g. George Larrick. At that time, though, the mandate for Jim Pearson when he had a small office staff was primarily to keep a good intelligence gathering operation, since at that time the agency wasn't really prepared to go into a lot of shared operations with the states. Perhaps in my judgment only, the next most positive federal state commissioners might have been Dr. Goddard and Frank Young. Frank Young as a person was more gregarious and more outreaching at conferences than many commissioners have been.

When Don Kennedy was commissioner, he was involved in a lot of things, and that particular year, Glenn Kilpatrick had really generated some work on the part of the AFDO executive board about the issue of preemption. An AFDO white paper

had been developed, and a number of state people had input to that. Ray VanHuss and a number of people. This document had been sent, as we always do, as an advanced communique to the commissioner regarding what the executive board might be interested in discussing during the annual conference with the agency. Glenn had seen that Commissioner Kennedy had a copy of this white paper and that this would be their discussion preference topic during his period of time with them.

(Interruption)

RT: OK, to step back and perhaps build a lead-in to what I was about to say, the agency has for many years worked closely with a number of state organizations, the lead, perhaps, of which is the AFDO or AFDOUS organization, being the first such organization that really tried to develop a rapport with the agency. And it was at the request of AFDO that the Office of State Cooperation under Bill Queen was originally began in 1913. So through the years there's been an effort to work closely with this organization. Traditionally the commissioner of Food and Drugs has been the keynote speaker at their annual meeting.

We've developed similar rapport with other organizations, such as the National Association of State Boards of Pharmacy (NABP), the American Association of Feed Control Officials, the Association of State and Territorial Health Officers (ASTHO), and the National Association of State Departments of Agriculture (NASDA), et al. So these organizations have come to look to the FDA commissioner as their keynote speaker at their conventions, and have traditionally invited the commissioner to their annual conferences. In addition, through the years we have developed a series of annual planning and briefing conferences with the executive boards of these organizations. We've had those meetings traditionally each year.

Coming back now to what I was about to say with regard to the white paper on preemption, this was a contribution that the state AFDO executive board members had developed to bring to the agency's attention their concerns about

preemption. So in the meeting with the board the year that I referenced, Commissioner Kennedy came to the meeting, and it was very apparent at the outset he had never looked at this preemption paper at all. And this was quite a disappointment, I think, to the AFDO board members. The main purpose for these agency meetings with the AFDO and other state organizations was to provide the commissioner or the center or bureau directors and other policy level managers to make presentations of what's going on in FDA. Also, to elicit state views on needs for greater interagency cooperation.

(Interruption)

RT: Historically, the executive board members really had never been asked to do very much except to come and communicate back what they'd heard to their state peers. So it was a disappointment to Mr. Kilpatrick that here we try to make a breakthrough and make them work a little bit, and they've done it, and now there seemed to be disinterest on the part of the commissioner, primarily because he hadn't found time to even look at the white paper.

Another time . . .

RO: Not realizing, apparently, that this preemption as far as the state people are concerned is a mighty sensitive issue.

RT: Right. Now that's one thing that, I guess, I would comment on with regard to the current way of appointing and having commissioners serve. The past is not necessarily good, but one of the merits of the old system was that George Larrick and others started out as a chemist or investigator and eventually worked up to be commissioner. Such career-developed commissioners had an opportunity to both learn and appreciate the value of intergovernmental relations as well as long-term agency objectives. When, under the current system, commissioners change as

political administrations change or even more often at times, in fairness, these commissioners don't necessarily have the opportunity to assess their own priorities in terms of long-term effect on consumer protection or the agency per se.

(Interruption)

RT: In addition, because of the more frequent appointment of commissioners and depending on their own orientation of priorities, some really haven't had the opportunity to take cognisance of state concerns or to really become familiar or comfortable with what some of the states have done. Generally, most all top administrators speak of the need and desire for good cooperation, and sometimes circumstances then create a different impression on the part of the state people.

Sherwin Gardner, who never was commissioner but served as deputy and acting commissioner for a time, came to one of these AFDO executive board meetings one time with the *Washington Post* in his hand. And so rather than making any comments, he just kind of sat there after being introduced and waited for something to happen. The executive board group were also waiting for him to begin, because they thought he was carrying them a message. He made the comment, "Well, if we don't have anything to talk about, I guess I can read the paper." Instead of there being a spontaneous dialogue initiated by the acting commissioner, there was a chasm of silence that was detrimental to good federal state rapport.

(Interruption)

RT: In the current administration of the agency, Dr. Kessler was a real breath of fresh air and encouragement to everyone, I think, about more active compliance. He came to the initial meeting with the AFDO executive board, attended as keynote speaker the AFDO conference in Grand Rapids, Michigan, and has met with the

AFDO board and other AFDO representatives several times. Because of the nature of the immediate commissioner's office organization that he's developed now, there are more individuals becoming involved in some of these interagency coordination roles. Through no fault of anybody sometimes a few faux pas have been made.

For example, the Association of Feed Control Officials (AAFCO) wrote and asked for the commissioner to speak at their national conference several months ahead of time, which he declined and asked that they approach another member of his senior staff. This senior staffer somehow never got anything done, and the invitation languished for several months until Federal State Relations was asked to investigate the nonresponse. Ultimately Bill Schwemer represented the commissioner in a very fine, effective way. But during the interim period this organization certainly had every reason to conclude, "I guess we don't amount to much in the Food and Drug Administration's view." And that's unfortunate, because I'm sure that's not the commissioner's desire.

Some of those kinds of things can happen. I guess my own thought is that it would be good if someone who was really grounded in institutional experience could be a part of the commissioner's inner circle. I think two of those individuals are, at a kind of distant location in the commissioner's current staff, are Dick Ronk and Bill Schwemer. The new people can't be expected, of course, to have the institutional memory and institutional awareness of the stature of some of these intergovernmental relation organizations or to appreciate the "political" attention they deserve from the commissioner's office.

Now as to, you asked about commissioners in a more broad sense. I think all the commissioners have been, at least on the record, supportive of interagency cooperation. There's one commissioner I've been trying to recall, and that was the rather slender man . . .

RO: Was it Dr. Hayes or Dr. Goyan?

RT: Dr. Hayes, yes. Anyway, most all of them have been quite good regarding intergovernmental cooperation. Dr. Edwards, I think, impressed people outside the agency as a very structured and proper fellow. State officials are like everybody else; some of them are indiscrete. One state official one time said, "I don't know how we can trust a fellow who never has a hair out of place." He recognized Dr. Edwards as being a very organized person. I thought one of the disappointments, and I believe it was Dr. Edwards who went to an AFDO annual conference, and when one state official who is less than maybe the more prominent thinker type discussed during a private session of the board with the commissioner the problems of grease on bakery cartons in donut bakeries. My question was what can Dr. Edwards be thinking of this organization if that kind of discussion is raised with the commissioner of FDA?

I think federal state relations has to be a two-way street through actions and discussions that result in mutual respect.

RO: You've mentioned before, Bob, I think, MOUs, memoranda of understandings, and contracts. When did we really start in on contracts with the states? What brought that about?

RT: Yes, that's a good point. In the period of the late sixties and early seventies I think the agency was under scrutiny from several sources, GAO studies, and perhaps OMB inquiries, and so on, about how we were dealing with problems in the food industry. A lot of efforts had been made to build up the drug clearance process, and Commissioner George Larrick had worked hard on that before retiring. Anyway, some of these studies indicated there was a high incidence of violations in the food industry. So there were two measures taken.

Clifford Shane was brought in from Cincinnati District to train a number of new investigators recruited under what was called Project Hire. It was recognized that there was going to be a training lag time before these people would really be out

there effectively doing compliance work. There had been an \$8 million escrow account, as I understand, set aside for developing a new facility at Chicago. So part of the \$8 million was used for Project Hire, and 4.3 (million) of that amount was proposed for use in contracting with the states to help us do food inspection work. The Division of Federal State Relations developed a proposal and sent it out as a feeler, and we found that the states did have that interest in doing food industry inspections for FDA under contract. So the program really got implemented with FY '72 funds, but operations really began in FY 1973. I think we had thirty-seven states initially involved, primarily in the food related activities of food sanitation: bottling plants, grain elevators, bakeries, and so on.

It was recognized that through the years state medicated feed control officials had been very cooperative with FDA since we had turned them around from primarily going in and making inspections for economic enforcement--fiber, fat, etc. The states had been trained and redirected to investigate cross-contamination problems with animal medicants in feed mill establishments. It occurred to us that they really ought to be included in the contract program, too, and be compensated for the cooperative work they had been doing with the agency.

RO: Had the agency, FDA that is, been accepting the states inspections of these medicated feed establishments?

RT: I think they had, although they had accepted them with qualification. I think we were still at the point that if we saw state inspection reports we used those as sort of an index of a problem. If there was a problem reported we sent our own staff out to confirm it. So we really hadn't gotten quite that far along. So that was the next group brought into the contract program. Then the x-ray area was added to have the states do field checks on compliance with federal x-ray standards. Later, we got into more special project activities, and now quite a broad array of medical device, human drug, and other kinds of projects are operated under the state contract program.

The budget increased and at one point got up to about \$8.5 million, but it was also a good striking target for the needs of the agency for resources and the SLUC (standard user level charges) by GSA. We found in one of those years that there was \$2.2 million needed more than the agency had planned for, so that amount was taken from the state contract account to pay GSA the SLUC account. The problem that it created for us and the staff that I had . . . Bob Dickinson and Gary Beard as project officers (very competent men who had done a marvelous job through all the years of this program) required incrementally funding of contracts and otherwise planning resources for the state contractors in a way that we didn't actually drop them. We had early recognized that many federal programs come in and fund state activities for a year or two, then they are withdrawn and the state either has to then find funding of its own or release personnel. We had committed at the outset of the state contract program that, pending available funds, we would operate it for at least three years.

This program has been a good federal state relations venture in a number of ways. It has brought our people in a forced way into planning conferences together with state officials across the nation. It has put our field managers in contact with state program managers in terms of state resource capabilities and so on, as the field has an endorsement responsibility for all the state contract awards that are made.

RO: Has this been accepted equally among all of our field offices?

RT: Well, at the outset of the program, and you were still here at that time, Ron, there were several district directors that were quite adamant that this was not the way to go, that these funds could be much more productively and usefully applied to our current activities. Paul Hile (the EDRO), in a meeting here in the building, finally put the gamut down by telling the field managers, "Look, we have these funds, but we have a personnel ceiling and we're going to do this." The detractors or less enthusiastic field managers as in any good organization, got into the swing of things

and were very supportive thereafter and made it work. I could name a number of people that were in that group, but I don't know that we want to do that.

RO: The states vary in their abilities to conduct certain types of inspections. Was there any way at all in monitoring the quality of their work after you let a contract with a state?

RT: We did. We had to, of course, develop a quality assurance program and we used the statisticians' input to develop a field management directive that called for the audit of state work within a lapse time of not more than thirty days in any case after the state inspection. An audit inspection, statistically based, again, in terms of the number of firms that a state would be contracted to cover was made by FDA field staff. And there were a few problems that were found, and those were eliminated, usually by the state, and, in a case or two, by non-renewal of a contract. In one state (Pennsylvania) some people in the medicated feed program were really not competent. There were a few other instances. By and large, the program was a success. We provided training where it was indicated, joint training and some formal course training through our state training function. For the most part the program came off quite well.

The entire program has been audited a couple of times. We had an internal FDA audit, and that never really came to fruition because it showed that the half-life of compliance by state work was just as good if not better than our own. So we didn't think that was a desirable conclusion to publicize, and that study never got beyond the draft stage. GAO also came in at one point and did an audit, and again, I think the commissioner affirmed the merits of the program. Well, they came up, as GAO often does, with a number of unusual ideas, one of which was not contract for a year and then see if it's any loss. Well, you can't drop and pick up with state governments on a lapse year contract program.

That touches on, of course, another assumption at the federal level that the states will do what we want them to do, that we can kind of draw all the parameters and they'll agree with them. Well, state government has different orientation and different responsibilities from their state legislatures and so on. One of the problems in a funding program like contracts is that in many states the revenue received or the remuneration received for their services goes into a general fund, so in a sense, the program manager deprives himself by being a cooperator with the federal agency, because then he either has to successfully petition his budget office or his legislature for restoration of those funds or lose them.

RO: I was wondering if some of the states took that as a means to cut back the state's program appropriation if they got some federal contract money.

RT: Well that's another consideration. That was a particular response in the state of Kentucky and some other states. So they've had to be rather chary as to what they get involved with and how much.

RO: What's the dollar fund now? It started out at \$4.3 (million) and you said it went up to \$8.something . . .

RT: Yes, and then it dropped down. It's really kind of a roller coaster across time. It's now about \$6.2 (million). After Gramm-Rudman--of course, that was an impact from which the funding level has never recovered. Of course, a million or two are frequently reprogrammed before it gets to the state contract program. That's an administrative decision made at upper management levels.

RO: Was this a line item appropriation?

RT: No, it wasn't. So again, that's a management discretion on how general appropriated resources are utilized within the agency.

RO: We haven't talked much about a lot of the individual state leaders and things in this program and their reaction to the Food and Drug Administration. Some of them, as I remember, have been rather opposed to FDA.

RT: That's right. At the time I came in to food and drug work at the state level, there were a lot of people both in the state organizations and in FDA who were sort of elder statesmen or long experienced persons, many of whom had taken these government jobs at state and federal level during the Depression era when government work was truly attractive and certainly more secure and stable. So many of those people were almost at retirement stage when I began my career, and many of them at both state and federal level retired in the several years following my work in the field.

At the state level there were a number of rather notable and outstanding people. One person . . . Well, I'll name a number. Milton Duffy in California, I think he retired with over fifty years of service. He was a pharmacist and had become a strong state administrator and kind of a czar. When we came into Food and Drug, Charles Pogue and I once reasoned whether he had been recruited for Milton Duffy and me for Ralph Horst or the reverse. Ralph Horst, a former FDA director at Denver, after retirement had gone to the Florida Department of Agriculture.

It was kind of an interesting question, because these two gentlemen generated more written inquiries to FDA than any other state officials in the nation. There was a difference. Mr. Duffy asked a lot of questions. When he got the answer, he either used it or didn't use it, but he was satisfied. With Mr. Horst almost every response generated a debate or a complaint that he needed more information than he was given. One of my first personal experiences was I had written something to Mr.

Horst, who wrote back to Director Jim Pearson and said, "You have a fellow by the name of Tucker on your staff now. He didn't answer my question very well." So Jim came in with the letter and laid it on my desk and said, "Write Mr. Horst again, will you?" So Ralph still got the same guy writing him, and I guess we finally got him satisfied. As I understand, Mr. Horst when he was a federal manager also seemed to need a lot of nurturing from headquarters people.

Other prominent cooperating officials included Abe Abramson in New York City who was an active metropolitan health agency person. Ralph Bernstein in the New York State Department of Agriculture and Markets was very active, and Dr. Vincent in Florida was a very prominent state official. There were a number of other key state people, Evan Wright, who was a sort of elder statesman in the state of Kansas with strong states' rights views. The state of Kansas, as a matter of fact, when the state contract program began, declined to become involved initially because they didn't want federal funds dictating the direction of their program.

RO: Evan didn't always agree with the federal government.

RT: That's true, he didn't. You had Harold Clark in Connecticut who was succeeded by Eaton Smith, both of whom were very prominent and active state officials for many years. There was Ken Carl in Oregon. All of these folks that I mentioned so far were active in AFDO and served on either the executive board or were president. There was a fellow by the name of Lyle Littlefield in the state of Michigan who was kind of a burr under our saddle. He always kind of liked to back you up against the wall, so when I used to go out to the central states association meetings I always appreciated George Daughters, who was the director of Detroit district. George would let Lyle nibble at you about so long, and then he'd kind of come in as a mother hen and let Lyle know, "It's enough now. Let's start being nice." Lyle later left the state and went to work for industry with Gerber Foods. I told him

one time, "You know, Lyle, you're a lot more pleasant guy to see at meetings than you used to be when you were a state official."

So we did get criticism at times. You know, the counties like to blame the state, and a lot of the states like to look to FDA to pull their chestnuts out when maybe they ought to be doing more of it for themselves. We had a guy in Texas (Joe Lakey) who was very active and critical through the Second Citizen Advisory Committee report, as I previously cited, of what the agency was doing or not doing with the states.

RP: Joe Lakey wasn't a very cooperative state official, was he? He didn't get along with people very well anyway, did he?

RT: That was my impression. That's right.

RP: You know his brother was state chemist, and he was an entirely different kind of man. A really nice guy. Of course, chemists tend to be that way. (Laughter)

RT: (Laughter) I suppose. Well, and speaking to one of them here now, I'd better agree with that. But anyway, we had active officials in Illinois and Ohio which were states that seemed to be a little more political than some of the other states. Lowell Oranger (Illinois) and Ray Davis (Ohio) were however aggressive enforcement officials.

With regard to people in New England, the state of Connecticut has usually had a strong leader. As I mentioned earlier, a fellow by the name of Harold Clark was in charge of the Connecticut program when I first became aware of other state programs. He was succeeded by Eaton Smith, a man who has made a very notable record of being a state food and drug program leader even into his retirement has remained active.

Mary Heslin, former commissioner of the Connecticut Department of Consumer Protection, in which the Food and Drug program is located, has also been a nationally prominent person, not only in food and drug, but also consumer product safety areas and serves now as an executive director of the AFDO organization since leaving her official post.

Dr. George Michaels of Massachusetts was an interesting character in many ways. He would come to conferences, including national conferences, and make a very convincing and profound presentation about Massachusetts since that state enacted the first food and drug law back in about 1864 or '67, somewhere in there. Then he would disappear and he would not be available for anybody to question about what was really going on in his state. His presentation was interesting but usually wasn't borne out by operations at his state level. He was an interesting man, also in that he's the only state official I am aware of who ever convinced his state legislature to give him a lifetime appointment in his job, which didn't occur in that some ethics discretions in accepting goods without payment brought upon his involuntary retirement.

What used to impress me as a young plebe at the state level is how these folks would convene and seemingly discuss ad infinitum issues that I wondered, "Is this the real concern of consumers?" And even at the AFDO meeting once in St. Paul there was a food committee discussion of Pillsbury Butter Cake Mix. The concern was that it wasn't real clear that butter wasn't an ingredient of that product. So I asked my wife when I got home, "If you buy a Butter Cake Mix, do you expect the butter's in there, or do you expect to add it?" And she said, "Well, I add it--of course." Well, balloon bread and other kinds of issues perennially were discussed at a lot of these meetings, and you really wondered, "Is that the main thing that the consumer on the street is concerned about?" And a lot of times I think the professionals got caught up in the, as Commissioner Alexander McKay Schmidt used to say, "the thicket of thin things." I thought that was a very good way of putting it since regulators can get lost in the less important issues of consumer protection.

I think the states fail sometimes to get involved with some more important things. I believe one of the most parochial groups of state officials are the milk officials. They don't seem to want to get into a lot of new things, although they're kind of being forced to do that now with the drug residue problem. Feed officials are a little bit the same way. They kind of have tunnel vision regarding their own program issues. An example of that, AFDO, as one national organization, has tried to get the consumer product safety commission and some other interests involved in their organization. When those speakers come to talk at their national conferences on drugs or consumer product safety issues, about half the audience walks out. So a lot of state people are parochial in their areas of professional interest; yet they're in the field of protecting consumers. I think the agency has succeeded in many respects to bring a broader insight to state regulatory officials in recent times through its cooperative programs.

RO: In the thirty years about, I guess--well, more than that when you consider your time with the state of Indiana--have you seen a difference in the role that AFDO plays in FDA matters?

RT: I think it's becoming more active. Sometimes it's time to get new people or different people involved. I think some of that has been happening. There's a new generation of state managers coming into play now, such as the Dennis Bakers and Dan Sowards of Texas, and John Misock, past president of AFDO from Wyoming, Tom Messenger of Colorado, Stuart Richardson of California, Tom Masso of Minnesota, and many others.

(Interruption)

RT: There are more backward or uncomplicated states getting involved in national affairs. And they're asking for audiences and getting them with FDA field and

headquarters managers. I think many are becoming considerably more active and broadened in their perspective. And they're becoming a little more assertive--and I suppose that's an apropos term--more expectant of FDA to work with them, to do some new and different things and not just the traditional side-by-side independent role activities. I think there's a definite gain as far as interagency communications are concerned.

In the earlier times we had no really good communication medium to the states, and we used to mail out information. As you know, government and Congress always make decisions on Friday, and we would be stuffing envelopes and sending out policy statements and press releases, recall notices, and whatever. Some of that mail got to the state addresses Monday, Tuesday, or Wednesday of the following week. Monday morning early, if not before, these state people were being approached by their local press, and they didn't know what the Food and Drug Administration said or was going to say on hot issues. We had the same problem in our own agency at our field offices and resident posts.

RO: Sure.

RT: As a matter of fact, I think it was Anthony Celeste, when he was here, kind of grabbed onto the NRSTEN idea for our own people, because some of the state people were getting messages earlier than some of our own staff in the field.

RO: You ought to describe what NRSTEN is.

RT: Well, the NRSTEN (National Regional Telecommunication Electronic Network) was set up several years ago to place a telegraphic receiver, one per state, in a host state agency. That was usually decided between Departments of Agriculture and Health and Boards of Pharmacy. Usually it was either Health or Agriculture. The problem was not that the message wasn't getting out quickly

enough. The agreement was that if I, the Health Department, have the unit, I will promptly notify my colleagues in the Department of Agriculture or Boards of Pharmacy. However, that wasn't happening very well in a number of locations.

RO: A lot of times those two units were fighting.

RT: They were, and some were competitive. You might have a lower grade person handling messages and not recognizing when something was important. And then some states, as we later learned, weren't reading their mail. They just weren't picking up on what they already had in their receiver unit, and sometimes even complaining about what they'd already been sent. That has gotten better. We've continually had and continue to have the expectation by many state people that they want to know as soon as the media. And there's no way we'll ever beat that; however, with the advent now of FAX usage, I think they're getting much better communications, more rapid, and we're encouraging all of the states to more fully utilize the FAX technology. It's facilitating, expediting submission of inquiries and so on.

One problem in communications: a lot of state people like to pick up the telephone and call in here, or even preferably call all over the agency directly to FDA staff and verbalize a question expecting a good answer. There's a lot of problems with that, so we continually have urged, "Put it in writing, because you usually get a better question." Sometimes people ask things they haven't really thought through or haven't framed in a way that you can really respond. So you send it down to Foods to a Ray Newberry or somebody there, or to Compliance to Dan Michels, or to whoever, and they're hard put to, (1), answer it, and (2), to be very interested in it unless it is presented in a coherent and descriptive text.

RO: We've talked, Bob, an awful lot about AFDO, and one of the things we should do, but before we leave this, I'd like to mention that our interviewee here, Mr.

Robert Tucker, has been the recipient of a very prestigious award from AFDO, the Wiley Award, which is awarded only to those people that are active in the association, have made significant contributions to the organization. That was several years ago, but for the record, congratulations.

RT: Thank you. That was in 1987. Yes, that was probably one of the biggest surprises in my life. As a matter of fact, just before the presenter was starting, I thought, well, this would be a good time to go to the rest room. And my associate, Richard Moats came in there with big wide eyes wanting to know what's the matter with me, and I said, "Well, I'm just getting ready to listen to this presentation." So they got me back to the banquet room, and as it went along, I never dreamed it would be me. I really felt stupid in retrospect on my response. It just kind of took the wind out of my sails. But then maybe if I had expected it, that wouldn't have been very good either.

RO: By reason of the regulated industry attendance at the AFDO meetings are the states and FDA better able to deal with them on regulatory problems? A lot of it is social, but there's an awful lot of business that goes on at those meetings, and there's some of the sessions that the regulated industry is excluded from, but for the most part they're open meetings.

RT: You know, my own impression is that it's a desirable involvement. I think the organization and others have always been quite discrete or want to be very discrete so that there's not an apparent conflict of interest development through those contacts. I would think they are. I think the sensitivity of the agency after the generic drug problem arose has made an impact on greater awareness on the part of federal people, at least, not joining in industry representative sponsored dinners and so on. And that has to be done in a discrete manner, too.

I think Heinz Wilms, the current director of the Division of Federal State Relations, and several of us, where we've faced that situation, have told the industry person that if we join we'll pay our own, but we've tried to do it in a way that didn't embarrass the state people by implying we're better than you are because you take a free meal here or there. In earlier times, I think we tried to exercise judgment and not cause embarrassment of state people because we didn't want to appear better than they were, but it is a real issue. And I think it's being handled in a careful manner by federal folks now, as well as by many state officials.

RO: Anything more you want to say about some of the state programs and state people?

RT: Coming back for a moment to Tim Sullivan, who during his tenure as leader of the program in Indiana did become a nationally prominent state official. He used to go around and give lectures on food and drug law, yet he never saw the inside of a law school. As a matter of fact, I don't know that he had a college degree. He was sort of a Horatio Alger success story. It's been my observation seeing him and another person who I don't think I'll name (an FDA person) with similar limited college education who have really overcompensated, striven, and done more in their field than many persons with a Ph.D. because of drive and commitment. Tim and my unnamed FDA friend certainly had that.

Tim Sullivan had one faculty that I always admired. When we started the hazardous substances program in Indiana, we frequently met with representatives of the chemical specialties industry from all over the country, and Tim would sit in on some of those. We had retained the state toxicologist, and I found it rather interesting that while some of the standards that we made for required labelling were empirical based on research of the literature and his experience, many of those were later sustained at the federal level. Tim in some of these conferences wouldn't maybe know very much at all about this product or the industry, but he had a faculty

of asking very poignant questions, and pretty soon he was asking questions of the visitor that they were finding it hard to answer. I thought that was a marvelous ability.

As a matter of fact, as a manager of the program, he had a great ability to make people enthusiastic. K. J. Baker, an associate of mine in those early days in one of the branch offices and a member of my FDA staff in recent years, and I would sometimes get a little bit discouraged, particularly when the state sanitary engineering staff would get higher increment salary increases than the sanitarians. Therefore, we'd go down and see Tim. Usually Tim really couldn't do anything for us, but by the time we left his office, we were really grateful to be working for him because he imbued such enthusiasm for what we were doing.

RP: I was tremendously impressed when I first met Tim, when I went to Indiana to testify in a case. And I had a kind of a jaundiced eye for most state people. But anyway, I thought Tim was really a charismatic fellow.

RT: Well, I think he was, and this is a good point to pick up. Well, at the time I was there, the Indianapolis (Cincinnati district) resident inspector was quartered in the Indiana State Board of Health, and as a matter of fact, I shared a room with Don Martin and Fred Carlson and several other resident inspectors that went through that station. Both Martin and Carlson had come from Boston where they had worked with state people in the New England area. And one state, Massachusetts in particular, had a director that was kind of maverick, even among his peers there, and certainly raised some question about his ethics and integrity on many occasions.

So as these people came in to the Indianapolis resident post at the State Board of Health, they tended to be rather secretive and avoided letting anybody know where they went as they didn't want any tip offs and so on, because they had apparently got that impression of state operations in Boston. As they were each there, they soon learned, or they learned in time anyway, that the people at that state

agency were as reliable as federal people although without federal salaries. And it worked out very well. As a matter of fact, the resident who had been there when I first arrived and preceding Mr. Martin was Ernie Adderholt, who had been there for eleven years. And Ernie Adderholt operated just as though the secretary at the state food and drug office was his own secretary. He would always let her know where he could be found and so on. So it was a good positive state to work in as far as FDA relations are concerned.

In a sister state, Kentucky, there was another prominent state person in office at that time, Sarah Vance Dugan, who was a lady who was a very personable and convincing, effective state administrator. She did not at that time have a modern food and drug law, and her peers in that central state region used to kid her about Dugan law, because she would postulate an enforcement position which couldn't have been sustained at all if it had been challenged in court, but she convincingly got a lot of compliance before her legislature finally enacted a uniform state food and drug statute.

RO: You mentioned a uniform law. How many states now have a uniform food and drug law?

RT: Well, as I recall, the Association of Food and Drug Officials first developed a Uniform State Food, Drug, and Cosmetic Bill in 1939. It was subsequently updated several times. And I think now we have about forty-five states that have what is considered the uniform law, and most of the other states that don't have it have amended their older laws to strengthen them, although some don't have all the provisions of the federal act to this day.

RO: Bob, it used to be that the states were very political. But are the top administrators in these states really subject to change of the political party in the state?

RT: Well, I think in the food and drug arena, by and large that's not now the case at the program management level. At the commissioner or secretary level, such as in either Departments of Agriculture or Health, these are cabinet positions, and they do serve usually at the pleasure of the state administration.

RO: Well, some of those, especially Agriculture, are elected, aren't they?

RT: They are elected, and some of them have had tenure for many years. Doyle Conner in Florida. Yes, Conner was a recent retired commissioner of Agriculture in that state and served as an elected official in that capacity for nearly thirty years. So there's not necessarily rapid turnover in that regard. Many states have merit systems. I think the examinations, for example, for qualification in California may exceed the federal entrance examination. The educational requirements in that and other states continue to rise, and the quality of personnel certainly is on the upswing.

RO: I'm just curious about the salaries of a lot of the administrators in the states. I would imagine it varies from state to state, but do you have any idea how they would compare, let's say, with something in the federal government?

RT: I think generally speaking federal employees, federal managers and administrators are higher salaried than state persons. That was certainly an incentive in my case to come to the Food and Drug Administration, seeing more career development potential, although my first year here was not a salary increase. I at state level was receiving \$7,200 a year annual salary, and my first year with FDA was \$7,200, which was a net loss, considering a move at my own expense. However, over time certainly I've been able to achieve much more than state work would have provided. That's a frustration for a lot of state people and presents an opportunity that the agency frequently has of picking up very competent state people for the greater career opportunities the federal level provides.

RO: When did you officially retire from the Food and Drug Administration?

RT: My official retirement date was the third of October this year, 1992. So in my career I've worked kind of in the federal/state arena for forty-one years, as I spent eleven years in Indiana, and had a lot of opportunity for intergovernmental dialogue and work with the Food and Drug Administration, having fortunately been in, at that time, a positive Food and Drug Administration oriented state agency. Unfortunately, that state I think in ensuing years with a loss of some of the people with real charisma and commitment has gone more back into its shell and doesn't hold the place of national prominence it once did. That does occur from time to time. A lot of the success of state programs is attributable to the commitment, resourcefulness, and abilities of the leaders.

RO: Well, of course, they're affected by budget the same as the federal government is.

RT: Exactly. You know, one of the areas of the country that has always been kind of problematic on federal state relations is California. I think it's attributable not just to FDA's leaders there, but also to the state agency. McKay McKinnon, who was a long-term career person out there, I think had a pretty good rapport with the states, maybe because of his long tenure. Those were again days in which only limited real interplay of operations occurred. Irwin Berch and Ron Johnson and some of the other folks that have been there since I don't think have really established as good a rapport with the state of California as had Mr. McKinnon.

On the state side in California, going from Milton Duffy to Jim Bell, who was brought into the state from the National Canners Association primarily because Mr. Duffy never groomed anybody to succeed him, and then to Ken Buell and Chambers Bryson and now Stuart Richardson, this succession of state administrators has not been as ready to roll over and play dead at FDA's suggestions. Mr. Richardson who

serves currently on the AFDO executive board is certainly one of those assertive members that calls the shots as he sees them, whether or not they align with the consensus of our FDA managers.

Individuality in the states I think is good. I think one of the errors in the federal government dealing with states is a presumption of predominance, a presumption of clearer defined priorities, and so on. To cite a personal example, I worked in a pioneering area--hazardous substances--and was very active and I think very successful in that state in that program. Then I came to the Food and Drug Administration, and the federal hazardous substances program was just getting underway. Talking to some of my associates in the agency here, one would believe that it all started here. It didn't all start here. It started here because some of the states such as the one I worked in, had generated the support of industry to have uniformity and get federal legislation through active enforcement of the state law.

So what I'm leading to is there's sometimes a presumption of implied superiority, which I think is something that the agency needs to continually work on to keep in proper perspective, not only from the commissioner but right down to the working investigator. Maybe one of the needs of the agency in this area is for some kind of an orientation session for indoctrination or orientation of new personnel regarding working with other agencies especially the states. While there will always be parameters beyond which we don't want to share some kinds of information except when it's properly protected, we don't have to play secrets with reliable state partners.

This recalls to me that the Division of Federal State Relations, in response to the states, developed as one of our first training initiatives, a series of inspection training courses for state people. It was called a Food Inspection Techniques Course, and a number of these were presented around the country in the 1964 and '65 period. I took one course up to New York and, because of the orientation of two individuals up there, had kind of a hard time with it. Weems Clevenger was then the district director, and Harold Post, who later came to headquarters and headed up training

here were concerned that the Division of Federal State Relations was getting in an area that they hadn't ought to be. So they kind of blackballed our course and called ahead when it was to subsequently go to Buffalo to alert the staff over there that, "Hey, really watch these guys. They're skating on thin ice."

I was susceptible of criticism from Weems Clevenger because I had talked about tolerances, and one of them that I had referenced was a mold count tolerance for tomato products. It was indicated I had given away an agency confidence. Industry knew what it was; everybody knew what it was. But in those days we weren't going to tell anybody anything our managers thought they didn't need to know. Well, we've come a long way away from that position today. Weems later being very supportive of intergovernmental cooperation. In fact he initiated a cross-commissioning process where he got some of his staff people credentialed to carry New Jersey state commissions. I talked to him about it one time and chided him about how he had been so concerned about me talking about mold counts, and he said, "Well, that was a different era." So he'd learned, too.

RO: Yes. Interesting.

RP: I think it's really good for you to get into this interview some thoughts like you've just been talking about. Good work. What advice could you give FDA to do a better job in this whole area? And you've just been talking about that. If there are any other phases of that, why I think you should keep talking.

RT: Well, I think that one thing that we're coming to a realization of and I think conscientiously working at it is to try to involve the states in early strategizing and policy or regulation development to the extent this is practical and achievable.

(Interruption)

RT: Continuing, the agency is moving ahead to I think work more closely with the states in getting them involved in the decision process. There's some practicality limits to that. There's also some very solid resistance in certain areas. In the Center for Foods and the retail food protection program, the manager is very reluctant to let some state people, namely AFDO, come in there, I think, and be involved in some of the code development.

In fact, speaking of faux pas, I think we have one currently there, and the agency recognizes it, and that is the Unicode Initiative. This is a project that would consolidate several separate codes for food service, retails, food stores sanitation, and I think beverage sanitation requirements and so on, all in one master code that might be then adopted by state/local jurisdictions. The problem is that the project has gone on for so long that the interest and zeal for the project has been largely lost by state/local officials and even on the part of industry that is going to be affected by it. It's an example of a situation where we have gotten ourselves so far along with a project that we apparently feel we're beyond the point of return.

Our field food specialists staff and state and local officials through their organizations are saying to us, "This isn't the most important thing you can do for us. You could give us interpretations of the current codes that are lapsing interpretation, and that would be more useful to us." The retail food protection program manager has been put in recluse more or less to finish the job, because it's now becoming an embarrassment to the agency at large. It's an example of one of those things that calls for an earlier assessment of the real interest and need and/or assuring resources to facilitate completion rather than letting the project languish over too long a period of time.

RO: This is a little different though than the regulations that we develop.

RT: That's correct.

RO: The agency develops codes that are meant for the adoption by the states, don't they?

RT: That's true.

RO: And so this isn't that type of code.

RT: This code, if completed, could be adopted at either the state, county, or municipal agency level.

RO: Didn't we have some problems as far as getting input from the states on regulations early on because of statutory limitations?

RT: That's true. The sharing of administrative confidential or investigatory information was a problem, and the commissioning of state officials--which is sort of a means the FD&C Act provides to make them deputies or special government employees thereby imposing confidentiality restrictions similar to those of federal employees--has been a way that we've been trying to get the states involvement and counsel earlier on. This past year Ronald Chesemore, associate commissioner for regulatory affairs, has assigned to the field the task of commissioning members of executive committees and boards of the major cooperating organizations of food and drug officials so that these officials then can share in early review and response.

RO: Well wasn't there a problem at one time, Bob, if the program manager were commissioned, but his boss for example was not?

RT: Well that's true, and we still have that constraint. That's a problem particularly when you have some either appointed or elective officials who may have holdings in regulated firms and they really don't want to give that up. Some states

don't find that a problem, whereas it is a problem at the federal level. So we may still have some occasions when the commissioning is not the answer to the problem.

RO: Yes.

RT: Let's see; I was going to say something else. Jumping back to the FDA commissioners as a thought occurs to me . . . I always thought it was kind of interesting, when Dr. Herbert Ley was commissioner, the way that he prepared for Congressional hearings. It was a common practice for the legislative staff to brief the commissioner on the proposed testimony when it's been developed prior to a hearing.

I mention Bill Goodrich, the former general counsel, here too, because Mr. Goodrich frequently would listen to all the comments around the table and then he'd say, "Well, I don't think this testimony is going the right direction at all." And as a member of the legislative staff at the time, I used to just absolutely deflate. I thought, "Oh, gosh, we've done everything we knew how to do, and now this man says it's not very good." Well, the merit of Mr. Goodrich was that he would take it and usually do what it needed to have done to it, but at the day before the hearing it was a rather startling pronouncement to hear from him.

I mentioned Dr. Ley. Dr. Ley was a very orderly commissioner and liked to do things on schedule. When we'd come in for these hearing briefing sessions he had a little oven timer like you would see in your home kitchen. And he'd say, "How long is this going to take?" You'd say, "Well, maybe a half an hour, Commissioner." So he'd set it on thirty minutes, and when the buzzer rang, that meant it was either over or bring it together real fast. I thought that was kind of a practical and interesting way of managing those meetings.

RO: Frustrating, though, to a lot of people.

RP: You're not the first interviewee that's mentioned that. (Laughter)

RT: And then, of course, there was another time when Dr. Goddard was commissioner when we were all seated around the table, and Mr. Alfred Barnard, who was a rather portly gentleman, was up near the commissioner. And a very demure, petite little girl who was on our staff, Judy Moore, was seated on the right side of Mr. Barnard away from the side of the table where the commissioner was seated. During the discussion the commissioner, as I recall, had a belch or something like that, and not knowing there were any women in the room, he felt at liberty to be one of the boys, I guess. So little Judy looked around the rather protruding stomach of Al Barnard, and that was the first time Commissioner Goddard knew she was there. So as we filed out, the commissioner said, "Next time make sure she's in front so I can see her." (Laughter)

RO: Anything else, Bob, you want to add?

RT: Well, in my early days I mentioned to you that I thought this was a very sort of structured organization, and Mr. Allen Rayfield was a very resolute and respected, if not feared, manager of the field at the time. I hadn't been there very long when I called up I think George Schwartzman, who was chief chemist out in Cincinnati, on a rather mundane matter, and I wrote a memorandum of telephone call. Mr. Rayfield, who read all of the circulating files, noted that and called my boss, Jim Pearson. Jim asked me to go over with him to Mr. Rayfield's office to discuss this impropriety on my part. I should have gone through, of course, Fred Garfield, I guess, and let Fred have called George. Fred was the chief chemist for the agency, then, as I remember.

Well, we went over there and I got a mild chewing out by Mr. Rayfield, but he never looked directly at me. He just looked at the wall. And I thought that was kind of strange, but I later heard from some of the other people that they sometimes, in his absence of course, referred to Mr. Rayfield as "old wall-eye," and I assumed maybe that was why, because he looked at the wall when he chewed people out.

(Laughter) But I thought, again, that that was something I wouldn't have had to do at state government. I could have called anybody in the organization without going through channels.

RO: As you know, since Rayfield left that has changed in the agency.

RT: That's right.

RP: Just as an aside, since you mentioned Rayfield, I interviewed him some time after he retired, went to his home down in Florida. And when he took off his guise as an important executive and so on, he became one of the nicest men you ever knew. He acted the way he acted apparently much of the time because he felt that was his duty and that was the proper way for a man in his position to act. But basically he was a very nice man.

RT: I made a similar discovery about J. Kenneth Kirk. I never thought Mr. Kirk was a vindictive fellow, but I always kind of thought he was very serious, maybe bordering on stern. When I was in the legislative office I had frequent opportunity to go in and see him on things. He once said to me, "I bet you hate to come in here, don't you?" I thought to myself, "Yes, I do," but I didn't tell him that. I found out through the course of those contacts that he was a very nice gentleman. I think a number of the top level people at that time may have felt, as Mr. Porter has just observed, a need to put on a rather austere countenance as part of being where they were.

I never felt that way of George Larrick; he was commissioner when I came in. Jim Pearson had made arrangements for a little write-up and a picture of both Charlie Pogue and I to be in the FDA Monthly Review Publication. George Larrick saw me in the hall--I had never been formally introduced to him--but he came over and welcomed me on board. I was just a flunky, and I thought that was kind of nice.

RO: Things changed.

RT: Yes.

RO: Well, Bob, if there's nothing else, we want to thank you for this interview. Bob, anything you want to add?

RP: No, I don't believe so. Also, though, if there are any publications or anything that you've had that you would like to make part of this transcript just as addendums to it, why we'd be happy to do that.

RT: OK. Well, I've got a lot of stuff at home in boxes. I don't know whether . . . I'll get around to look at them sometime maybe.

RO: This will end the interview.

(Interruption)