

History

of the

U. S. Food and Drug Administration

Interviewee: J. David Clem

Interviewer: Robert A. Tucker

Date: October 25, 1994

Place: McLean, VA

DEED OF GIFT

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J. David Clem

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CASSETTE NUMBER(S) 1 & 2GENERAL TOPIC OF INTERVIEW: History of the Food & Drug AdministrationDATE: October 25, 1994 PLACE: McLean, VA LENGTH: 90 minutesINTERVIEWEEINTERVIEWERNAME: J. David ClemNAME: Robert A. TuckerADDRESS: 1624 Craig LaneADDRESS: Rockville, MDMcLean, VA 22101FDA SERVICE DATES: FROM: 1961 TO: 1987TITLE: Chief, Shellfish Sanitation Branch, Bureau of Foods
(Last FDA position)

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RT: This is another in a series of interviews in the FDA oral history program. Today the interview is with J. David Clem, former chief, Shellfish Sanitation Branch, Bureau of Foods at the Washington headquarters of the Food and Drug Administration. The interview is being held in Mr. Clem's residence in McLean, Virginia, and the date is October 25, 1994. Present, in addition to Mr. Clem, is Robert Tucker. The transcript of this interview will be placed in the National Library of Medicine and will become a part of FDA's oral history program.

Dave, to start these interviews, we like to begin with a brief autobiography. Would you start with some of your early years, where you were born, raised, educated, and include any work experiences you had prior to coming to FDA.

DC: OK. I was born in Everett, Washington, and spent twenty years in that area growing up and being educated. I attended public schools there and then went to the University of Washington, where I graduated in 1960 with a bachelor's degree in civil engineering. Shortly thereafter, viewed with a necessity to serve my military obligation, I wanted to find a way to do that and at the same time use my newfound knowledge in engineering. So I learned about the Public Health Service Commissioned Corp needing sanitary engineers. I made out an application and was accepted for a job in Washington, D.C., in early 1961. I entered government service at the same time that President John Kennedy was being inaugurated. This was a time when there was good feeling about being hired for government service. People came to work in a lot of different programs, like the Peace Corps, and there was just a resurgence of patriotism about how you could serve your country.

I started with the shellfish program at the outset. I was hired as a staff engineer in a headquarters job. There were a large number of different kinds of activities even though it was a very small program. It only consisted of just a few people.

RT: David, I might ask you at this juncture, was that in the Public Health Service rather than in the Food and Drug Administration, the earlier Public Health Service organization?

DC: Right. I'm leading up to the early stages where I began in the Public Health Service in what was known as the Bureau of State Services. The Bureau of State Services housed a number of environmental-type programs, such as air pollution, radiological health, solid waste, the interstate carrier program (which was concerned with public water supplies), the milk and retail food sanitation program, shellfish, and the sanitation program. These were all embodied in what was called the Bureau of State Services. At headquarters, we were responsible for development of guidelines and standards; training of state personnel; and research and standards development. Headquarters for doing R & D in-house was primarily located in Cincinnati at the Robert A. Taft Center. The PHS also had grants and contracts, which supported our extramural research programs. Another large activity was the development of policies and interpretation that went to the Public Health Service regional offices as well as our concerned and involved state health officials.

RT: Do you recall, David, at that point who was the surgeon general or head of the Public Health Service? That was in the Kennedy administration, wasn't it?

DC: No, I can't recall the name of the surgeon general at that time.

RT: How about the Taft Center? Who was heading that?

DC: The Taft Center director? I don't recall the director of the center, but heading up the milk, food, shellfish research program was Dr. Keith Lewis. He, of course, played a part later, as I'll mention, when PHS/FDA had the transition. The main point that I wanted to emphasize historically was the strong federal-state

relations that the Public Health Service and state health departments enjoyed and, of course, with some state agriculture and conservation agencies. This was influenced to a large extent through the Association of State and Territorial Health Officers (ASTHO) association, ASTHO as we called it. This was a body or a group of people that through interaction of the surgeon general and the state health officers influenced these federal-state programs. Many policies and ideas that we tried to get across in advance were indeed aired through the association and directed through them. ASTHO had a strong influence on how our programs operated. Now, a subset, a group of people associated with ASTHO was the state sanitary engineers. These engineers worked under the state health officer to a large extent back in the early sixties.

The well respected division director of environmental sanitation programs in Washington was Wesley Gilbertson. Under this division was John Faulkner, who was the branch chief for the milk, food, and shellfish sanitation programs. At that time, the shellfish program was just a small section headed up by E. T. Jensen, and that's where I got my initial introduction to government service and the PHS. I had a wide ranging indoctrination, you might say, to federal service. I learned about a number of difficult scientific questions and how federal-state programs operated. The shellfish program had international operations at that time through agreements with Japan, and I had responsibility to help write some of the trip reports.

The Public Health Service was not the only federal agency involved with the shellfish sanitation. We had operating agreements with other federal agencies, such as the Department of Commerce. Also, I remember quite well that we interfaced with the Food and Drug Administration on such questions as microbiological methods and standards. One name comes to mind is Robert Shelton. I believe he was the liaison officer for FDA to the Public Health Service shellfish program. I knew Bob Shelton quite well during my early beginnings with the shellfish program. We were again involved with combining resources from a number of federal agencies to carry forth the responsibilities we had under the federal-state cooperative shellfish

program. I also began to learn about what "congressional oversight" meant. I assisted in drafting responses to congressional inquiries into the effectiveness of these federal-state cooperative programs.

Well, that was my early introduction to federal service. The PHS began investigating in November of 1961, an infectious hepatitis outbreak in Mississippi due to the consumption of oysters. The reason I mention this is that this was a very important outbreak in the annals of the shellfish program. This is the first food-borne outbreak in the United States caused by a virus--infectious hepatitis virus. Prior to this time, the only recorded outbreak of this type had been in Norway. Public health officials generally held that it couldn't happen in the United States, because we had good sound standards and effective operating state programs. So word of this outbreak caused concern to us as to why this had occurred.

It was fortunate that federal government epidemiologists were able to start the investigation early. The focus of the outbreak was in Pascagoula, Mississippi, where nuclear submarines were being constructed in a shipyard. The Navy had already assigned officers to those submarines, even though the keels were just being laid. The officers followed through the whole construction program. Well, the Navy health officer who was responsible for the health of these Navy officers noticed an unusual incidence of infectious hepatitis among his officers. He believed the cause was related to some local environmental problem. The naval medical officer immediately reported the situation to CDC (Center for Disease Control).

CDC responded by sending an EIS (Epidemiological Intelligent Service) officer to Pascagoula. His name was Dr. James O. Mason, later to become the Assistant Secretary for Health in Department of Health and Human Services. But this investigation turned out to be a textbook epidemiological story, a pride and joy of the EIS. The story was repeated many times to subsequent classes of EIS officers by Dr. Alexander D. Langmuir, who was director of the EIS at CDC.

It was found through well-documented case histories and environmental surveys that a significant number of people had become ill in the area of Pascagoula,

Mississippi, from nearby sewage-polluted waters. I spent three months in Mississippi assisting in the study. So the standards of the federal-state cooperative National Shellfish Sanitation Program (NSSP), which I will abbreviate NSSP, were found to have been violated. But, nevertheless, the question remained among health officials as to whether or not the virus of infectious hepatitis could be transmitted by shellfish, and would our current NSSP standards protect those consumers?

RT: Dave, I'll interrupt to ask either here or maybe a little later if you would include in your remarks something about the structure or effort at the state level independent of perhaps federal programs in the control of shellfish, sort of the beginnings of that endeavor at the state level. You may want to do that somewhere else. I just think it would be helpful to cover that as well.

DC: OK. I'll digress just a second to mention that the shellfish program, the NSSP, had been formally in existence since 1925. There has been a cooperative effort between the state agencies--state agencies meaning health agencies, conservation agencies, other food control agencies--to implement recommendations and standards of the NSSP. This program had been developed through consensus of this body of state agencies, and the Public Health Service, with input from the federal Food and Drug Administration. These deliberations took place in what were called "National Workshops." There was a long series of workshops through the history of the program. When the workshops came through with endorsements for changes in the NSSP, these were aired by the Association of State and Territorial Health Officers and again mostly embraced by that organization. So there was a strong binding force between the Public Health Service and state health agencies. The enforcement of NSSP activities was and still is carried out to a large extent at the state level.

One survey that we did showed the states spent ten dollars for every one dollar that the federal agency spent in shellfish control. So the state agencies were the hands on, the operating level, the people who did the investigation, inspected

processors, conducted surveys of state growing areas, tested water samples, and patrolled closed waters for illegal harvesting. And today that is still the way the NSSP operates.

RT: You mentioned 1925 as a significant date in the bringing together of the states and so on. Do you recall what would be the earliest time in the country's history that there was any organized state and government activity for shellfish per se? Do you recall anything along that line?

DC: Historically, the state agencies, of course, have been involved in various degrees. From the turn of the century, it was recognized that shellfish could convey communicable disease if they weren't taken from clean waters. The recorded history goes back to surveys done by state agencies as early as 1910. The pivotal point in the program that brought about the NSSP was 1925 when there was a large shellfish-related typhoid fever outbreak. That coalesced the state efforts that were rather independent at that time to come under an umbrella of the NSSP. As a federal response to the outbreak, the Surgeon General appointed a committee to recommend measures that should be taken. The committee consisted of federal, state, local regulatory officials and shellfish industry representatives. The committee delivered a number of recommendations that later became the basis of the NSSP.

There was an early determination made by the Public Health Service that issuing regulations was not an appropriate *modus operandi* for the program. Rather the PHS chose an approach through the cooperative spirit that existed through--historically now--the Association of State and Territorial Health Officers that was then a strong influential organization. But in time we see the loss of the older strengths that existed between the PHS, state health agencies, and ASTHO. In particular, the environmental protection movement of the 1960s began to weaken the cooperative strengths of the NSSP.

Well, let me pick up the story again in 1961. Again, we had an important public health question like we did in 1925. Now, in 1961 we have a virus threat. The people in the Public Health Service, the program leaders at that time (Wesley Gilbertson, John Faulkner, and Eugene T. Jensen) had been concerned about some of the public health issues confronting shellfish sanitation. However, they had not had an appropriate avenue, an issue, to bring to the agency or to the Congress that might enlarge the program to investigate these newer concerns. The hepatitis threat was used to explain to Congress why the PHS needed to investigate the adequacy of our present NSSP standards. Congress was led to understand that we should investigate and research this major issue thoroughly which was imperiling consumers of shellfish.

Within just a few weeks of the Mississippi outbreak another infectious hepatitis outbreak occurred in and around New York and New Jersey that involved clams taken from Raritan Bay. Now the issue takes on a much greater scale and prompts PHS to ask Congress for some research resources.

So they went to Congress and found some sympathetic legislators on the Hill by the name of Congressman John Fogarty from Rhode Island and Senator Lister Hill from Alabama. These men were important prime movers on congressional health matters. Congress passed a supplemental appropriation, which authorized the Public Health Service to build research laboratories and expand the shellfish program. We became committed through testimony to build two new research centers along the coastal areas that would investigate the problem of health hazards associated with shellfish, primarily the question of viruses in shellfish. Also the public health question about chemicals in shellfish, such as Minamata Disease, industrial mercury poisoning, was questioned. Additionally, the perennial problems that the NSSP always had with the Red Tide or toxic dinoflagellates was to be addressed. So we had a broad-ranging mandate.

The existing Public Health Service shellfish research effort consisted of a vagabond group of about five researchers located in Purdy, Washington.

(Interruption)

DC: The first task was finding an appropriate location for two other shellfish research centers. I was part of the team that submitted the report for the two site selections. Well, strangely enough, as time went on, we found that Alabama and Rhode Island had suitable sites and these were selected.

The two research facilities were built on Dauphin Island, Alabama, and near Saunderstown, Rhode Island, on Narragansett Bay. Congress was told that the new research centers would be built, staffed, and fully operational in less than two years. This was unfortunate because it forced compromises on building and hiring too rapidly. Some personnel selections proved to be poor. The centers became operational in 1963-1964 as shellfish related research centers.

During the mid-1960s--moving right along here in history--the shellfish program peaked in filled positions of about 120 persons. That included the staffing of three research centers, headquarters, and the regional field offices. Plus there were several million dollars of on-going extramural research grants and contracts. So at its height it had grown to a considerable program within the Public Health Service. Some mistakes were made along the way. The first was promising Congress a fully expanded program inside of two years.

RT: The grants and contracts. Were those awards to state governments or private sector contractors?

DC: They were both. We had research and training contracts with universities, and some with public agencies. I can recall we had an ongoing research grant with the State of Alabama, as a matter of fact, to investigate Mobile Bay. That project was going on for quite some time--years. So the monies were quite widespread. I had an opportunity to visit some of these researches and see what was going on. We didn't have a great deal of staff to audit them. From a program point of view, it was

quite enlightening to see the approaches they were taking and how we could complement our work both intramurally.

I want to again mention that when you go from a staff of several to well over one hundred personnel and have a multi-million dollar program in just a matter of a year or two, you tend to make some mistakes along the way. As I said before, the PHS promised to Congress that we would build and operate these new facilities in just two years. We had planned on using temporary buildings often referred to as Butler-type construction. That was a mistake. We didn't know that Congressman Fogarty was a former bricklayer, and he pointed out to us that he wanted a permanent facility in Rhode Island, not something that was going to be moved around like the military. So back to the drawing board. We had limited construction money available to us, so we had to downsize our dreamed laboratories in Rhode Island and Alabama. So we didn't get quite as large facilities as we had hoped for, but nevertheless they still met the most immediate needs.

RT: In staffing these facilities, what kinds of professional expertise were recruited? Were they microbiologists or what disciplines did they represent?

DC: We had quite a wide range of disciplines. Of course, the major thrust was trying to find some leading researcher in microbiology/virology. E. T. Jensen, the shellfish branch chief (focal point for the hiring), managed to--this is almost unheard of--but he managed to get in a field station a scientific research GS-16 position established for a highly respected scientist, Dr. Oscar Lui. Dr. Lui was instrumental in the early polio vaccine research. This was one brilliant stroke on his part to bring him on board. But, by the same token, the director of the laboratory was established at a GS-15. This set up some throes of contention. The director that they finally hired was a misfit. Let me put it that way. Other scientists hired came from academia, new to government, so lacked the understanding to follow program goals.

The disciplines that were hired came from a wide range of scientific endeavors: oceanographers, biologists, engineers, chemists, public health, and lab techs. Chemistry formed a strong component because of the heavy metal question. Microbiology was the greatest focus however.

But what was also promised to Congress was that we would look at commercial ways to purify shellfish. The term used to describe this process became more commonly known as "depuration" of shellfish. The Public Health Service believed that depuration was a way for the future, i.e., to establish a process that would ensure the consumer safe shellfish. It was envisioned that depurated shellfish would be much like milk that goes through pasteurization, although that's a poor analogy. Because pasteurization is a physical process, whereas depuration is a biological process. Therein lies the foibles of the depuration process by trying to make an animal drink. A person can place an oyster or clam in water, but it doesn't necessarily perform as it should.

RT: So depuration is a process then of purification. Is it putting shellfish into clean waters and letting the biological process eliminate the chemical residues or other elements of concern?

DC: Primarily microbiological elements, because we'd learned that to rid shellfish of any chemical, it takes a much longer period of time. To be practical, the purification process should be accomplished in twenty-four to forty-eight hours, as it would apply to commercial operations. That was the aim of the R & D at the centers, because we have different shellfish, different species that are of concern. We needed to address those differences in all these coastal locations. While that was a major ongoing effort, PHS program persons were telling state officials and industry members that, "We can see in the future mandatory depuration." Well, that did not set too well with state officials or the shellfish industry. They objected. They believed depuration unnecessary, unproven, too costly, and that the animals would

lose flavor in that kind of a process. So the Public Health Service backed away from that posture. In the meantime, the aim of the PHS research was to make the depuration process applicable in specific instances and situations.

I might mention as an aside that a great deal of attention was given to shellfish R & D at the expense of field operations. Field operations had the primary responsibility to audit state programs. Shellfish headquarter staff devote most of their time to the research effort to underpin the standards and methods of the NSSP and to keep Congress abreast of program advances. My perspective changed when I was assigned to the Atlanta PHS regional office to become the shellfish consultant (known as specialists today) in 1964. I was stationed in Atlanta from 1964 to 1968 and annually audited five southeastern state shellfish programs.

During this time period, we were seeing the emergence of environmental programs that were growing and receiving their own legislative mandates, such as the Air Pollution Control Act, the Clean Water Act, and the Solid Waste Control Act. What that did to state programs that we had traditionally worked was cause state sanitary engineers to grow independent of health organizations. Many of them broke away from health organizations and became independent environmental agencies in response to this federal legislation. The state shellfish programs got caught up in the fight over resources. The creation of the Environmental Protection Agency (EPA) likewise caused the splitting up of the PHS shellfish resources.

(Interruption)

DC: The state shellfish sanitation programs had fixed resources and found they had to give up some of their effort or contribute some of their effort to the new state environmental programs. So in some respects, the states were weakened in their efforts to carry on an effective shellfish program. Indeed, a number of states faced a need to increase their shellfish resources while they were unable to do so faced with other legislative demands.

In 1968, the department--that is our Department of . . .

RT: . . . Health, Education and Welfare?

DC: Exactly, HEW. HEW decided that it would be in the interest of efficiency in government to relocate food related programs under one umbrella, i.e., place them all under the federal Food and Drug Administration. At the same time, while FDA had been rather independent under HEW, it was felt that they should be placed under the umbrella of the health component, that is the Public Health Service. With this wisdom, there occurred a reorganization that in effect brought the shellfish, the interstate carrier program, and milk sanitation program to the Food and Drug Administration.

The prime movers in determining the split in resources was John Faulkner, who I mentioned before. His personality was like General Patton. He was a strong, boisterous individual, and you knew if you got on his bad side that he would let you know. He was a real task master, but I enjoyed working for him. Representing the FDA was Ken Kirk. These two were appointed by the department to make a smooth transition of these programs to FDA.

RT: I think Mr. Kirk was associate commissioner for compliance or regulation at that point.

DC: That is my recollection. There was a list of people made up to head these programs, and I was put on a short list to be considered for the chief of the Shellfish Sanitation Branch. I was called from Atlanta to Washington, and I was interviewed by Ken Kirk and Winton Rankin, who was then I believe deputy commissioner of the agency. I was offered the position, and I accepted. I thought this would be a tremendous challenge. I did have headquarters experience. Even though I had an

opportunity to go with the EPA public drinking water supply program, I thought this would be a better job.

RT: So you were assigned at Atlanta at the time the call came for this move to Washington?

DC: That is correct. I had responsibility for the regional shellfish program much the same as the current FDA shellfish specialists. However, I had a larger role in that I also worked in water resources and the interstate carrier program. My job title was something like Regional Water Resource Engineer. But I felt that the shellfish program offered a great opportunity. I had the background knowledge of what had occurred leading up to this point, and I felt that the Food and Drug Administration was the right place for the shellfish program. I wanted to be associated with a public health agency and not EPA. This turned out to be a much wiser choice than I realized then.

RT: When you were at Atlanta then you were not assigned to FDA's district office but rather with the CDC? Is that where you were?

DC: Actually, it was under the department's regional office where we had Public Health Service representatives assigned. The CDC is a national, separate organization. CDC stands by itself. It would be akin to what we call FDA district office or regional offices today, the same thing. The FDA district lab was located just one block away from the PHS regional office.

Coming into the Food and Drug Administration, there were several ideas about where to place these PHS programs. They were recognized as federal-state cooperative-type programs, therefore, should they really be placed under a strict regulatory-type oversight? Ken Kirk and others were mindful that there were very strong objections being voiced by state agencies about moving these programs to the

FDA. There was fear that FDA would take these programs and turn them into federal regulations. That was voiced early on. In fact, the milk sanitation program, because the milk industry voiced such very strong objections, was delayed a half year in transferring to FDA. The interstate carrier program and shellfish program actually came in advance of the milk program. The reason for the delay was to try to appease the milk industry about transferring this program and saying, in effect, that there was no aim to alter the program.

Well, the transition and absorption of these programs into the FDA I believe went quiet well. There was good support, interest in the program operations, even though there were some old FDAers skeptical about how it operated. Some said, in effect, that these programs had no teeth. Well, I would have to counter with the fact that while that may seem the case, the states themselves were audited and operated in a regulatory mode, and we helped to mold and influence how these regulatory programs operated at the state level. And indeed if a state program became so deficient, we did have the threat to withdraw FDA or PHS endorsement of a state program. Now, this threat was always perceived by the states as a very persuasive incentive to accept PHS/FDA's recommendations and advice. And indeed this kept the states pretty much in line, and as I said before, the strong federal-state relations that it had enjoyed with the Association of State and Territorial Health Officers was a strong influence.

Well, FDA operated the program from 1968 to 1972 very much as it had been under the Public Health Service organization. Nineteen seventy-two proved to be a very pivotal year for the NSSP. What happened was that the audit of the Virginia State program was found to be significantly deficient, primarily in its growing water surveys and classification scheme. A strongly worded letter was written to the state agency in Virginia saying that, "If things were not corrected, that we would withdraw the endorsement of the program"--that is FDA. This letter was handed to the Virginia State counsel, who in turn wrote to our FDA counsel saying that, "You have no authority to do that"--that is to withdraw endorsement.

At this time, our general counsel was Peter Barton Hutt. Mr. Hutt wrote back to the state agency saying in effect that, "We have every intention to follow up on our actions, and we will continue to do so." This was a show of force, of course, by Mr. Hutt. Unfortunately, he did not counsel the Bureau of Foods when he developed the letter. He learned later on that indeed the shellfish program was not underpinned by any federal regulation. No one in the program had really advised us in the past that a withdrawal of endorsement would be perceived as a severe federal sanction and would be violative of a law passed under President Truman's administration. The law said in effect that if any federal agency is going to take a sanction that would somehow economically injure or stop private citizens by whatever force and effect it might have, they first must publish such a statement in the *Federal Register* and announce it and put it in the form of a proposed regulation.

This caused a great deal of discussion and deliberation within FDA's policy-making mechanisms, and it was determined by then Dr. Virgil Wodika, who was director of the Bureau of Foods, and others such as Peter Hutt, that FDA better get on with the task of developing regulations that would underpin the NSSP. I then reviewed with my superiors what kind of strategies and timetable we could develop. Obviously, there was some urgency to do a proposal as soon as possible, because now we were . . . you might say "an open book," and our threat to withdraw had been weakened considerably. The states by this time, via the grapevine, had learned that FDA did not really have that sanction available to them. This caused, of course, some weakening, if you will, our posture with the states as far as auditing their state programs, and they were wondering what FDA was going to do in response to this challenge by the Virginia state officials.

We proposed then in 1975 NSSP regulations, which in effect would codify the NSSP manuals of recommended practices that had been in existence since 1925 and updated regularly. We thought that this would not be, in our innocence, too much of an impact. After all, the states had already pretty much adopted these rules and

regulations modeled after these guidelines. Well, unbeknownst to us, there was indeed mounting concern that these regulations would cause considerable impact on the states and do economic harm, both on the state agencies and the industry. Through special interests on the Hill, Congressman Bauman from Maryland sponsored language that passed, which became known affectionately as the Bauman Amendment. This amendment placed a moratorium on FDA's rulemaking on shellfish regulations until such time as an economics study could be performed. There was a suggestion that a cost/benefit analysis would be in order. I was told this was the first time FDA had been so reprimanded for proposed rulemaking.

I think we see now an emergence in the strength of special interest groups beginning to frustrate the regulatory process. But, nevertheless, it did indeed stop our rulemaking process, making us go back and rethink and look at the impacts and the costs involved. This proved to be quite difficult. FDA had hired a group of economic specialists for other tasks, and they took it upon themselves to help us. We did draft an economic impact study.

RT: Was this an individual or an organization that was hired to make this assessment?

DC: It was an internal group under Barkdoll.

RT: Jake Barkdoll?

DC: Jake Barkdoll, who was programming, associate commissioner for program evaluations or words to that effect.

RT: That's right.

DC: Under Barkdoll, there was a small group of people that were economists. Names escape me right now, but their duty was to try to help and put it in economic terms. We went out to make appraisals to overcome the objections raised in the Bauman Amendment and revised the regulations accordingly so that they would have somewhat less impact but still retain the essence of the NSSP guidelines and so forth.

Well, if people remember during the 1970s, rulemaking became more and more difficult with the objections of federal oversight and the costs being placed on industry and matters of that sort. So in my own judgment, as well as some other people within our staff, we felt that if we were to come up with regulations, they would have to be almost revolutionary or come maybe on the tide of another crisis, which did not happen. The difficulty continued in trying to push forward any kind of rulemaking that we felt would have any teeth and be successful.

I remember a comment made during one of our internal program reviews with the commissioner and bureau staff. I was shellfish safety program manager, and I had to brief new commissioners which seemed to come and go every two years or so. As designated agency program managers, we'd have to keep them advised on their responsibilities. After one of these reviews, Sam Fine, who was then associate commissioner for regulatory affairs, made a side comment that I operated a "non-program" for FDA. That hurt, because we were doing everything that we could possibly do; and in the meantime, our relationships with the states were sagging. FDA didn't have as effective a program as we should have had. We didn't really have a substitute or an alternative answer to the question. In fact, we didn't have rules or regulations to underpin us.

I had a chance at a meeting in Ocean City, Maryland, with state officials and industry to describe current NSSP activities. This was called a seafood seminar. I floated out the idea that we needed to do something that would maintain the integrity of the NSSP program both on the federal and state levels, or otherwise we would just continue to deteriorate over time, and the relationships would get worse and worse.

I thought that one thing we might consider would be an organization of state shellfish officials modeled after the milk sanitation program. It appeared that the milk program had overcome the objections of sanctions, in that the state agencies themselves imposed that upon their own sister agencies, in effect; whereas that removes the onus on FDA to have sanctions, as it were, and the organization is administered primarily by these state agencies. The NSSP program would operate in a great measure like the milk program, and it might be successful. So why don't we explore that idea as an alternative to rulemaking?

So thus was born the concept for the Interstate Shellfish Sanitation Conference, or as it is called, the ISSC. Instrumental in that--and I must give a great deal of credit to a man who is deceased, i.e., Bob Stevens, and my good friend K. J. Baker, who was then in EDRO's federal-state relations office. We worked out some language for an MOU (Memorandum of Understanding) and other draft papers which became the foundation for the ISSC. FDA rallied around that idea and then it was presented again at several meetings with state agencies. It took off.

RT: So this was a pattern, just to reference the name of the milk organization, that was the National Conference on Interstate Milk Shipments (NCIMS), and the ISSC then derived some of the concepts that were embodied in its laws and bylaws from that milk organization?

DC: From the bylaws and also the fact that there was an MOU developed with that organization. So FDA then could recognize the fact that there was a working body of state agencies out here that worked together for a common interest, and more importantly, it kept an arm's length between industry and the regulatory agencies. That was one of the difficulties we were having with the shellfish program in that the shellfish industry was having a great deal of say in the recommended rules and guidelines, which gave an appearance as though industry had too much influence. But this ISSC, as we formulated it, became the *modus operandi* for the NSSP and

became more widely accepted. As the ISSC became operational, FDA was able to say to the public through the *Federal Register* that we would no longer propose federal regulations, but indeed we now have an effective state-federal program that we can recognize as being effective in carrying forth the old-line program, the NSSP.

RT: Now, in the National Conference on Interstate Milk Shipments, I believe the industry can participate in the discussions, but they didn't vote in the administrative sections of business meetings on the final rules. Was a corollary set up in the ISSC for industry participation short of voting, or what was their provision for input into the ISSC?

DC: This voting was kept so that the regulatory agencies did control the outcome of any recommended procedures and standards. Industry--in fact the whole public--is invited to participate. It's an open meeting; it's not a closed meeting. Anyone can participate; anyone can have a voice. There are procedures to petition. Anyone in the public can write to the organization and state comments or grievances or whatever the issue might be. Then the ISSC has to address these issues. But the ultimate is that there is a voting procedure which is protected so that the state agencies themselves and FDA have the only input. One of the provisions of the FDA/ISSC MOU is that the ISSC cannot pass anything which would be violative of any Federal Food and Drug Administration rule or policy matter. FDA has an overrule function there. But that is the way it's modeled, and it seems to be working successfully.

RT: How often does the ISSC hold these meetings?

DC: Initially the idea was to have them annually, with the thought that maybe a few years down the way, as they grew and matured, they could be less frequent. But I believe they have been holding them annually.

RT: I recall while I was in the agency that they were held annually for a number of years, and I'm not sure whether that's still the case or not. I'm sure you would know about that perhaps better than I.

DC: I would really like to conclude my remarks by making mention that I was served by a very dedicated staff in FDA during my tenure as the chief of the Shellfish Sanitation Branch, and I hold my hat out to many FDAers that helped me along the way. But I would really be remiss if I did not mention particularly my senior staff members, George Morrison, Dan Hunt, James Verber, Maynard Presnell, and Santo Furfari, who all made tremendous contributions to FDA's shellfish safety program, not just myself alone. And, of course, the very capable and dedicated staff of shellfish specialists in the FDA field offices. I'm very proud to have served and felt privileged to be a part of FDA.

RT: Well, Dave, we have covered many areas of the program. I don't recall, for those that wouldn't be familiar with it, whether we have fully explained the role of the field shellfish specialists and what their activities are with regard to the states.

(Interruption)

RT: OK, Dave, I wondered if maybe a little clarification on the role of the personnel in the field in this program might be of interest to those reviewing this interview.

DC: The shellfish specialists were located to cover all the coastal states. The fact is that all coastal states have shellfish sanitation programs, including Alaska and at one juncture even Hawaii was involved. The shellfish specialists in our field offices were responsible for auditing state shellfish control programs. In most cases, it meant at least two agencies per state that they had to interface with, and they were responsible for seeing that they carried forth the guidelines and recommendations of the NSSP in an effective manner. The audits became more and more refined, and they were given more detailed instructions as we learned better how to present audit reports. The response from state agencies was good. In fact, the audit reports were most helpful to them in giving them ammunition to defend their program activities and resources. Of course, a few agencies would object to such a detailed audit, but in the last analysis, it has done a lot to strengthen the state programs.

One person that was instrumental in improving upon the state reports was Darrell Schwalm. He came in from the Boston regional office to head up these cooperative programs in the bureau, or as it is now called, the center. Darrell was good at formulating these reports so that they were indeed effective and had a great deal of impact, not only at the operational level of the state, but was able to raise the concerns to higher levels within the state agency through our regional Food and Drug directors.

RT: And Darrell had served in the field as a specialists, is that correct?

DC: That's right. He worked as a shellfish specialist in the Boston regional office.

RT: Now, in the annual assessment of the state programs, was a report developed for the ISSC to consider the special problems together with the agency as it related to particular state programs or program weaknesses?

DC: If there was lack of response on the state part and the issue went unresolved between FDA and a particular state, then that would be elevated for consideration by the ISSC. The ISSC Executive Board would take a look at a particular problem. It may be referred back to a committee for further study or ISSC may recommend a sanction by the ISSC, if indeed that was appropriate to do.

RT: The sanctions that might be considered by the ISSC, would they include decertification or removal of interstate shipping privileges from a violating state?

DC: That particular sanction is so great that it is almost inoperative, you might say. So what they were looking for in terms of sanctions were lesser, much lesser ones, more fine tuned to hit the particular problem in question. If it was a growing area standard that was being debated, which I recall one of the issues, then that was what was dealt with by deliberations within the ISSC. The state responsible then was either given an opportunity to rethink their position, coming back now with the force and effect of all the states coming down on them with a particular issue in mind and . . .

(Interruption)

RT: Do you want to pick it up again, David? That is, to continue kind of with the thought where we changed tapes, Dave.

DC: Yes. The state agencies that had deficiencies in their programs, that were not fully resolved between FDA and the individual state, these matters were referred to the ISSC and dealt with through committee actions. If the issue was so violative that the ISSC itself felt that they needed to bring about corrective action, they in turn would involve themselves in handling the problem directly with the state. So when an entire group of state agencies come down on an individual state they felt the need

to take corrective action. This can be quite forceful, particularly if publicity is part of the force. Member states of the ISSC can say to the violative state, "If you continue to ship your product interstate commerce, we won't accept it in our state." That becomes forceful; that has been done.

RT: Dave, we've referenced the milk organization and, of course, there are milk producers and consumers in all of the states. In the shellfish industry, not all states are producing states. Some are only receiving states. What's the extent of participation of the states in their total number in the ISSC?

DC: I don't recall the count precisely, but there were invitations given and accepted by a number of the inland states for participation in the ISSC, particularly where you have big markets, where distribution of shellfish occur, and they did come in quite willingly to participate, and they did give a nice objective viewpoint to the organization, because they represented really what was happening out in the marketplace.

RT: I seem to recall too that the Food and Drug Administration, through its Division of Federal-State Relations and the state contract program there, awarded some contracts in the shellfish program both to producing and receiving states. Do you wish to elaborate any on your recollections of those activities?

DC: Well, I guess from day one of the program there has always been this concern for the freshness and quality of shellfish shipped in interstate commerce. The concern that would occur in inland states is they may sample a shipment of shellfish as they received them and find them to be microbiologically, by their testing anyway, exceeding what were the recommended market standards. There was a great deal of back and forth between the receiving state and the producing state over the quality of such shipments. A number of difficulties occurred with the amount of time

that has elapsed before a receiving state could get microbiological results. Of course, the shipments in question would already have been consumed or distributed, and no one could take action.

The state contracts, as I recall, were to see if there were ways to monitor these shipments more effectively and sample them at appropriate points where these microbiological standards had application. I know they made some revisions in the guidelines for sampling shipments of shellfish in interstate commerce. Going beyond just microbiological testing, they looked at the condition of shipment, refrigeration practices, the sanitation within the trucks, and so forth. So it became a somewhat better program as time went on.

RT: Well, having worked in the Division of Federal-State Relations and being manager over the staff that did the state contract activity, I seem to recall two inland states that were quite active. These were Colorado and Arizona, which one wouldn't normally think of having great interest in shellfish. But they were active with those contracts. And then off the New England coast there were some problems with Red Tide. I think the states of Massachusetts and maybe another one up there or so did some state contract work in conjunction with Massachusetts researching the prevalence and effect of Red Tide on shellfish in that offshore area.

Do you remember . . . ? You mentioned that there were frequent changes of commissioners, as there have been in recent times. Do you remember any commissioners that had any particular interests above that of others perhaps in this area of shellfish protection? A number of commissioners have managed the agency during your tenure, of course.

DC: Right. I recall having to brief many of them, but I don't recall any of them that really questioned specifics. Some of them were quiet fascinated with how the program operated. They were interested to learn of the fact that the states spent so much resources on this compared to FDA. The comment was often made that we

leveraged these programs at the state level by our involvement. Our data showed FDA spent about a dollar to every ten dollars that the states spent. I think that a number of the commissioners we briefed were quite impressed by these federal-state relations programs and gained a better understanding as to their importance. So I do recall that scenario.

RT: You know, there was also a reorganization or a development implementation perhaps of an Office of Seafood Safety. Did that occur following your retirement from the agency or was that underway then?

DC: Yes. I retired from the Food and Drug Administration in February of 1987, and at that point in time, there was move afoot to try to consolidate some of the seafood activities, but it had not come to any conclusion at that time.

RT: All right. Now the National Marine Fisheries Service (NMFS) was another federal agency in the Department of Commerce to which FDA's shellfish program activities related. Do you care to comment on what respective activities this agency was involved with as they related to FDA?

DC: Well, the National Marine Fisheries Service had maintained a fish inspection program under their authority or rather under their marketing responsibilities that comes actually from the Department of Agriculture. The thrust of their inspections, which were voluntary in nature, was towards quality and appearance of fishery products. I did not have a great deal of interaction with the National Marine Fisheries Service on shellfish matters. The NMFS had more regulatory compliance difficulties. I can recall many regulatory difficulties that occurred between their agency's inspection practices and our responsibility under the Federal Food, Drug and Cosmetic Act (FD&C Act). FDA had responsibility for wholesomeness, safety, and labeling of fishing products.

Sometimes conflicts would occur. I think the National Marine Fisheries Service had a conflict of interest. Their inspection service was paid for by the industry, and I think this had a built-in bias. If there were lots (i.e., shipments) of fishery products that were not in compliance with the FD&C Act, there would be occasions when they may even try to hide that fact from the agency. I think the right move was made to consolidate the National Marine Fisheries Service fish inspection program within the FDA.

RT: I remember that Paul Hile, who was associate commissioner for regulatory affairs, and Tom Billy, who I guess had a comparable position at National Marine Fisheries Service, had periodic meetings. And then when the Office of Seafood Safety was established in the FDA, I believe some of those National Marine Fisheries Service personnel came over, as indeed did Tom Billy to be director of that operation in FDA. I think another person was David Dressel, who came over and became an FDA staff person in the seafood safety program.

DC: I might say on the side I was personally responsible for recruiting Dave Dressel to my old position, Chief, Shellfish Sanitation Branch. We had looked at potential candidates for this position, among career FDAers. None of the field specialists were interested in coming to Washington. I believed that Dave would fill the bill because of his academic background, and he had been very much involved in the NSSP affairs as he followed it for the National Marine Fisheries Service. He had a great deal of personal interest, and was NMFS point man, sort of the prime mover, on the follow up to the Bauman Amendment legislation. He had a great deal to do with responding to Congress on that particular piece of legislation. So he was very much involved in the operations in the NSSP prior to his coming to FDA.

RT: There was one law that was available to the National Marine Fisheries Service, the Lacey Act, that had some provisions of enforcement that at that time,

prior to the bringing together of the staffs, FDA did not have itself. Would you care to comment about the Lacey Act and how that was helpful in enforcement under the National Marine Fisheries Service program?

DC: I'm a little bit fuzzy on the background of the Lacey Act, because while I do remember the act, I don't recall the specific provisions that gave them . . . I do know they had unique authority on interstate commerce of shellfish, I think for disease organisms that might affect other resources in another state, but that was my . . . I just don't recall the entire playout of how that brought out what they did in terms of . . .

Well, wait a minute. I do recall that we were working on some difficulties in Louisiana where there was illegal shellfishing going on, that is people harvesting from waters that were classified as closed or prohibited for harvesting. This has always been a nemesis of the NSSP and the state patrol programs--that is, trying to arrest and deal with this bootlegging activity. The Lacey Act did give the National Marine Fisheries Service agents specific authority to move against those people, if I recall correctly, even before interstate commerce occurred, and that was something unique in federal law. I may be mistaken in that, but I believe that was the case.

RT: I think that's the way I recall it, too. There was a case or two of bootlegging where that law was put into play and some seizures were made. It seemed to be something that FDA didn't have at the time, so I guess we may have it now. I don't know whether the agency has enforcement privilege of the Lacey Act now that there's been a combining of those services or not. But if not, certainly there is still cooperation with regard to that enforcement tool.

Well, are there any other items that you would like to mention as we bring this interview to a close, Dave?

DC: Well, to those people who are historic buffs, I've written a chapter in a book called *Environmental Indicators in Shellfish Safety*. I can give the reference in full detail later. But I have written . . . Going back to the time in memorial of how shellfish standards were derived and implemented by agencies as far back as Old England and the Old World, and I found some quite obscure references in our National Library of Medicine that I did not even know existed at the time when I was operating the program. I found that in the late 1800s a university professor in England had laid down about ten points of how to control shellfish. One of them said, in effect, that if we're not able to control them, we're going to have to depurate them.

RT: Interesting that it should be such a historically-based term. Well, Dave, you might care to enter some information about that text in the record here in case any researchers would want to pursue that.

DC: This text is published by Chapman and Hall and edited by Cameron Hackney and Merrill Pearson. It has a copyright date of 1994. My chapter is called "Historic Overview"; it runs from page one through thirty.

RT: And it was published by?

DC: By Chapman and Hall, 29 West 35th Street, New York, New York 10001.

RT: That may be of interest to someone who wants to explore early histories more than the information this tape has provided.

Dave, we discussed earlier the placement of the shellfish program in the Food and Drug Administration. Was there a question at that time as far as you and your

staff were concerned as to where this voluntary program might be placed, and indeed where was it placed?

DC: The transfer in 1968 was one that was of concern to our cooperating state agencies and shellfish industry, particularly those concerned with appearances. Some state officials likened FDA to a police agency, and some people felt that FDA's only concern was with regulatory compliance and would fashion these cooperative accordingly. It would be difficult to explain how a voluntary program could exist under such an atmosphere.

The Food and Drug Administration was organized with a Bureau of Voluntary Compliance, and this seemed a likely spot to place these cooperative programs. The bureau was headed by General Fred Delmore. As we learned later, that would have been a disaster for us if we'd been placed there. General Delmore did not enjoy a very good reputation within the agency. Rather, it was determined that we would come under the Bureau of Regulatory Compliance, headed up by Al Barnard.

This gave me, first, a great deal of concern because of the very nature of the name of the bureau. But as I found out, Al Barnard was a great champion of our program. He had been appointed to that position recently by Dr. James Goddard to take a fresh look at the way FDA was doing its business. Al Barnard was very fascinated over how these programs operated with federal-state agencies, and he was very helpful in explaining to the field staff and others within the agency how they could be effective and if they're managed properly. So my hat was really off to him in helping us to make that transition as smooth as possible.

RT: Well, I think that was certainly fortuitous that it did get placed where it was, because the program I think has been a successful effort in the Food and Drug Administration.

Well, Dave, we've covered a lot of ground. Are there any other points to be raised? If not, we could conclude the interview at this point.

DC: I thank you for the opportunity to express my personal experiences, having worked in the Food and Drug Administration. Again, I just want to say it has been my privilege and proud honor to have been able to do so.

RT: Thank you, Dave. I know you've made an admirable record in the program, and we appreciate your input into the FDA oral history program, as this is perhaps the only interview to date that has dealt with the shellfish sanitation program. Thank you very much.