

History
Of the
U.S. Food and Drug Administration

Interviewee: Charles W. (Bill) Sedgwick

Interviewer: Robert A. Tucker

Date: June 21, 2006

Place: Lenexa, Kansas



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NAME: Charles W. (Bill) Sedgwick



NAME: Robert A. Tucker
5600 Fishers Lane
Rockville, MD 20857

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Interview with Charles W. (Bill) Sedgwick

June 21, 2006

TAPE 1, SIDE A

RT: This is another in the series of FDA oral history interviews. Today, June 21, 2006, we're interviewing Charles W. Sedgwick, who we'll identify later in the text as Bill. Bill was the former Director of the Kansas City District of the Food and Drug Administration from 2000 to 2005. The interview is taking place in Lenexa, Kansas.

So, we'll begin the interview, Bill. If you would give us a brief overlay of the personal history you have in terms of where you were born, educated, how you got to the Food and Drug Administration, any employment that you might have had prior to that time, and then get into the career that you pursued.

CWS: I was born in September of 1942 in Kansas City, Kansas, at a hospital called Bethany. This hospital no longer exists. I grew up in a small Kansas community, Bonner Springs, and went to grade school and high school there. I then attended a small Methodist college in Kansas called Baker University. I graduated from Baker in four years, and while there, I had some friends who had, when they graduated, gone to work for the Food and Drug Administration.

RT: I might interrupt just a moment and ask, when did you get your degree from Baker?

CWS: I got my degree in 1964.

RT: Thank you.

CWS: I have a bachelor's degree in biology and psychology. My major professor, Dr. Ivan Boyd, along with those people I previously mentioned, encouraged me to work for the FDA.

When I graduated in 1964, I think I had maybe two weeks off, and immediately went to work for the Food and Drug Administration in Kansas City. Basically my entire professional career has been working for the agency.

RT: Do you recall who interviewed you for FDA?

CWS: I really don't remember; however, there were two or three people.

RT: Well, that's not too relevant.

Do you recall who was the Director of the district?

CWS: Yes. My first director in Kansas City was Al Barnard.

RT: Barnard, right.

CWS: The Director was a man who [sic] nobody would visit without being invited. It was a very different world then than it is today.

RT: Do you mean in the office?

CWS: In the office. There was a very structured hierarchy, and nobody got to the director's office without being invited. You didn't just walk by and say hello. It was just not done.

RT: Well, your experience was somewhat similar to mine when I first joined FDA in 1964.

CWS: It was also somewhat unique in that, in those days, we had spit-and-polish inspections. Our desks had to be a certain distance apart; everything in the desk had to be neat; our shoes had to be polished; we had to wear a suit and tie everywhere we went. This dress code made it a little difficult trying to inspect grain elevators and feed mills. These firms' staff would look at you as though you had horns. Nobody except the FDA went to an elevator or feed mill dressed in a suit.

RT: Well, actually, wearing a tie in some industry inspections probably was a bit of a hazard in terms of getting caught in the machinery if it wasn't tied down good.

CWS: Well, we all had whites, as we called them, or coveralls, that we would change into after we got wherever we went. But when we issued the notice of inspection, we were to wear a suit and tie.

RT: When you began your FDA career, did you go through a certain period of training, on-the-job training?

CWS: Yes. There was probably at least a year's training in just general work of the agency, how to write collection reports and write inspection reports.

I can remember so well my first supervisor, E. Pitt Smith (the retired District Director in Buffalo, New York). Pitt was an excellent mentor and supervisor. He would review your reports word for word, and when he had finished with his red pen, it looked as if it had been bloodied. Pitt taught me to write as the agency wanted me to write, not the way I thought it ought to be. I learned from that and used it throughout my career. I got my own red pen over time. That was a good lesson.

After I got my basic training, so to speak, in food and drug law, inspectional techniques, report writing, then we did get to work somewhat independently, but we still had a regular mentor almost for the entire year.

RT: What was your entry grade level, Bill?

CWS: I started as a GS-5, and in those days, if your work was satisfactory, in six months you could be promoted to a GS-7. And thereafter it was 7, 9, 11, 12, 13, 14, 15. All

inspectors (investigators) started as a GS-5. However, in those days the Agency would hire in a chemist at a GS-5, step 10, because they were in very short supply. I thought, that doesn't seem right, but that's the way it was.

RT: At the time you came to the agency, were you hired somewhat individually, or was there a group hiring? Was the agency expanding its staff at that point?

CWS: It was very much expanding. In fact, my swearing-in ceremony was handled by the Chief Chemist named Andy Allison. He swore in, I think it was 15 or 16 of us that day, about half chemists and half investigators.

RT: That wasn't part of Project Hire then?

CWS: Oh, no. Project Hire occurred in 1972. This was in '64. After that period and until 1972, the District would hire one or two staff at a time. I think mine was one of the largest introductory classes in the Kansas City District.

Kansas City had a reputation in those days of being a district who could hire a lot of people, and then once they were trained, they'd be sent to other districts. Some places such as Chicago or other large metropolitan cities had difficulty hiring. As a result, Kansas City hired, trained, and sent a lot of people to other Districts.

RT: Your initial work, was that primarily food, or did you get into other industries as well?

CWS: In those days, we were generalists; however, most of the work in Kansas City at that time was food related. So that is where I began. Basically what I did was make inspections of food processors.

Later in my career, I attended a number of training courses such as basic drug school, bac-T [phonetic] school, and Food and Drug law classes. As you finished this type of training, your career level and your activity expanded.

And after I left Kansas City, which I'll get to in a minute, I did more drug work than I did food work.

RT: That was human drugs?

CWS: Both human and vet drugs, because my next duty station was in Omaha, Nebraska. Omaha had a number of drug firms, both human and vet. This is where I began my drug inspectional work.

RT: In the animal-feed area, you were looking for what? Pesticides or . . .

CWS: Feed mills, in those days, were looked at as though they were a small drug plant. This was probably a very poor way to regulate this industry because you're talking about a dusty, dirty place. Basically what we would do in those instances was look at the amounts of drugs used in each batch and weigh those raw materials to see if they'd been

keeping a proper accounting of them. It wasn't sanitation, it was drug control, if you will, to determine what quantities went into the finished feeds that were fed to animals.

RT: Was there a check on cleaning of equipment, in other words, prevention of cross-contamination?

CWS: It's an interesting question you ask because it's been one that's bugged and bothered the agency for many years. Nobody has figured out a good way to clean mixtures from one feed batch to the next. In those days, firms would say, "Well, we'll throw in a couple hundred pounds of corn following the wash," and save for use in the next similar batch. Nobody was ever really convinced that it did a great job of cleaning out those mixers. But on the whole, my impression has always been that there was never significant cross-contamination to worry about, but I don't think we ever found a decent, good way to assure that there was no cross-contamination.

RT: Was there any regulatory effort at that time to do oversight on some of the peddlers to farms, where off-label use might be promoted?

CWS: I don't remember that was a significant issue in the '60s. I can tell you an interesting story about following up on an issue involving animals and feed.

I was in Nebraska at the time, at the Omaha Resident Post, which I went to after I'd been in Kansas City for two and a half years. We got a report that some cattle were dying, dairy cattle were dying, and it was unusual. And so they sent me out to visit the

dairy farm. What had happened, to make a long story short, was the farmer had sprayed his cattle with a fly spray. It turned out that the fly spray had been mislabeled, and it was dieldrin. Dieldrin is a persistent and dangerous pesticide.

Well, the problem was not just some of his cattle were sloughing their hide, and some of them died, but as a dairy farm, all the milk went to a cheese plant. So, without a lot of asking for permission or, "Can I do this?" I started following that trail. Anyway, I followed the milk to a cheese plant, and for two or three days I sampled cheese in coolers and sent those samples to Kansas City for analysis -- sure enough, there was dieldrin in the cheese. The cheese went from there to a major cheese manufacturer, who blended it. We had thousands of pounds of cheese that were recalled because of that.

I think this was probably one of those activities that just made you feel good, like you'd done something worthwhile this time, instead of going out and sampling grain out of a railcar, which I thought, oh, this is not my idea of what somebody with a bachelor's degree ought to be doing with his life.

RT: Did you receive an award or recognition?

CWS: I received some kind of a District commendation. In those days there weren't a lot of national awards like we have today. But the District did recognize the time and the effort.

RT: Well, that's good, because I had known FDA staffers when I was still at the state level who seemed to need an assignment direction for a lot of what they did and didn't get into, apparently because of the lack of latitude to do like what you just reported.

CWS: Well, as I said to you before, the FDA, at the time I began, was very structured, I mean, infinitely structured, with director and supervisors, chief inspectors, chief chemists, and you were to follow their directions.

RT: Probably not.

Now, when you went to Omaha, did you anticipate this would result in an advance in grade or other career advantage?

CWS: I did. In fact, going to Omaha as an investigator -- in those days, an inspector -- saved my career, because, as we talked about previously before we started this tape, the FDA was very structured. You traveled two weeks and you were in the office for two weeks, and it was every two weeks.

At the same time I was doing that work at the FDA, I was in the National Guard, and they were gearing up what they called Selective Force Reserves, because Vietnam was starting to warm up (it wasn't a war yet), but they were anticipating the need for troops. So I would go on the road for a week, I would travel back to Kansas City and go out to Fort Riley for the weekend. I'd leave on Sunday afternoon for the second week of my two-week trip. I would come back and go to Fort Riley for the weekend. And this

went on for months. And my wife finally said to me, "I just can't handle this. You're gone all the time."

So I said to a lady there in the office -- her name was Ann Moberly (she was sort of a mother to all the new investigators, inspectors) -- that I thought I was going to be looking for another career. This was too much travel.

And not long after that, I got a call to come to the director's office, which, you know, when that happened, you were probably in big trouble or something was wrong. He said, "I'm going to transfer you to Omaha." I said, "What?" He says, "You don't have nearly as much travel in Omaha, and we want to keep you." So, he moved me to Omaha, and we stayed there for four and a half years.

My Reserve units were never called to active duty, but I served seven years in the Reserves. And while I was in Omaha, my two children were born.

We were there for four and half years, and that's where I began some of my drug work. They used to have what they call intensified drug inspections, and you would actually go into a drug plant and you would stay there for months. You would go in, and every day it was like reporting to duty at the drug plant. I did that at a firm called Cudahay Laboratories -- Cudahay Pharmaceutical Laboratories, I believe it was. They made thyroid and digitalis from animal organs. In those days there were a lot of problems with salmonella in glandular drug products.

RT: Was Cudahay related to the packing company?

CWS: Yes. It was a division or a part of that firm. That's where they got all the organs that they used to process the thyroid and digitalis.

I was always kind of curious about eavesdropping because I had an office there. I always thought the firm had it bugged. I wouldn't have been at all surprised. If I wanted to make a phone call, I would leave the plant and make the call. I just was never sure that they didn't have the place bugged. Maybe they didn't, but I wasn't taking any chances.

RT: It was certainly a career-building opportunity for you.

CWS: Well, I was in Omaha for four and half years and, as I said, my children were born there. My wife had been teaching school until our children were born, and when they were born, then she basically retired from teaching until they were in high school.

From Omaha, I was given the opportunity to go to Washington, D.C., and I worked in what was then called the Bureau of Foods, and I worked for Taylor Quinn and Ralph Strand.

There, I was called the assistant to the director of regulatory affairs, who was Taylor Quinn, one of the most knowledgeable and dedicated people I've ever met.

RT: They both were; they certainly were.

CWS: I liked them both, and they were good mentors.

I became what in those days they called a food and drug officer in the Bureau of Foods, now Center for Food Safety. I stayed there for two years.

RT: That was what year when you started in Washington?

CWS: Let's see. I went to Washington in 1970 and left there in '72.

RT: I just wondered, because I was in Washington from '64 on, so I might have ran into you sometime. I don't recall.

CWS: When I was in the Bureau of Foods, I handled regulatory cases. Districts would write reports and recommend a prosecution or a seizure of something, and then, as a food and drug officer, I would review that along with people who were more senior and decide if the Center or the Bureau could concur with that before it went off to the Office of General Counsel.

Another thing we did was to write a lot of policy kinds of letters. I remember reading in the *Congressional Record* that the then-general counsel of FDA, Billy Goodrich . . .

RT: Billy Goodrich.

CWS: . . . had told Congress that the FDA had the authority to require date coding on food. Well, I thought if he said it, it must be right.

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As I said, we wrote policy letters, and after reading in the *Congressional Record* that Mr. Goodrich had said we could do that, I wrote this letter to this firm that said, “The FDA has the authority to require date coding on food.” Well, I thought I was on pretty solid ground.

As I have said, in those days, when somebody in charge called you to their office, you knew you had a problem. So I get a phone call from Taylor Quinn, who says, “Sam Fine wants to see you.” I thought I was going to get fired for something.

That afternoon I went to Parklawn from downtown D.C. I took the questionable letter with me because I knew that was the subject. I was sitting in his outside office just fidgeting. I was sort of the new kid on the block, and this man is God number two, you know. So his secretary looks over at me and she says, “He really won’t bite.”

Anyway, I went in to see him, and he said, “Now, what did you base this on?” and I handed him the *Congressional Record*. He says, “That may be what he said, but that’s not the agency’s policy because I said it’s not the agency’s policy.”

Mr. Fine did make agency policy, and when he made it, we all marched to the same drum. It wasn’t like 10 people all deciding what we ought to do at 10 different times. It was consistent, it was predictable, and I just don’t think we have that kind of finite control today that we had then.

RT: Well, Sam Fine was a very disciplined, self-disciplined person.

CWS: Yes, he was.

RT: And very organized. When you went to see him -- I, too, had to go to see Sam Fine a few times, and Sam never had any paper on his desk. It was either in the in-box or the out box. It wasn't a sea of paper. And when you resolved whatever you were there for, Sam dismissed you by just starting to read something, and you knew it was time to go.

CWS: Right.

Well, anyway, as I said, I worked in Washington for about two years, and I reviewed cases, I approved prosecutions and seizures.

Then, that was '72, and Project Hire was begun. Not only were they hiring a lot of new investigators and new chemists for the field, but they wanted to populate the field with some more experienced people. They needed supervisors, they needed compliance officers, as they're now called, instead of food and drug officers.

I remember going to Taylor and/or Ralph Strand, and I said, "I like my work here," I said, "but I really would rather be in the field."

And I remember Ralph saying to me, "Our job is to get you trained and get you back out into the field if we can, because you'll make our life a lot easier if you know what we're looking for." He was right.

I was really pleased, because at the time when they had this big draft for people in the field, I had offers from Dallas, from Kansas City, and from Denver.

RT: Now, if you'd taken the one in Dallas, you would have had as director Sam Fine, wouldn't you?

CWS: No. Sam had already left Dallas and gone to Washington.

RT: Oh, yes, of course, my error in not recalling what you just spoke of a little earlier regarding your headquarters visit to Mr. Fine's office.

CWS: I had three choices. I could go any of those three places; however, I chose Dallas. I had been in Kansas City and thought if I went back to Kansas City at this stage, there's too many people that I grew up with that I might end up supervising. In those days, compliance officers, food and drug officers, were in charge of casework, and if you went to trial, you were their supervisor. I'd worked for Pitt Smith before and he was now in Denver. I thought, let me try something new. So I went to Dallas. And I went to Dallas and stayed there for almost 16 years.

That probably wasn't the best thing for my career, but my family comes first. My wife and I decided that we were going to rear our children in Texas. They went to school in Texas, and when they had graduated from high school, we would be ready to go. In fact, the day after my daughter graduated from high school we began our move to Ohio.

RT: What was the span of years you spent in Dallas?

CWS: Well, let's see. From '72, and add 16 to that.

RT: That would be 1988, wouldn't it?

CWS: '88, right.

So Dallas was just a great place to work and great people to work with. My director of compliance there was Bob Hatfield, who was just a super mentor. He was a good technocrat; he was good at writing reports and reviewing reports; and he left you alone to do your work.

In Dallas, I probably had, as a compliance officer, more trial experience than nine out of 10 other people in the field. I managed a number of prosecutions with the U.S. attorneys' offices.

In fact, there was one that was kind of funny. It was in East Texas, and East Texas was still fighting the Civil War. So, it was a little different life in those days in East Texas.

We went to the U.S. Attorney's office in East Texas to work on this case. An attorney from general counsel accompanied me, and "he was going to be in charge." Well, it soon became evident from the U.S. Attorney that he was not going to be in charge. One of the things that caused a problem for him was that he had long hair. And the Assistant U.S. Attorney said, "You've got to get a haircut before you go before this judge." Well, he got his hair trimmed and he didn't get it cut short enough. So the U.S. Attorney said to me, "You sit at counsel table, the general counsel attorney can sit back there."

RT: This individual with you, was he a minority?

CWS: No, he wasn't.

RT: He was just kind of a hippie type character, I guess.

CWS: Well, he wasn't, but, I mean, in those days a lot of people had long hair, but you didn't look like you were a beatnik, so to speak, in East Texas. And the judge was named Judge Justice [sp.], and he had been a former U.S. Attorney. He ran a tough ship.

The reason I said they were still fighting the Civil War, I remember, as we went over there for trial, we took everybody who was involved in the case from the district, including our sample custodian. He was a black man named Mr. Dansby. I never heard him called anything other than Mr. Dansby. He was an elderly black man, and we took him with us to East Texas. I made reservations at this hotel, and he said to me, "I can't stay there." I said, "Why not?" I mean, I was a little naïve in that regard. He says, "I just shouldn't stay there," he says, "but I've got some relatives in the area I can stay with." So we arranged that.

And I said to the U.S. Attorney's office later, I said, "I don't understand this. We have this elderly black man who wouldn't stay in the hotel." And he said, "I think he was afraid." He said, "He should have been." And that was sort of an introduction to a life and issues that I had never really had to deal with before.

RT: I had a similar experience when I worked in the state of Indiana years ago. This fellow was really a nice fellow. He was sort of a property man or something, a black man. There was a meeting in Louisville, Kentucky, and he had the same feeling. He

couldn't stay where the meeting was. To me, a naïve Westerner, I couldn't understand that either. So we had to become more cognizant of where we were, I learned.

CWS: There were really three things that happened while I was in Texas that I thought were really noteworthy.

One was a lot of trial work. As I said, I handled more trials, I think, than any other compliance officer had for years. Most of them were prosecutions or seizures. The industry that was there would fight. They didn't just give up or give in. They would battle you.

I had several trials in Oklahoma. A lady named Mildred Trumble was one of the more unique. Mildred Trumble manufactured in her kitchen a drug called liliverium [sp.], and she made it from Easter lily flowers. She would distill the flowers and put it into a vial and inject it into people.

Well, the prosecutor won, and the judge put her on probation. Then she violated her probation. And we tried her again, and he put her on a longer probation. And she did it the third time, and finally he put her in jail.

Well, I spent weeks and weeks in Tulsa, Oklahoma, prosecuting that case.

TAPE 1, SIDE B

CWS: Our entourage would troop into Oklahoma and then back we'd come again. It seemed as though it never ended.

That was an important case for us.

We found that we could charge both civil and criminal contempt. It was not something we'd done before. In those days we had to usually choose one or the other.

The FDA started to expand its use of law from just Title 21 violations of the food and drug statute to Title 18 violations. That is when I got involved with steroids.

FDA has always been able to and tried to step into the breach when somebody else wasn't taking care of business. That happened in the old BDAC [Bureau of Drug Abuse Control] days, when there was abuse of stimulants. I didn't get too involved in those, but . . .

And then the Treasury's narcotics people and FDA's BDAC people went together and they formed a new agency, which is now the Drug Enforcement Administration.

RT: I might ask you, Bill, for those that may review this transcript, can you just briefly clarify the Title 21 versus Title 18?

CWS: The two are Title 21 and Title 18, U.S. Codes. The food and drug statute is in Title 21 of the U.S. Code. Title 18 is the general criminal code. It would include things like conspiracy, defrauding the government, wire fraud, bank fraud. Those crimes are normally, and have in the past, usually been used by the FBI and Treasury, people like that who were more hardcore policemen, if you will, in the federal system.

RT: Would the Bureau of Narcotics been under 18?

CWS: I believe they are. I mean, I didn't deal a lot with them. But narcotics in those days included things like opium and heroin, really what I'd call hard narcotics.

Nobody in those days, other than the FDA, was dealing with the stimulants: the amphetamines, the barbiturates. So FDA stepped into the breach. We had a unit that made undercover buys and prosecuted those distributors and peddlers of stimulants.

RT: Was that the Office of Criminal Investigation?

CWS: It was at that time a part of the regular district office staff. They took that staff and put them together with the Bureau of Narcotics. This new group became the Bureau of Narcotics and Dangerous Drugs, which eventually became the Drug Enforcement Administration, which is in the Justice Department.

RT: As a matter of fact, I think Al Barnard got into the BDAC operation in headquarters after he left Kansas City.

CWS: I remember walking into the Kansas City district office as a new investigator when I first started, and over on one side of this big room where all the inspectors sat, there were these people in leather jackets and beards. I wondered, "What kind of a place is this?" I'd never seen anybody like that before! But these were undercover guys.

You know, it's an interesting story -- and I backtrack a bit. You think about things that I hadn't thought about for a long time.

They decided that they needed an undercover, a young undercover guy to buy some drugs from some prostitutes in Wichita. I was there on a training inspection with another investigator, and these BDAC types came into our hotel room looking for fresh meat, as they put it, and said, "We need somebody to go out and make buys from prostitutes." And thank goodness, the trainer I was with said, "No." Anyway, that was about as close as I got to that drug issue.

RT: That did become a problem in that field because a lot of these people, investigators, got known to the underworld.

CWS: Right.

RT: And they needed some . . .

CWS: Fresh meat.

RT: In the state, my city experience, I was asked to do that one time, and I didn't feel comfortable at it at all.

CWS: One time they asked me to go to a drugstore to make a buy. You have a prescription, and then you go back and try to get it without the prescription, and I did that a couple times, and I always felt guilty. I just was not good at that sort of thing.

RT: Sort of entrapment in a way.

CWS: It wasn't, but I just didn't feel good about it.

But, anyway, getting back to Dallas.

Other than my trial experience, I had two other things that I thought were really noteworthy.

I began to work on the steroid issues because that's another, as in the BDAC days, which nobody else was taking care of. Steroids were getting to be a big issue, a problem for the youth. They were basically being sold in an uncontrolled way. Bodybuilders, weightlifters, power lifters, those sorts of people were really into steroids. There was some suggestion that professional athletes were using them.

So I began working on steroid cases, and as a compliance officer, probably testified as often as anybody ever did when it came to trial work about steroids.

It was brand-new territory for us. We had never dealt with that kind of an issue in that way. What I mean by that is that we would go and make buys, or we'd have buys made, and then we would do searches and seizures of homes.

But I remember making two or three searches and seizures in Texas. One time there was a coach in a middle school that we had found was dealing steroids. We were going to search and seize the products at his home before he went to school, but he left early that day. So, we had to go to the school to get him. I went along, and had two, not uniformed, but officers carrying weapons. They were in the U.S. Marshal's Service. We went to the school principal and told him we were there to escort this man back to his

home because we were going to search it. We wanted him there. His only comment was, “Well, please walk him out without handcuffs. I don’t want the kids to see that.”

We took him back to his home, searched his house, seized anything that related to steroids. I think the thing that upset the man more than anything else was finding marijuana in his son’s truck. He was furious that his son would have marijuana. I mean, he didn’t think steroids were a bad deal. But anyway, he pled guilty and went to jail.

What I was going to tell you about that steroid work was not just learning how to use Title 18, and searches and seizures, but working one-on-one with U.S. attorneys. Before this time, that was basically the general counsel’s purview. You worked directly with the U.S. Attorney’s office, drawing up seizures, drawing up summons to the grand jury, and I went through many, many grand juries on steroid work. I just had never done those things before.

We had one trial in Texas which set a precedent for us, for the agency. We used to think that the people who were purchasing these steroids were being defrauded by the person who sold to them. We were at trial and this guy took the stand; this guy who had bought the steroids took the stand. He went through a litany of side effects, and somebody was saying, “How could he be defrauded? He knows more about the steroids than we do.”

Finally the judge, he says, “You know, I don’t think you’re making a very good case for defrauding this man.” He says, “Have you considered that the government’s being defrauded?” Bingo! Lights went on all over the place, and from then on, the Justice Department attorneys included defrauding the government as a charge in these

steroid cases. So it made a marked difference in the casework and what kind of proof we had to bring.

RT: That's certainly interesting, isn't it, how that revelation came to the agency and changed your modus operandi from a source you wouldn't normally expect.

CWS: Yes. Anyway, that was a really excellent case.

The other thing that I did when I was in Dallas that I am very proud of was being on a cadre of six people who taught food and drug law courses throughout the Atlanta and Dallas Regions.

RT: Was that something that Al Gottlieb of the Office of General Counsel was involved in?

CWS: He wasn't involved in it. I knew Al; I knew him well, and he was a prince of a man.

One of my favorite things about Al was, he'd say, "Now, if you go to trial and you get into trouble, I'll give you a quarter and you can call me." He was a great resource. At the time of these courses, he'd already retired.

We traveled all through the Atlanta and Dallas Regions teaching the law course to everybody, including the regional directors, district directors, and down to the sample custodian. Everybody had to take the course.

RT: Did you train any non-federal regulatory people?

CWS: Not in that course; however, when I was in Cincinnati, which followed my Dallas work, I did a lot of work with Ohio and Kentucky. I did work with the state of Texas as well, in fact received a Commissioner's Commendation for that effort.

I always thought that as a relatively small agency with limited resources, the only way you can really make an impact was to involve your state counterpart. We should encourage them to do the things that they could do best and for us to do the things that we could do best. In many instances, they could take actions much more quickly, much more efficiently, than we could.

RT: Well, many of them have an embargo power, which at least can be applied immediately if you don't have the legal process that the federal system . . .

CWS: I worked with Dennis Baker, who became the ACRA [Associate Commissioner for Regulatory Affairs] and went back to Dallas as a regional director. But I worked with Dennis when he was in the state of Texas. In fact, I taught him food and drug law.

RT: I see.

CWS: When he was the ACRA, he chose me to be the district director in Kansas City.

RT: I see.

CWS: Dennis was a good friend and, as I said, I spent a lot of time working with him and others in Texas.

While I was in Dallas District, I also went to New Mexico, which at that time was part of the district, and traded work with one of their people. They came to the office of Dallas and worked; I went to Santa Fe and worked in their office for two or three weeks. And I wrote regulations for the state and helped them with their work. It was just a great way to build bridges and to get to know somebody a little better. It was a worthwhile venture. As I said, I don't think we would do well as an agency if we don't include our state counterparts.

RT: When you were in Dallas, did you have any liaison or contact with officials of the Mexican government?

CWS: No, I didn't. In those days, we had a compliance officer named Ramon Longoria, who was our primary contact with U.S. customs and Mexico. He oftentimes would take trips with other FDA officials into Mexico. No, I didn't really have anything to do with imports at that time, and I didn't work with Mexico at all.

RT: Okay.

Then, after Dallas, did you go to Kansas City as the director?

CWS: No. From Dallas, I went to Cincinnati, Ohio, as the Director of Compliance. And there I supervised a staff of compliance officers. In that compliance branch in Cincinnati, we also did the import work.

RT: When you went to Cincinnati, who was the director of the division, of the office?

CWS: Jim Simmons.

Anyway, I was in Cincinnati when they moved from their old Rayfield Building to a new facility, and spent probably a year of my time as Director of Compliance, overseeing part of the construction activities and the movement of the office to the new facility.

Like I said before, you kind of step into the breach wherever there's a hole and kind of put your finger in the dike. At that time they didn't have anybody who really knew too much about construction. While Cincinnati's primary move issue dealt with the laboratory, the district office also moved to this new facility.

RT: Somewhere along the line, I don't recall when, we got into a management-by-objective performance evaluation system. Did that complicate, for you as a manager, or even as an operative, your procedures?

CWS: No. I don't think that did as much as when we went from what I would call traditional supervisory roles to teams. Teams were supposedly to pick up an issue and go

from beginning to end, and if the issue that you were dealing with wasn't something this team normally would cover, they didn't do it.

I remember one time going to an AFDO [Association of Food and Drug Officials] meeting. Industry representatives were talking about reorganization of FDA along team lines. Their comment was, "We hope you don't do what they did with Pacific Region, because nobody there seems to be in charge of anything."

Neither the Cincinnati nor Dallas offices ever went that far with it. I mean, they maintained a structure, a supervisory structure.

Anyway, as I said, we had gone to Cincinnati, and I was the Director of Compliance. I had half a dozen compliance officers. And one of those fellows, Leonard Farr, was also one of those steroid gurus. Leonard was probably one of the most knowledgeable food and drug compliance officers I'd ever met. He was always interested in expanding the statute. He had had a lot of experience with steroid work, so I backed out of that. I mean, he could handle it out of Cincinnati. I didn't have to deal with it.

I found, at this time in my life and career, that you could be a good, what I would call technocrat -- technician at one level and one series of things, which didn't mean you were good at others. I found management is a very different animal, and it took some adjustment to not want to do the day-to-day work myself. I was good at being a compliance officer. I had a good grasp of the statute, I had taught food and drug law so many times that I felt like I could do it in my sleep. So it was difficult for me to give that up and manage people who were supposed to be doing it. So in some respects, it was a

continuation of the training, the teaching aspects of my work that I had done in Texas and teaching the compliance officers to do the things the way I wanted them done.

RT: Well, that's a common tendency. There used to be a state official in California. He was there 50 years, and he was very much that way and he never really groomed anyone to be his successor. So when he finally retired, they hired a person from the National Canners' Association to come in and manage the program. Later, there were state people who had been groomed for taking the program leadership job.

CWS: Well, I think that's one of our jobs. Our job is to train the people who are coming behind us to do our work. I mean, I don't think we should be so protective of our own position or our own ego. Our job is the protection of the consuming public, and if there's nobody there to do it when you leave, you wasted your career in many respects. So I think that's very important.

In Cincinnati, we did a lot of casework, and life was changing, or was beginning to change. As opposed to having all the trial work we used to have, we seldom ever brought any cases anywhere unless there was some monstrous thing like an injunction of Eli Lilly or something like that.

RT: From an enforcement perspective, in which you had been for so many years, was the move more toward industry education and voluntary compliance a thing that you found difficult . . .

CWS: Very difficult. I was upset by that because I thought, while you want voluntary compliance as much as you can, when you get to a certain point you say enough is enough. You know, here's the line in the sand. You've got to either fish or quit. And I think we've really, just from a personal perspective, I think we've gone too far the other way, and in many respects I think industry looks at it as kind of a toothless tiger in that we talk a lot, but we don't do much about it.

I think the other thing that was interesting in that respect is that, when I began my career, the commissioner was Larrick, George Larrick, who headed, from my perspective and view at that time, a nonpolitical science agency that used the law. I think it has gotten to be so politicized anymore that any decision that's made has to run through some political hierarchy before it's approved. That just doesn't seem to me it's using the science and the law the way it should have been used. But, again, that's just a personal perspective.

In Cincinnati, we did have some casework. We had a few precedent cases there that I thought were unique. One of them involved a firm called Twentee. That was a case that involved a decision of whether or not a live animal was food.

Under the case law, we often will go to the court and say, "We want you to take notice that this apple is a food," and the court will say, "Yeah, sure, an apple is food." But there were some instances when you ask a question, is it really food, is it something that you can really regulate. In this case, here is a live pig. Now, is that pig on the hoof food? Sure, it's regulated by the Department of Agriculture in some respects. But if it comes to residues in this food, is it food until it's slaughtered and on the table? Well, we ended up, in this case, getting a good decision, and it's served us well. So animals on the

hoof are food, and that Twentee case is the one that made that decision. So it's used as a precedent case.

RT: About what year would that case have been adjudicated?

CWS: I would say about, somewhere around 1994 or '95, something like that. I mean, I may not have the year exact, but it's somewhere in that era.

RT: Pretty recent anyway.

CWS: You were talking about getting people ready to replace you. That's one thing I really felt good about in Cincinnati. We did a lot of training of our young investigators and bringing them in through the compliance branch to teach them law and evidence. There are a number of those people who are now serving in compliance positions. I really feel good about that. I think all of us look back through our history and the people that have mentored us and we have mentored. It's great to see some of the fruits of those labors.

RT: I think CFSAN [Center for Food Safety and Applied Nutrition] was also a supplier, if you will, of staff for other locations. When I was working in Indiana, there were a few people who were transferred to New York and to places that many people would maybe not voluntarily elect to go to, but they had an opportunity to advance and contribute their skills.

CWS: When I was in Kansas City the first time, in '64, we were told we're going to send you somewhere. Somewhere in that era, it started to change from "we're going to send you somewhere, would you like to apply for something."

RT: Do you think that was about the time the EDRO [Executive Director of Regional Operations] organization came into being?

CWS: It may have been in the same era, yes. EDRO didn't last very long, but I think it was a good segue. I mean, the ACRA's office absorbed EDRO again. But Sam Fine was the original ACRA, if you will. He was the Associate Commissioner. He was number three in charge, and there was no question that he was in charge. Now I couldn't even tell you who's in charge.

RT: That's true. Of course, he was a colonel prior to that.

CWS: Well, maybe. He was somewhere up there. When he said jump, you all did.

I left Cincinnati in 2000 and went to Kansas City as the District Director. I went through the interview process, and, as I said previously, was selected by Dennis Baker, who was the ACRA. I found that interview process grueling but very thorough. Jane Henney was the Commissioner, just one of the most pleasant people I've dealt with.

When we went from the non-politician to the M.D.'s as commissioners, some of those were pretty good, some were not very good. Jane Henney was one of the best ones.

But, anyway, I remember visiting with her about the job and what she expected.

Anyway, I went to Kansas City. I came back to Kansas City then, after beginning my career there as its Director. At that time the district had already moved out of its old Rayfield Building on Cherry Street in Kansas City, Missouri, to Lenexa, Kansas. It was a modern facility.

There were a couple of things that I thought noteworthy while I was there. While I was in Kansas City as its director, I was able to do some new construction, rebuilding of the laboratories. And in that five years I was director there, we put over a million and a half dollars' worth of construction renovations into the facility. We went from an agency that literally had almost no security of its building to one where we had armed guards.

RT: Not having visited your Lenexa facility, is it in a populated part of this city, or is it out in the outskirts?

CWS: No. It's in a business park, and there's a lot of other small businesses in that area. There's no housing in the general vicinity.

It was a nice facility. There are actually two buildings there. One was basically a large conference room.

While I was in Kansas City as its Director, we expanded our work with the department. Before, FDA set out here by itself; the department did their thing, we did ours. I became an active member of the Federal Executive Board and worked hand-in-glove with the regional director here in Kansas City, who was a political appointee, but I think we trained him well. We hosted a lot of meetings, both federal and state official

meetings, in our facilities here in Kansas City. As I did in Texas, as I did in Ohio, I worked hard to bring our state counterparts into the queue. Not just do what we want you to do, but let's work as partners on these things. We just can't do it alone, and you can't either.

RT: I know that Dennis Baker would have supported that because the State of Texas worked pretty closely with the agency in a number of cooperative things. Then we got into the state contract operations a number of years ago, and some of the states did inspections and so on for us. Are some of those contracts still in operation?

CWS: Oh, very, very much so. In fact, Kansas City District, which included the states of Kansas, Nebraska, Iowa, and Missouri, had contracts in each of those states for various things. Some were feed inspections, some were food inspections. We had some regional staff assigned and stationed here in Kansas City who worked with the state officials and certified them to do food work.

RT: Now, the decision to relocate, what was the primary motive there? Was it the fact that the downtown Kansas City building was not adequate? What was behind the relocation?

CWS: Well, some of that I don't know the answer to because it happened before I got here, but my impression was that the old Rayfield Building, particularly its laboratory, had essentially outlived its usefulness. Things, after 30-some years, just wore out. And

the lease was up. And so I think with some political push from probably Senator Dole, they moved the facility from Missouri to Kansas . . .

TAPE 2, SIDE A

CWS: We were talking about rebuilding the facility in Kansas City and move to Lenexa.

One thing that's going on at the same time that the facilities in Lenexa are being built and are still relatively new is that there was a consolidation of laboratories. This had a major impact. At one time, every district office had its own laboratory. But the costs of maintaining laboratories and the cost of the equipment and training people is just enormous, so there was a consolidation effort.

For example, when I was in Cincinnati, it went from a district laboratory to the Forensic Center, which served basically the Office of Criminal Investigations, amongst others. Kansas City, on the other hand, maintained a district laboratory, and one reason it did is that we have a food program that looked for minute quantities of pesticides in the total diet. Every year, reports were sent to the Center for Food Safety. As I said, FDA maintained a laboratory in Kansas City while closing a lot of other laboratories. Kansas City's facility had about 150 people, more or less, assigned to the District either in resident posts or in the District office. About half that number were analysts or chemists.

District laboratories are centers of excellence. These centers of excellence, I think, will serve the agency well because they've consolidated not just into location, but they've consolidated the ability to purchase and, hopefully, maintain equipment that will

serve the agency's analytical needs. When you're talking about equipment that costs a quarter of a million dollars for one piece of equipment, you can't have a lot of them.

Kansas City's major laboratory program looks for minute quantities of pesticides in foods and reports that information to the Center for Food Safety. I think this program assures the public that there's a safe food supply, but it serves to say to politicians, "Is it safe to eat our food?" With more and more foods coming in from outside the country, primarily from south of the borders, I think there's a constant need to monitor food supplies. While we may regulate very carefully the use of pesticides in this country, a lot of those pesticides that are banned here are used overseas, so we have to keep watch and be mindful of that.

RT: So Kansas City, in this area, would receive samples and import samples taken on the docks and so on as well?

CWS: Some. That wasn't our primary goal. This program that I described would sample what is called a Total Market Basket. We would send people out around the country from Boston to San Francisco, and on a rotating basis, go into grocery stores and buy food off the shelf that the consumer would buy. Those foods were shipped to Kansas City and processed, cooked if necessary, and analyzed to see what pesticides were actually being consumed by the public. Their determination of what to buy is based on what the Center for Food Safety says an average person of 18 years old would consume. So you might buy 12 McDonald hamburgers and six cases of sodas.

RT: You mentioned the 18-year-old. I believe it has been concluded that, at that age, the volume of food consumed is greater than at any other age.

CWS: Probably so. But, again, the quantities that were purchased and brought to Kansas City for analysis might cost a couple thousand dollars. We did four market baskets a year. The food was comminuted, and then we would actually take components of that and send a portion to Atlanta for nutritional analysis. Some went to WEAC [Winchester Engineering Analytical Center] in Boston for radiological analysis. The analysis for pesticides, heavy metals, were all done in Kansas City.

RT: Do you have about the largest cadre of those scientists of any of the labs?

CWS: No. The regional labs in New York, Atlanta, Arkansas, and California are mega labs, and each has several hundred. Kansas City was a relatively small lab in comparison to those.

But I think the FDA is going to find, and probably have already, that mega labs are almost uncontrollable, I mean, from the standpoint of getting something in and out quickly. That was one of the advantages of a district lab. If you had a case that you wanted to prosecute, you'd bring the samples in to your district lab and you'd say, "Those have priority. I want them done today." You send the sample to a mega lab and you've got lots of people saying, "Mine's most important," you know, and they have to put them in a queue and see what comes out.

RT: Well, I'm sure that's true.

As far as the agency being a science-based entity, do you see that's going to continue as related to regulatory action?

CWS: Well, I think my answer to your question is that I hope so. But I think the science is there. I think we are not enforcing the statute as we could or should. We're too concerned about having a big case as opposed to smaller ones that impact more directly the local market, if you will.

I'll give you an example. When I was in Omaha one time, I visited a warehouse. They'd been prosecuted for having a filthy warehouse, and I was one of the first inspectors that had been in after that occurred. Well, the owner got a slap on the wrist. In those days, the fine was a hundred dollars. Well, he got a hundred-dollar fine. What a waste of our time! Maybe, but what happened was and what I'm trying to suggest here is that even these small cases have great impact beyond what you think they might. The owner said to me, "Well, I only paid a hundred dollars," he said, "but I was on a federal chartered organizational board, and when they found out I was convicted, they kicked me off of that." He said, "I went to get an SBA loan, Small Business Administration loan, and they wouldn't give it to me because I'd been prosecuted by the FDA."

So, I mean, my point is that while in some instances the fine or the penalty seems really not terribly important, they have ripples. And I think if you ignore things like that long enough, there's no ripples out there. If you're a large mega-firm and you get prosecuted, sure, that makes the news. But the little guy on the corner who's doing 90

percent of the work doesn't believe it impacts him. I think we have to on some occasions take on some smaller things just to make your presence known.

Now, we have been told for years that if you're trying to pick out agencies that people recognize, the FDA is one of those most recognized. There's the Park Service and the FBI, and FDA comes in there pretty high on the list because we make a lot of news. We make news when we say we regulate 25 cents of every dollar people spend. Well, that's important to the consumer, and especially if it gets something in their food supply. The public says, "Well, you're not protecting me." And I think we need to occasionally bring a case that brings us a little higher on that level of recognition.

RT: In more recent times, too, we've extended our efforts to consumer education, the consumer affairs staff persons in the field and so on. Has that been a successful venture, do you think?

CWS: Yes, I think so. I think anytime you can interface with the public, whether it's in the courtroom or if it's in consumer-affairs issues like presentations to the local community groups, I think yes, that's valuable. And there's a marked change in our history from the standpoint of compliance officers, food and drug officers, used to do what these consumer specialists do now. I mean, they used to answer the phone and fill in the interstice, if you will, and consumer-affairs officers have taken that role, which is fine. I think it's a good idea.

RT: The consumer-affairs officer, having a dedicated mission, probably get involved in more public forums than the food and drug officer.

CWS: Right, and I think that's good. I mean, I think it has worked well for us.

Consumer-affairs officers, like other positions, sometimes are not sure for whom they work. I mean, there's a headquarters unit that deals with that, sends out directives, "We want you to do these things," and yet they still work for the district director and the district. Sometimes those dual-role positions are in conflict and you need somebody in the position who can moderate their activities and try to meet both masters' needs.

RT: How do you foresee the future of the agency? There have been proposals at times from the Hill and others that the Food and Drug Administration, as it's been historically known, should be modified with the split-off of responsibilities, foods perhaps to the Department of Agriculture and drugs and biologics to NIH or somewhere else.

CWS: I have some real mixed feelings about that, having grown up for 40 years in the agency that was sort of covering all those bases. But the world has become so specialized, you can't be the generalist that one time you were. Each Center has their own issues, their own way of wanting to do something, and they have more impact on the field than they used to. The field did their thing and fed things to the Centers. Now the Centers want to feed it back the other way and tell you what they want done.

I don't think there's anything wrong with reexamining the agency. I mean, I think change is good in some respects. People who fear change just are not current. I mean,

they need to deal with change in a positive way as opposed to fearing it. But I think a food agency might be good; however, the problem in moving, for example, Agriculture and the Center for Food Safety together is that the FDA law is a regulatory issue, the Agriculture law is basically an agricultural protect-the-industry kind of an agency. I don't think it would work well to put those two laws into one bag and say, "Now you do it all," because this side is going to be trying to promote agricultural issues, and this side is going to try to be regulating some of the same things, and just don't work well together.

Drugs I think probably could be a different group.

RT: The recent acquisitions of other entities, like the former Bureau of Biologics and now, of course, Devices, some of those disciplines historically have been more education oriented than regulatory, so the marriage there has caused some stress within the agency.

CWS: It still is. The Bureau of Biologics, the old-timers in that, if you want to call it the old-timers in that group, don't understand regulatory affairs. It's, "We'll walk them through it and get them fixed," you know. And you can beat your head so many times against the wall; then you've got to start using a hammer instead of your head.

RT: Right, to get their attention.

Is there anything else, Bill, that you'd like to cover here? You've served under a lot of commissioners. Do you have any impressions of any of them as being unusually beneficial to the agency, or less so?

CWS: Well, certainly I'd be more inclined to talk about those that I thought have done a good job. As I said, Jane Henney I thought was just one of our best. I mean, at my level, until just the last few years, commissioners were somewhere out there in space and you didn't have that many contacts with them, and it's probably good that you didn't. But when I worked in Washington, I didn't have any contact with the commissioner except to meet him on the elevator one day. Commissioner Edwards, or Prince Charles, as we called him, was a very nice man.

RT: I remember when I first came into FDA in 1964 -- and, of course, it was then a smaller organization. They had the *Monthly Review*, a little agency newspaper that circulated, and they took pictures of myself and another state guy who had come in, and I met Commissioner George Larrick in the hall, and he come up and shook hands, spoke my name, and welcomed me to the agency. I thought, "Gee whiz, he's really something." But as the organization has mushroomed, those kinds of close contacts with and between operating and administrators is more infrequent.

CWS: It's all but disappeared. In fact, you mentioned previously about the Rayfield Buildings.

RT: Rayfield?

CWS: Rayfield Buildings were built by Alan Rayfield. While I never actually met him, I understood that when he would come to a district conference, he would come with a portfolio of every person's picture and some description of what that person did. He had the ability, apparently, to sort of work the crowd, if you will, by name.

RT: Well, historically, I'm a little older person than you. I wouldn't expect you to remember that, but I grew up in the days of the Franklin Roosevelt administration. The then postmaster general, Jim Farley, had that same reputation. If he went to some little one-horse town or city post office, he'd obviously done some background work, since he'd call the postmaster by the first name. That's unusual, but it does do a lot for the morale of the troops.

CWS: I think it does.

But you asked me a while ago if there was anything I'd like to say, and all I can tell you is that I am pleased with my career in the FDA. I think that as an agency, we've done a decent job. We could certainly do better, and I think we'll do better, hopefully, in the future. If we can get politics out of the business of regulating the industries that we're involved in, I think we'll be better off.

I wish that we could recruit on a regular basis instead of having to hire in big bunches of people. I think we could train them better. I think we ought to have an FDA university where we take people and train them. I know we tried that and we have some of that to a degree, but funding has been so poor in the last couple three years that that's just not been completed as well as it should have been.

I know Gary German in ACRA's office and each of the Centers have some schooling activities, but we'll do better if we had a university, if you will, that we could train our people, and train them all alike instead of each district trying to kind of fill in their own issues.

I think we need to get back to some mobility that we lost to some degree. With two people in the household trying to earn a living, it makes it more difficult to move people around.

But, again, I'm proud of the fact that I was part of the FDA, and I think it's a worthwhile organization, and it's worth putting some extra effort and energy into.

RT: Well, Bill, having heard your input into this interview, it's obvious that you're one of many very talented folks who started out at the grassroots level and successfully achieved some management positions that are very worthwhile. We appreciate very much that you permitted us to do this interview with you.

CWS: Well, I appreciate it as well.

RT: Thank you.

END OF INTERVIEW