History

of the

U.S. Food and Drug Administration

Interviewee: **Ted L. Anderson**

Interviewer: **Robert A. Tucker**

Date: **June 22, 2006**

Place: **Springfield, MO**

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

CASSETTE NUMBERS 1 & 2

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

DATE: June 22, 2006 PLACE| Springfield, MO LENGTH: 120 Minutes

INTERVIEWEE: INTERVIEWER(S):

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FDA SERVICE DATES: FROM: October 1, 1969 TO: January 5, 2006

LAST FDA POSITION HELD: Lead Investigator, FDA Resident Post, Springfield, MO

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Interview with Ted L. Anderson

June 22, 2006

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RT: This is another in the series of FDA oral history interviews. Today, the interview is with Ted L. Anderson, who recently retired as Lead Investigator in the Springfield, Missouri, Resident Post of the Food and Drug Administration. The interview is taking place at the Resident Office in Springfield.

Ted, as we begin, would you please give a brief review of your personal history, where you were born, raised, educated, and so on, and if you had career experience before coming to FDA, a brief overview of that. Then please move on into your career experiences with the agency.

TLA: All right. Well, I guess we could start from the very beginning.

I was born and raised in Topeka, Kansas, in November of 1944. I spent most of my summers on the farm with my aunt and uncle, doing all the farm chores that any farm kid would do, including running a tractor, helping with the wheat harvest, hauling hay -- spent a lot of time hauling hay in the summertime. I attended school at Topeka High School in Topeka, and in the summertimes in my high school years, I would work in the wheat harvest with a custom-cutting crew. We'd start down in Oklahoma and we'd follow the wheat harvest as it ripened up north, and we'd cut up into Kansas and Colorado.

RT: What year did you graduate from high school, Ted?

TLA: I graduated from high school in 1962.

RT: Did you go on to college soon thereafter?

TLA: Yes. After graduating from high school, I went to Kansas State University. I went there for a year and decided I wanted to see the world, so I joined the Army, and I was a medic. My primary MOS [Military Occupational Specialty] was as a medic in the Army from October, actually the 3rd of October, of 1963 until the 19th of August 1966, when I was discharged. During that time, I spent two years on Okinawa, and I traveled a little bit in the Far East, including Vietnam, Thailand, Taiwan, the Philippines, and Japan.

After I got out of the service, I went back to school, and I got my degree in zoology from Kansas State University. I graduated in 1969. I had a major in zoology and a minor in chemistry and physics.

RT: When you were in the service, did you do any service related to these subject areas, in other words, chemistry or anything like that?

TLA: I worked in a hospital dental clinic. I also worked in the field of dental x-ray, and I worked in the dental laboratory for a while. So I had a little exposure to medical

devices and pharmaceuticals in the hospital environment where I worked there on Okinawa.

RT: The reason I asked is I wondered if your medic experience might have led to your interest in setting into Food and Drug work.

TLA: Well, actually, I had no intention of working for the Food and Drug Administration. I was sort of interested in dentistry, and that's one of the reasons why, after my basic training as a medic, I took some advanced training in the dental lab and that sort of thing.

When I graduated from college, I was interested in going into the National Park Service, and my college professor told me that I needed to interview, and it was hard to get in, so I needed to interview with some federal agency, get a job with some federal agency, and at that point maybe I could transfer to the Park Service.

So I interviewed with the Food and Drug Administration in Kansas City in 1969, in late summer, and I think everybody remembers their first FDA interview. It was with Roger Flesch, who was a supervisor there in the Kansas City office. And, as I recall, Leonard Blanton was the Chief Inspector and Charles Armstrong was the District Director.

Roger Flesch asked me why I wanted to work for the Food and Drug Administration, and I didn't really want to tell him "because I want to transfer to the Park Service," but I told him I wanted to use my science background. So he assured me that I would be able to use every bit of science that I had, and that was certainly the case.

RT: You came into FDA at what grade level?

TLA: Well, I came in as a GS-7 because I scored well on the Civil Service test that we had to take at that time; plus, with the fact that I was a veteran, I had some veteran preference points, so that gave me a score over 100 combined with my other score, so I was able to get in at a little higher grade. Most folks were starting as a GS-5 at that time. And the salary in those days was $7,639 per year, and I thought that I was rolling in money.

RT: Well, you were somewhat at that time, I'm sure.

TLA: So I started out in the Kansas City office there.

One of the interesting things that I remember early on about working in the Kansas City office was I worked with a lady named Mary Margaret Richardson, and Mary Margaret Richardson was one of the first female investigators in the agency. I'm not sure that maybe she wasn't the very first.

RT: I think she was an early one. We interviewed her, and she was a pioneer, if you will, for women in the agency in field investigation work.

TLA: Right. So I had the opportunity to work a little bit with Mary Margaret Richardson, a very interesting individual. We used to call her Mike.

My first supervisor in FDA was Harley Eugene Shevling, and, of course, he has since passed away.

RT: In the initial days of your work, since you had some medical background, did you touch on that, or were you primarily started as a food inspector?

TLA: Well, back in those days, I think they started everybody out as, with basic filth work because the interstate documentation and case development and that sort of thing -- all those elements would be present, you know, taking photographs of filthy conditions, recording your observations. It was kind of considered basic training at that point.

When I came into the agency, nobody had been hired in Kansas City as an investigator for the past two years, so, and I was the only one at that time, so they kind of threw me to the wolves, so to speak. As far as training, I would go out with one or two people, and then I was pretty much on my own. So I had a few mentors then, early on, and later on one of them was Pat Pozar.

RT: How long would you say, into your career, were you let go on your own? Was that after six months or so, or . . .

TLA: It was pretty early on for me. Like I said, we didn't have much of a formal training program. I'd go out with one or two people and then I was pretty much on my own.

I started out, like I said, in some, doing some filth work. But one of my early cases happened to be a vet-drug case, and I talked to Warren Souder, who was the district drug specialist. They sent me out to an old place called Veterinary Labs that was in downtown Kansas City in an old rundown building.

[tape recorder turned off for approximately 15 seconds when telephone rang]

This was my first drug inspection. I talked to Warren Souder, as I mentioned, and he said, "Well, it's just a vet-drug firm, so we probably won't be able to do much with them if they're violative."

Well, when I went in there, I saw all sorts of violative conditions, including different-colored residues, drug residues, on a milling machine. I took pictures of that and was able to develop a case. And we actually made a case against these folks, although it was a little unusual at the time because we did not have a lot of enforcement actions early on in the vet-drug industry.

RT: Because this firm probably hadn't been inspected before, did they resist or object to the photographing of the exhibits you collected?

TLA: No, no. I didn't get any resistance there. My only concern was there was so much dust. They had tablets, they had bolus presses and tablet machines side by side, and there was so much dust, I was afraid my flash might cause an explosion.

RT: That's always a hazard in a dusty situation, particularly in elevators and so on. I assume in this district, you would have done some grain-mill work too.

TLA: Yes. We were well aware of the explosion hazard of grain elevators, being out here in the Midwest. And, in fact, we had had some specific training on things to be aware of as far as safety goes in grain elevators, which reminds me of an old grain elevator that I was in.

They used to have what they called man-lifts. It was like a big belt with a step and a handhold on it where, and it was a continuous loop, and you'd just step on that, and there were holes in the floor where you could go up however many floors and just step off at the top. I was in an old elevator and I went to get on the man-lift, and the step was missing, and I was able to jump back and avoid being drug up the man-lift hanging on by my fingers, but it gave me a cheap thrill at the time.

RT: I don't know whether it occurred in this district, but somewhere in the field, one of the inspectors, as they were called then, somehow didn't let go in time and was taken clear to the top and was injured quite a bit. Or it might have been an industry guy. But, anyway, the story was told about the hazard of man-lifts.

TLA: Most of them had an automatic shutoff so that you couldn't go over the top of it. But you had to be alert, and if you were trying to carry equipment with you, like a grain probe, you'd have a grain probe in one hand and you'd only be hanging onto that little handhold and on that little perch going up nine or 10 stories high, and it wasn't for the faint of heart.

RT: Well, that's true.

TLA: I used to, I would train some of the newer people, and when we did elevators, even as recently as probably the '90s, I would take the trainees out and I would give them an orientation on how to ride a man-lift, and then we'd do it -- and most of them had some pretty choice words to say about that part of the training, but I'm sure they remembered it.

RT: I'm sure. In this area, there was a lot of travel. Were you on the road quite a bit?

TLA: Yes. In Kansas City, we covered Iowa, Nebraska, Kansas, and Missouri. So the far end of our territory was Scottsbluff, Nebraska. It was about a full day's drive at 70 miles an hour to get out to Scottsbluff, Nebraska, to do an inspection out there.

But we normally took two-week road trips, two weeks out and two weeks in.

I worked in Kansas City for about five years, from October of '69 until January of '75. I then transferred to Denver as a medicated-feed specialist in Denver District. And then I traveled out of Denver. At that time we covered North and South Dakota, Montana, Wyoming, Colorado, and Utah. And so the road trips up to North Dakota and South Dakota were such that there was no way you could get back for the weekend, so that made for a long trip.

As a matter of fact, when I transferred out to Denver in January, the first thing I did was travel. One of our investigators in Fargo, North Dakota, was involved in an accident, and we investigated our own vehicle accidents. So I drove to Fargo, North

Dakota, in the dead of winter, in knee-deep snow up there, to investigate an accident that our Resident Post fellow was involved in up there. So that was my introduction to traveling in the far West.

RT: I have lived in both Dakotas, and I know the winters are pretty severe there, and it's not a good time to travel except on business.

TLA: I was introduced to the term "snirt" up there. The Dakota people call a mixture of snow and dirt "snirt" because once it snows up there in that country, it seems to linger there most of the winter, and it's not the pristine white snow you might think it would be.

RT: When you transferred to Denver, did you get a promotion in grade?

TLA: Yes, I did. I got my GS-12 when I moved out to Denver.

RT: You had become raised to an 11 grade level at Kansas City. Is that right?

TLA: Right. I got my 9 in Kansas City, and then President Nixon froze the promotions, so it took me a while to get my 11. I didn't get it when I thought I was due. I had applied for a number of resident posts, and I finally got the position in Denver, and that's the way I got my 12.

Back in those days, unless you had multi-district experience, it was pretty difficult to move on up the promotion ladder, because the journeyman grade was 11. Later on, they bumped the journeyman grade up, but in those days it was a GS-11.

RT: You apparently had some experience in medicated feeds in Kansas City to transfer to that kind of work in Denver. Is that right?

TLA: Yes. As a matter of fact, in my FDA career, the only trial that I testified at involved a company in Nebraska called John R. Jirden Industries, and that was a cross-contamination case that involved precedent-setting GMP issues for medicated feeds. I testified for, I don't know, it seemed like forever, but it was, I think, two days in that trial. And that was the case where, during the inspection, I actually saw contamination when they were making a DES feed [diethylstilbesterol]. I could see the dust floating over and landing on some non-medicated mineral that was subsequently used in other feeds. So, DES was a carcinogen, of course, and it was later banned from animal feed. But they cross-contaminated the feed there, and that was the basis of the court case.

RT: Where was that adjudicated?

TLA: The trial was actually held in Omaha, Nebraska, in federal court in Omaha, Nebraska. However, I knew we were in trouble when John R. Jirden, the old man that was president, walked into the courtroom and said, "Howdy, Judge," you know. It was one of his old buddies. So I think the judge -- we got a conviction on some counts, but he

threw out the critical GMP counts because I don't believe the judge quite understood the concept of GMPs. And he made a comment that he knew that FDA was kind of breaking some new ground here, but he wasn't sure what it was. Eventually, he threw some charges out just because he couldn't understand them.

RT: I wonder if that led to an initiative on the part of general counsel or the attorneys to orient judges and magistrates to some of the refinements of the FD&C Act, because those are probably not common cases in many areas.

TLA: Oh, I think that's definitely true, that they aren't common cases, and you do have to educate the judges, and sometimes the attorneys, on the nuances of the Food and Drug Act and that sort of thing.

RT: Who was the director at Denver when you went over there?

TLA: The director at Denver was a fellow named E. Pitt Smith.

RT: Thank you.

TLA: Who eventually went to Buffalo, I think, after his tenure in Denver. But he was the District Director, and I think Fred Lofsvold was the, he was -- well, I don't know if he was . . .

RT: He might have been the director. I think there was a situation there at one time where Fred was the director and Pitt was a co-director for a short time. I don't recall the reason for that, but they were both there.

TLA: I recall them as being District Directors, because the Regional Director was in Kansas City. But I think you're right that Fred was about to retire.

RT: Yes, I think that was it, and Pitt was going to take over, which he did. He was a gung-ho type guy.

TLA: He was what I would term a hard-nosed regulatory-minded director. He wasn't afraid to take cases.

In fact, we took on a case up in Wyoming against W. R. Grace Company, J. Peter Grace. And, again, that was one of those DES contamination cases.

RT: That was taking on a pretty formidable firm, wasn't it?

TLA: It was. And we prevailed in that, as I recall.

RT: How long were you in Denver? Did you get into other work or other issues than medicated-feed work when in Denver?

TLA: Yes, I did. I did a little bit of everything when I was out there. I did a lot of tissue-residue work when I was out there, in conjunction with my medicated-feed inspections.

Oh, I had an interesting case where a bunch of cattle were brought in off the range and fed a feed, and they died, and so they sent me out there to investigate. And what had happened was, the guy that owned the feedlot had these cattle on a poor winter range, brought them in and fed them, started them off on a 44 percent protein pellet that had urea in it, and that's why -- they died of urea poisoning. It wasn't the defective feed, but that's an extremely high-protein pellet, and he had it custom-formulated, and apparently he did not know what he was doing, and that's how come the cattle were killed.

RT: Those cattle were dead, so it wasn't a matter, then, of tracing them into human food channels, like slaughterhouses and so on.

TLA: No, no. That wasn't a chemical-contamination case.

But there was a chemical-contamination case that originated in that part of the country, and that was a PCB [polychlorinated biphenyls] case that involved a transformer that was stored in a warehouse, and the transformer began leaking. It went into a waste-oil receptacle, I guess, and it ended up being used back in animal feed, and contamination occurred. It went all over the country and even internationally, and that was a big PCB-contamination incident that had wide-ranging ramifications. I know some of that product went to Japan. It ended up in poultry feed and it got into the eggs, and then it got into

cake mixes and everything else. It was a massive effort to trace all the different directions that that product went.

RT: Where did that occur?

TLA: It was, I believe it was up in Montana or Wyoming. I think the actual contamination occurred -- I wasn't involved in the actual location; I was involved in tracing some of the products that went, so . . .

RT: But it was in the Denver area.

TLA: Yes. It was in a Denver District firm. Like I said, they covered that part of the country at the time.

RT: All right. Anything else in your tenure in Denver that was unusual or significant?

TLA: We had a human-drug manufacturer named Cord Laboratories. They had been one of the generic firms that we'd always had trouble with, and they moved from Detroit to, I think it was Broomfield, Colorado. It was north of Denver. They manufactured primarily tablets in a variety of generics, and they had a number of GMP problems. I collected a lot of documentary samples, and we got a mass seizure out there, and we seized something like 15 million dosage forms from that manufacturer.

RT: Were those human or veterinary?

TLA: Well, actually, it was human and veterinary; they made some veterinary drugs also.

One of the things I remember about that inspection that was kind of funny was, I had a yellow tablet that I was writing notes on, and the quality-control man had a yellow tablet that he was writing notes on, too. The quality-control man left his yellow tablet out in the plant during the inspection. And when we broke for lunch and came back, well, he told me that somebody thought that his yellow tablet was the one that I had been taking notes on, and so they snatched it up and they made copies for everybody, thinking it was my notes, but it was his notes!

RT: That's interesting.

How long were you in Denver?

TLA: I was in Denver about 18 months. I kind of missed the bass fishing out here in the Ozarks, and so I heard that Ed Dee [Edwin S. Dee] and Jan Longenecker were gone. Ed was the Resident-in-Charge at Springfield. Ed transferred to Minneapolis District, and Jan Longenecker transferred out to California, so I took a lateral move to come to Springfield. That was in August of '76. So I left Denver and moved to Springfield. When I moved here, the resident post was in the old Landmark Building. It was the old Frisco Railroad office building, up on the third floor. I then started my tenure here in Springfield.

The Springfield area is primarily dairy, so there's a lot of feed mills. There are also several infant-formula manufacturers. It's the headquarters of what used to be Mid-American Dairymen. There were a lot of cheese plants at that time, small cheese plants. There was not a whole lot of drug work in the area.

RT: I think you mentioned that apparently there were two FDA residents inspectors, and they left. When you came, were you the only resident here at the time?

TLA: I was by myself initially and ran the resident post by myself. The first person who came down to Springfield was a lady named Janice Hickok, who transferred down from the Kansas City office.

RT: You were the senior person here. Is that correct?

TLA: Yes. I was the Resident-in-Charge and she was the junior investigator.

RT: And you've been here ever since. During your tenure here, Ted, you've gotten into quite an expansion in your activities. I'd like to get into some of those. I think you've done a lot of foreign inspection work. How did that happen? How were you selected to do foreign inspections?

TLA: Well, there was a chemical company here in Springfield. Actually, there were two companies, one in Springfield and one in Verona. They used to do business as

Syntex Agribusiness, and they had two plants. Those plants made various types of choline salts, like choline bitartrate, choline chloride, and they also made some other basically bulk pharmaceutical chemicals. I had done inspections of them.

In fact, one of those plants early on had made Agent Orange used during the Vietnam War, and they had some sludge in a tank over there at Verona, Missouri. There was a lot of publicity about dioxin residues from the production of that chemical. It was found that the Verona chemical plant had dumped some of their sludge on some farmland that involved dairy cows, and so there was a lot of concern that there might be dioxin contamination of the milk supply from that standpoint. So I did an investigation of that, and the media was involved in it, and it was kind of high profile.

The EPA brought out their incinerator -- they called it the Blue Goose -- and they incinerated the soil where some of this material had been dumped.

RT: By incinerating, was that a process of heat that eliminated the dioxin residue?

TLA: Apparently, that took care of the dioxin residues when they incinerated that soil.

RT: What kind of a process would that involve? Was it a matter of collecting topsoil and bringing it into a heat machine to process?

TLA: Right. It was like a big furnace, and they'd bring the topsoil and they would run that topsoil through that furnace and heat-treat it. And then they'd collect samples of that soil to assure that the dioxin had been removed, and they had chemical scrubbers to make

sure that it wasn't going back out into the environment. And they had to report to us all the test results and things like that. We didn't find any milk contamination, but that tank was out there for a long time because trying to figure out what the heck to do with the concentrated residues was an issue. They finally were able to get that resolved by EPA.

But we looked at some of the other things, too. Like the choline salts, for example, which are used as an ingredient in infant formula. There was some concern there.

RT: In this soil treatment, to what depth was the topsoil taken? Was it just a thin surface layer?

TLA: I don't really know because that was an EPA issue, since it was just dumped on farmland. They brought the incinerator to the site, and they actually did it on-site there so they didn't have to haul it around. I didn't get too involved from that standpoint, but I was looking at the factory and seeing if there were possibilities that there was contamination there.

As it turned out, they had a flood in 1980, and there was some concern that those residues would have contaminated some of their equipment. So I went out there and worked that flood.

At that point in time, there was also a train derailment east of here, near Houston, Missouri, which involved a pentachlorophenol spill. That got into the groundwater, and there was concern that dairy cattle were drinking contaminated water and they were going to have pentachlorophenol residues in them.

The Kansas City District Director at the time called me up, and I was out at midnight collecting milk samples at the dairy so that we could catch it before it went to human consumption. And, fortunately, the contamination did not get into the milk. Again, mainly that was an environmental issue, but that was also a big, high-profile environmental contamination.

RT: In collection and analysis that had to be really accelerated, did a special laboratory cadre get involved?

TLA: Our laboratory in Kansas City, I believe was able to run those samples, because they were the pesticide laboratory. That was in the days before Fedex, and so I put those samples on the bus and we shipped them up there on the bus.

RT: Kansas City became a national center lab, didn't it, for pesticide work?

TLA: Right.

RT: With the total diet study and so on.

TLA: That reminds me of another contamination incident that occurred in southwest Missouri.

Back about that time frame, as a part of our pesticide screening that we did in Kansas City, we picked up shell eggs, among other commodities. One of our inspectors

picked up some shell eggs in the market in Kansas City, and they came up with chlordane residues. Chlordane is a very unusual -- it's unusual to find chlordane in shell eggs, and it's unusual to find it in much of anything, but it's very persistent.

Well, we started backtracking and tracing the contamination and found out that these eggs came from a company called Moark Productions in Nesho, Missouri. I visited with the president of Moark Productions and tried to determine the source of these eggs. We were able to trace it to a particular farm out in the country. It was south of Neosho. The producer's name was Harry Glassburner.

RT: That's an unusual name, isn't it?

TLA: Yes. I usually can't remember names, but I remember Harry Glassburner's name.

We were very concerned about this finding due to the toxic nature of chlordane and its persistence. It happened to be the 4th of July, and, again, the District Director said, "Anderson, I want you out there. I want you out there following up on this contamination incident." So on the 4th of July, I went to the Harry Glassburner farm, and I remember it was hot as the blazes. And Harry Glassburner was kind of a stocky little guy, and he came out of the house wearing Bermuda shorts and cowboy boots. And I'll never forget that picture of him in Bermuda shorts and cowboy boots. He had a contract-layer operation for Moark Productions, and he had 50,000 laying hens in his chicken house. So I went out there and I told him up front that I was looking for chlordane contamination, and asked if he used it on his birds. We had heard that he was bragging that he didn't have any fly problems in his laying houses, so that kind of raised some

suspicions. And he said, “Oh, no, no.” The only thing he did was he had treated his house around the foundation with chlordane for termites.

Well, I went out in the laying house, and in the corner of the house, by golly, there was a jug of chlordane. And, oh, that’s just where he kept it so it wouldn’t freeze. So I started collecting some samples, and I collected even manure under the caged layers, and we basically found chlordane everywhere in everything we looked at. He never admitted to spraying chlordane in his laying houses. But the manure pits underneath the caged layers was just a breeding ground for flies, and of course the flies would be so thick that they’d pester the birds and they wouldn’t lay. So there weren’t any flies in his laying houses, and that was a little suspicious.

We immediately stopped all the egg shipments and tied them all up. They went out to the dump. But the company did not want to kill all those 50,000 laying hens, so they thought they would try and feed the chlordane out of them. Well, there was no way to do that, but they wanted to try, so they kept feeding them. They thought they’d maybe try and throw them into a molt. Didn’t help. Every week I would go over there, and I would make sure that all the eggs that were produced would go to the landfill. They finally decided that there was no way they could feed the chlordane out of those birds because the samples kept coming up positive.

They dug a big trench and gassed all those 50,000 birds, and they took them out there and buried them. I didn’t witness that. They didn’t let me know exactly when they were going to gas them, and they did it on a weekend, so I wasn’t able to actually witness it. But they dug the trench a little bit too shallow, and this was the middle of the summer, and the dead birds started fermenting. It made like a little volcano, and the gas from the

decomposing birds kind of erupted to the surface of the soil, and I guess it was a sight. They had to rebury them, and it was a pretty nauseating mess for them.

RT: But they voluntarily did that, made that decision, or were they sort of led to it by. . .

TLA: Well, there was nothing, yes, there was nothing else they could do with them because we wouldn't let them ship their eggs. Obviously, they couldn't sell the chickens for any purpose because the residue of chlordane persists for a long time, since the breakdown products are just as toxic as the chlordane itself. There's a lot of different isomers in that particular product.

RT: Did this proprietor then discontinue the poultry-and-egg business?

TLA: He never could put any more birds back in those houses because there was no way to get rid of the chlordane contamination. Mr. Glassburner may have continued in the business with a different house, but he never, as far as I know, did go back into the business.

We didn't prosecute him partly because they were out of business, for one thing, in that particular area. They had lost 50,000 laying hens and they had been hauling hundreds of dozens of eggs to the landfill for weeks until they decided there was nothing they could salvage. So their economic losses were significant.

RT: Yes, it would have been.

That was a somewhat unusual enforcement action.

TLA: That reminds me of another sort of interesting contamination incident that occurred down there.

RT: Our tape just reversed, so I'm assuming there's no loss in our presentation. If so, we can fill it in with words later.

TLA: Okay. Well, I was out sampling corn from various dairy farms on a survey we were doing, and I went to a dairy farm down by West Plains, Missouri. When I went over to the corn bin, the corn kernels looked kind of like popcorn, and they were stained, they were dyed red, and that indicates, obviously, that it's treated grain. I collected a sample of that corn, and I got concerned when I saw this dairy farmer was feeding treated grain to his dairy cattle.

I went into the dairy barn, and there weren't any cows in there at the time. But in the stanchions, in the feed bunks, there was red grain. It had been ground up, but there was red feed in there, so I collected samples of it. I did a little more investigating and found out that this producer -- his name was Don Profitt -- also had some beef cattle as well as a hog operation. He was a big producer in that area. He had, I think, about 90 head of dairy cattle, quite a few hogs, and about 100 head of beef cattle. I went over to where he was feeding his beef cattle, and the same colored grain was in the feed bunks,

so I sampled that too. The same thing with the hogs. The hog feed had that same characteristic, treated seed color, and I sampled that too.

RT: That's treated with mercury, is it?

TLA: No. Actually, we found out what it was when we ran it through the lab. It was pesticide residues. Normally, they treat seeds with captan, which is not that toxic of a material, but we found out it also had heptachlor in it. So that was great cause for concern because we knew this was going to result in residues in the milk. We could tell that from the compounds we found. Heptachlor is apparently converted by the animal to a form called heptachlor epoxide, so you can tell whether the contamination was direct or the contamination was a result of being metabolized and going through the animal, depending upon the type of heptachlor residue it was. So we had scientific evidence that these animals ate contaminated feed, and it came out in the milk because we collected milk samples, too.

To make a long story short, he immediately took all his milk animals offline. He destroyed the hogs. He couldn't ever get the heptachlor out of them. They're so fat and the contamination concentrates in the fatty portion of the animal. He just had to end up burying all his hogs, and he dumped all the milk.

What he decided to do with the beef cattle was feed them real poor-quality hay and see if he couldn't get them to lose enough fat to get it down below the tolerance level. EPA had said that they would let him market those beef animals if he got them down to the tolerance level. He got those beef animals so skinny, they were starting to

die of malnutrition, and since that was under the auspices of the USDA, I never did find out whether he was able to market any of those beef cattle or not. He may have been able to, but I know he was sacrificing them to do fat samples from the carcasses. So that was a pretty old steer by that time.

I found out later that this Don Profitt was a member of the Missouri State Milk Board.

RT: That's interesting, isn't it?

TLA: Yes, which made it pretty embarrassing for him.

What he had done was buy treated grain and had roasted it, thinking this would drive off the fungicide, the captan, for which there was a tolerance. But since it was treated grain, it had been hauled in trucks that had hauled other treated seeds and had thereby been contaminated with some of these other pesticides.

RT: I wonder where he procured the treated grain in such quantity.

TLA: He got them from the seed companies, like up in Iowa, all the big seed companies. They'd treat the seed so they can keep it from year to year, for the next year's crop. If they've had any leftover treated seed corn that hadn't been sold, well, they'll dispose of it.

And, as a matter of fact, that resulted in some more heptachlor, a big heptachlor contamination incident, a different one, close to the same time because they were using

this discarded treated corn as feedstock for ethanol production at a plant down in Arkansas.

RT: Would the supplier to the sellers, the seed companies, be culpable for introducing it into interstate commerce?

TLA: They could be culpable. They put on their invoice "not for food or feed use," and if you then buy it and you've got that invoice, then you're the one that's responsible.

RT: So that would . . .

TLA: That got them off the hook because they knew what this stuff was. But if somebody wants to buy it cheap, for just pennies on the dollar, and think they can treat it, get rid of the residues, and then feed it as cheap feed, well, it ended up being pretty expensive feed.

RT: Sure.

TLA: But the same thing with the heptachlor incident in Arkansas is that the ethanol plant byproduct is good animal feed. Distillers' grains happened to be contaminated. So, again, it was fed to dairy cows and it got into the milk. We had a list of every dairy farm and we sampled every dairy farm in southwest Missouri. We had the state milk inspectors out, too. We had set up a command post at a hotel here in Springfield, and we

had about half of the Kansas City office inspection staff going out and sampling milk that summer.

RT: Ethanol production, because of the petroleum pricing and so on, is that something in this part of the country that is increasing? And thus, if increasing, will that generate more regulatory oversight by FDA?

TLA: It is increasing, not so much in southwest Missouri because we don't grow much corn down here. But I think there is a new plant they're building in Missouri, and it's still kind of borderline being economical to do that. But I'm sure that, based on our experience with what sort of contamination we've seen in some of these feedstocks for ethanol production, that FDA will certainly be doing sampling to prevent those sorts of incidents in the future.

The original question was, how did I get into the international pharmaceutical inspections, and that goes back to the two plants we were talking about, the Syntex plants. They were basically synthesizing the bulk chemicals, and at that time we called them APIs, active pharmaceutical ingredients. I think they changed the terminology to BPCs or bulk chemical compounds. But, at any rate, it's actually the synthesizing of the active molecule. The equipment used are various types of large, glass-lined reactor vessels, and it's basically big chemical reactions where they form the active ingredient, they purify it, and usually they dry it and put it in a form that the dosage-form manufacturers can use.

RT: To check on my notetaking, API really meant what? Is it an acronym for active pharmaceutical ingredients?

TLA: Yes.

RT: Thank you.

TLA: So, the equipment is pretty unique for those sorts of manufacturing processes, and in the early ‘90s, a lot of the APIs were being manufactured overseas. A lot of this was just the dynamics of the business, so there weren’t a lot of manufacturers in the United States. FDA’s Charlie Wayne was one of the original foreign inspectors who did a lot of these bulk pharmaceutical chemicals or these API plants abroad.

Peter Smith actually was involved in doing a lot of those types of inspections, and he was in -- what did they call it then -- DEIO [Division of Emergency and Investigational Operations] back in headquarters. I had been doing a lot of canneries because we’ve got infant-formula canneries here, and they put out a call for an inspection cadre for drugs, devices, and canneries. So I thought, well, I am familiar with canneries, and so I thought, well, I’ll throw in my hat in the ring for international cannery inspections because I’d done quite a bit of that. I had done cannery inspections up in Iowa before there were even LACF [low acid canned food] regulations.

I believe it was in the early ‘90s, maybe ’93, they had the first international inspection training course in Baltimore, and I went to that course. Peter Smith was there, and he found out that I had done inspections of those two Syntex bulk plants and was

familiar with that type of manufacturing equipment. He took me aside and twisted my arm and said, "We really need people who have this kind of experience. We don't have very many of them. Would you be willing to do bulk-drug inspections instead of cannery inspections?" That's how I got started in doing them. In fact, I started specializing in API inspections and bulk-drug inspections . . .

TAPE 1, SIDE B (BLANK)

TAPE 2, SIDE A

RT: As the tape changed, we were just getting into your overseas inspection experience.

TLA: Yes. The initial orientation training course for foreign inspections was held in Baltimore in 1993, and in early '94 I took my first foreign inspection trip, and that was a trip to Japan. Normally, you will take a trip with somebody who has done one before just because of the nuances of traveling in foreign countries and that sort of thing. Since there weren't enough experienced people around, I went with a fellow from Seattle District -- and I can't recall his name. I'll think of it here in a minute. (Harold Sanders) We both went and had assignments in Japan. That was my first foreign trip.

Since I'd been in the military and had traveled to Japan before and had spent two years on Okinawa, I was comfortable traveling in that part of the world. Some people did not like to go to Japan because a lot of things were not in English. A lot of the signs --

most of the people don't speak English; so the signs are all in Kanji, which is difficult to decipher. The food is different, and it's really a change. There are some difficulties traveling in Japan if you're not familiar with the culture. There are other cultural things to deal with there also. But I felt real comfortable traveling to Japan, and I got about all the Japan trips that I wanted.

As a matter of fact, every time I'd go to the Tokyo airport, I'd pick up a little memento. They had these little porcelain Sumo wrestler figures, and so I'd get one every time I'd go through the airport, and now I have a whole collection of them at home in various different positions.

RT: When you went over there, were you going for human pharmaceuticals or drug inspections?

TLA: Yes. We would do both human and veterinary APIs, but it wasn't limited to just APIs. I'd had enough drug experience that I could do dosage forms too.

So it would usually be just bulk drugs or just dosage forms on one trip. Peter Smith, when he was in charge, did not like to mix dosage forms and APIs because it takes different sets of reference materials and that sort of thing. And early on, we didn't have a lot of the stuff on computer, so we had to actually carry the paper guidelines, and when you have four or five different firms, then you have to have four or five different copies, and the paper gets real heavy.

I learned early on that the mantra of a foreign inspector is to travel light, and I tried to pass that along to a lot of the people who I had trained and who I took on their

first foreign trips. You can ask any one of them and they'll remember "pack light." I'm sure they'll remember because I hammered that into their brains. I came back from my first foreign trip with calluses on my hands because in Japan, you travel by train, and to get to train tracks, a lot of times you have to climb stairs and go up and over the tracks, and you have to carry everything you've got. We learned on that first trip that a heavy suitcase and all your FDA papers and things got pretty heavy. Not only that, every place you went, the companies flooded you with paper, and you had to carry those documents, too, so your load got to be pretty heavy by the end of the trip.

RT: These inspections, of course, were to check the quality and the reliability of products coming in for import in the United States. Is that correct?

TLA: That's correct. One of the reasons why we were actually doing the on-site inspections was, at this point in time, we were getting a lot of counterfeit APIs into the United States. So one of the things that we did during our inspections was to collect what we called forensic samples that would be authentic samples of an API from an approved manufacturer. We would send them to our Cincinnati forensic laboratory to establish a library of authentic, fingerprinted chemical APIs. When we found counterfeit products, we can compare the chemical fingerprints and pretty much definitively say that this is in fact a counterfeit product. I have seen counterfeit products side by side with the legitimate products. Under a microscope, under polarized light, you can see a difference in some of those. So every place we went, we would collect these forensic samples.

I was maybe more fastidious than some FDA people. Some of them had the company send them. I'd always seal them up and, if they sent them, they sent them under my seal.

RT: Was the industry over there cooperative? I assume they were because of their wish to send products to the United States.

TLA: As a general rule, the U.S. is, of course, one of the biggest markets in the world for these other countries, so they would do about anything to get their product approved. They were cooperative as a rule, but some of them were deceptive also. And some of the countries, like India and China, are notorious for deceptive and counterfeit practices and not respecting intellectual property like manufacturing processes and that sort of thing.

As a matter of fact, one company I inspected in India didn't have any copy machines in the place because they didn't want their employees stealing their records. They had no copy machines in the place.

RT: How did you resolve that problem?

TLA: Well, we resolved that problem by waiting until their courier went to the nearest town and made photocopies and came back, and it was a two-hour process, anything we wanted copies of. We also took photographs. As a matter of fact, that particular plant was one that we had suspected that there was problems with.

Representative John Dingell had been on an FDA oversight committee and had criticized FDA's handling of some of the criminal things, prior to the time that we had our own Criminal Investigation Division. So the House Commerce Subcommittee sent a couple of their staffers, along with the Dennis Baker, who was at that time the Associate Commissioner for Regulatory Affairs, on a couple of foreign inspections. They went to China with another investigator, then they came to India and accompanied me on an inspection of this factory in India.

As a matter of fact, with the ACRA and the congressional staffers looking over our shoulders throughout this inspection, we managed to show that they were falsifying their records, and, there again, we had the two-hour delay in trying to get photocopies. We had our camera and we took pictures. We found a number of violations, including falsification of the records. And here we had the congressional staffers and Mr. Baker. That was probably one of the most high-stress inspections that I'd ever conducted.

RT: When you made those discoveries, what action occurred as far as the FDA is concerned?

TLA: Well, as I recall, that was their pre-approval inspection. They were trying to get approval to ship their stuff, and obviously they didn't get approved. So although we didn't have any legal authority in the foreign countries to do anything, we could prevent their product from coming to the U.S., and we did that on several of the firms that I was involved in on foreign inspections. We would issue an import alert.

In one case, a company had already shipped a container of an API en route to the U.S., and they flunked the inspection, and so we alerted the port not to let it in, not accept it into the country, because they were betting that they'd pass inspection, and they didn't.

RT: That's an extension of protection to the American consumer that probably many consumers really aren't aware of.

TLA: Exactly.

That reminds me of another inspection I did in Spain. This company in Spain was wanting to ship their product to the U.S., and they sent an application in that said they had a nice clean room, a special changing area, and the chemical dryer was located in this clean area. I went over there and found out that, as a matter of fact, they did not have a clean area, and they were packaging this material out in the open factory, and they also made antibiotics in a nearby factory. The windows were open; they could get cross-contamination.

Their dryer was actually outdoors, and they were building a building around that dryer that was supposed to be their clean room, but it wasn't there when I was there. So I took pictures. I had a Polaroid camera with me and I took pictures of this. Their application was fraudulent in that they said they had this when in fact they didn't. When I went over there and looked at it, they didn't have it.

RT: Well, the dryer, for the uninitiated, does what function, with regard to the product they make?

TLA: In that particular process, you have a saturated solution of the active drug ingredient. It's actually manufactured in a liquid medium, and the pH is changed and the temperature is changed to precipitate out the active drug ingredient, and that's actually part of a purification step to get that drug to precipitate out, and sometimes they may do more than one of those steps.

Well, when they precipitate it out, it's just kind of crystals, just like salt, only it's wet, and you have to get it dry. And so you put it in, actually, a big, tumbling dryer under heat and vacuum, and that removes the solvent, whether that's methanol or water or some other solvent that they've used to precipitate this out with. Sometimes they will actually wash the crystals with a solvent that does not dissolve the crystals in a centrifuge, and then they will empty the centrifuge into the dryer, and it's called wet cake, and they will dry that wet cake inside the dryer.

So that's the final purification step. They may run it through a mill to make the particle size what they need, but after it comes out of the dryer, frequently it goes right into the bulk container, a fiber drum with poly liners, that is the final step.

The manufacturing environment is critical to the purity of the drug, and doing it outside, obviously, is not acceptable. So that's why it was so significant that they said they did it in a clean room when in fact they did it outdoors.

RT: That's interesting.

How frequently were these trips for you? In periods between them, I suppose you were involved in the resident operations here. But you sort of became a national expert in some of these overseas experiences, no doubt.

TLA: Well, I took -- the trips that I took varied. I think the shortest one was one I took, well, it was just before Christmas, so that it was like two weeks in Germany and Scotland, so that was absolutely the shortest trip. They liked to do three-week trips. The longest trip I took was five weeks, and that was to Singapore and Australia and the Far East, where it took a long time to get from place to place. I tried to do two trips a year, so that was about all I could stand because it was just inspection after inspection after inspection, and frequently I'd be writing my inspection report up like, particularly in the Far East, on the train when I'm going from one point to the next. So I guess between the time I retired and the time I started it, I spent about 10 or 11 years doing foreign inspections. Obviously, I did my own domestic work when I came back. Nobody did my work for me, so I had that piled up to do too. So it was sort of a thankless job. And we really didn't get any extra pay for doing foreign trips.

As I think back on it, I'm not sure exactly why I did it, but I liked the new experiences and I liked going to different countries. I think the last time I counted, I traveled also in Europe, and I had been in China and India, Singapore, Taiwan, Korea, Japan many times, Australia, New Zealand, Spain, Ireland, Germany, Switzerland, the Czech Republic, and I'm sure there are probably a couple more that I've forgotten, Sicily. Oh yes, Canada.

RT: Well, that's certainly an expansive field experience.

During these visits, I assume that if it was a different language, they had an interpreter for you. So, was communication, though, a problem in getting information that you needed?

TLA: Communication was a big barrier, particularly in China and -- not so much in Japan because I know a little bit of Japanese, and I know what some of the Kanji characters are. Their applications have to be in English, though, so I was always able to compare the applications to actual practice. But, yes, most of the time they furnished an interpreter.

Sometimes the interpreters were very good. There was a fellow in Japan, the best interpreter that I ever had. He was an engineer and a pharmacist, and he had designed some of the actual manufacturing equipment for some of the really state-of-the-art, leading-edge plants that I was in in Japan. I could ask a technical question, and he knew what I was asking, you know, he knew; he would always rephrase it and explain and make sure that they got exactly what I was asking. People that just knew the language and didn't have the scientific background -- if they were poor interpreters -- they didn't know what an HPLC [high performance liquid chromatography] was, then that made it real difficult because you would have to explain to them the nature of the question, also.

But looking at documents, I could look at documents that were written totally in Chinese and I found documents that were incomplete, missing data, just by looking for the patterns, you know. If they were supposed to have five pieces of data and there were only four numbers down there, I knew that that was not complete. So even though there

was a language barrier, the equipment is the same and the records and a lot of the things that you could look at, you'd be surprised how much you could find out.

I had an interesting experience in Japan. They were doing validation of the suitability of the bulk container for export shipment, the bulk drug container. I asked them for documentation of their validation test. They brought me a document, and I looked at it, and I could tell it was incomplete. They didn't have some of the data there. So the next day, I asked for the same data from a different fellow, and he said, well, he didn't have it right now, but he'd run over and get it.

Well, about 30 minutes later, he came back with the documentation, and that was a case where it looked like the ink was still wet because he brought me the same document that I had collected the previous day that was missing the data, only now the data was in there. And so I called a halt to the inspection.

I got the top guys in a room so that I wouldn't embarrass them, because they had everybody in the factory, you know, all the managers were involved in the inspection. So I got the top two or three people. I called them aside. I set those two documents down side by side on the table, and I said, "This is fraud," you know, "and I don't expect to get this kind of response from my next question, anytime I ask for additional data here. If it's missing data, fess up to it, but don't falsify the data." And I had run across that before.

And the same thing in India. You can tell when people are being deceptive.

There's little techniques like that that you could use to tell when they were twisting your arm.

I was in a firm in France, and I saw a dirty piece of equipment that was totally unsuitable, and they said, "No, we don't use this piece of equipment in processing the stuff for U.S. consumption." I didn't really believe them, but I knew enough French that I heard them talking later about the fact that, "Well, should we really tell him that we do use that one?"

But I got the number off of the machine. When I looked at batch records for the U.S. production, they used that machine number, and I just laid it on the table. Actually, I slammed it on the table and I said, "You lied to me about using this machine. You blatantly lied about it." I said, "We're going to go back out here and we're going to start all over again." And I made everybody march back out to the factory, and we started the inspection all over again, and I got straight answers from them, out of them. But I knew that they were lying to me, and I could prove it.

RT: When you were in foreign countries, dealing with foreign governments or regulatory folks, were they interested or in any way involved in our being in their country and checking their industries?

TLA: Yes. There was. That happened to me several times.

Once in Singapore, I had a message when I checked in at the hotel. It was from the head of the Singapore FDA, who was a woman. She was also a pharmacist, and she wanted to meet with me. I figured I had to do it. So, before the inspection, I had a meeting with her and a couple members of her staff, and basically they didn't have much in the way of an inspection program, and they wanted to know if FDA would be willing

to do inspections for them on a contract basis. And so I diplomatically said, "Well, we have a hard enough time doing our own inspections." But I had some contact information for the liaison in headquarters, and I gave them that information.

On a subsequent trip to Singapore, they had established their pharmaceutical inspection folks, and they had gotten them training, and they wanted to know if they could send one of their representatives along with us on the inspection. We agreed to do that. It was common in Japan also that the local prefecture government representative would have one of their inspectors accompany us. I felt like most of the time that we were sort of training them in our inspection techniques, because frequently they would tell me that they did pick up things, that we looked at some things a little differently, and they picked up some techniques that they could use in their evaluations of some of their firms. So that was not unusual, to be accompanied by the local regulatory authorities.

In Switzerland, there was an incident that was on the German TV. It was kind of their equivalent of like "48 Hours," one of the news programs, that there was a big flap about asbestos particles in injectable vitamin K. Injectable vitamin K is used in newborns. If they're a little jaundiced, they use injectable vitamin K. And so there was a big flap about asbestos particles that had been found in one of Roche's injectable products.

So they sent us over there to do an inspection, and I met with the Swiss, basically the Swiss FDA authorities, and I had a Swiss drug inspector accompany me during the inspection. We went through the factory, and they put on a dog-and-pony show. They did everything they could do to roadblock our inspection to keep us from spending time out in the plant without outright refusing. I'd ask a question, and they said, "Well, we

can't answer this without going through the whole procedure," and I put up with that for a little bit. But finally I just stood up and I said, "We're going to go in the factory and we're going to do this inspection."

Well, I come to find out that, son of a gun, we did find asbestos being used everywhere in that plant. We found loose asbestos particles. We found it in the airflow system that could result in the contamination of the product as they were moving it from one vessel to the next, and they were in the process of replacing everything. But they were quite a ways behind the U.S. when it came to eliminating the use of asbestos.

They spent a lot of time showing me statistics that asbestos particles weren't going to be toxic or pass through a certain pore-size filter. They were using a lot of statistical data to try and back up their arguments. Of course, that in itself, to me, was a big red flag, and, as a matter of fact, we did find there were deficiencies there from that regard. Whether that was a health hazard or not, I don't know, but that was a big issue, and they were very reluctant to show us anything. They wanted to show us their new factory. I didn't even go to the new factory.

RT: The United States is reputed to have the most effective and strict requirements for pharmaceutical production, and perhaps for foods and so on. Based on your foreign inspection experience, are there any countries that you would identify as being, if not equal, closer to our standards?

TLA: Yes. The two best countries from that regard -- and even within the country, I've seen a range of passable to state-of-the-art -- Japan probably has more state-of-the-art,

high-tech API plants than anybody else; Germany is a close second. One of the best plants I've ever been in was in Germany.

I've been doing this a long time, and I usually can find issues, deviations, maybe not major but minor; I can find them.

I was in a new plant in Singapore, and I found a significant design defect. It was a brand-new plant, just been commissioned, gone through all this validation and testing, and I found cross-contamination in the design defect of equipment that I'd never seen before.

One new plant in Germany was one of the best I've ever been in, and I couldn't find anything.

I take that back. I found the wrong identification tag on a pipe in their water system, but nothing significant. And I looked at a heck of a lot of data.

RT: Was that a producer of human pharmaceuticals?

TLA: Absolutely yes, injectables and some very significant drugs, some that are very bioactive. They had some cancer drugs that were real cytotoxic, so you couldn't have any human exposure. So a lot of it was basically isolated and untouched by human hands. It makes it real difficult to clean up that sort of thing because you can't get in there. It's got to be kind of CIP [cleaning in place] cleaned or that sort of thing.

One of the plants that was the top plant in Japan that I was in, basically it was the same sort of thing. They had one of the new immunosuppressants that was used in liver-transplant patients to keep them from rejecting their liver. Since it was an

immunosuppressant, if you got exposed to it, you would have no immune system. It would be like you had AIDS. So you couldn't have any human exposure to the manufacturing environment. They had a lot of closed-circuit TV monitoring, and the operators that did have to be in the manufacturing environment were wearing moon suits with self-contained breathing apparatus and monitors to make sure that they didn't get that kind of exposure. So you could see a lot just by sitting there and looking at the TV monitors and that sort of thing.

The plant in Germany, all the computer systems were integrated, and everything was computerized. And it's real difficult to do the validation on those computerized systems when everything is integrated.

For example, when they weighed out the active ingredient on a scale in the weighing room, it automatically translated that to the batch record; the batch record calculated the batch size, depending upon the potency and the weight of the active drug ingredient being used. So that was one of the things that I selected to check on their validation, because if their calculations are wrong on the weight and the potency of that particular drug -- and the potency varied, so you couldn't have a standard amount; you had to calculate it -- so if those algorithms weren't right, then they'd end up with a screwed-up product, and they had the best validation documentation I ever saw. Of course, it was a major company, but they had the best documentation, and that was one of the better plants. It was a brand-new facility. That helped too, because they were able to build in state-of-the-art things, like even their raw materials were picked by robots, and these little robots would go around and they were laser-guided. They were so precise that you could see little tracks on the floor where they went, and they went to the same place

every time, and there were no tracks anyplace else. So it was really high-tech and state-of-the-art.

I have lots of little tests that I use to determine if things are in control in places like that, and they passed all the tests. I'm not easily impressed, but they impressed me, so those two countries were towards the top.

RT: How about the United Kingdom? Is it somewhere in between the best and the worst?

TLA: I did one, let's see. Well, I was in some pretty good plants in Ireland. I did one in Scotland that had some problems; I was unimpressed with it all. And some of the other plants in the U.K., I didn't do any API plants in the U.K. There were some good ones in France. It's kind of like anything else. Some of the major countries are a little more advanced in their technology.

RT: Some of the countries that are maybe less impressive that way, like India and similar countries, I know quite a few surgical instruments and so on are made in there. That wouldn't have been in your venue to check on, I guess.

TLA: No. Those would be medical devices, which, I didn't do medical devices inspections, even though I had done medical devices. I was doing medical device inspections before we even had GMPs for medical devices, in some of the Becton-

Dickinson plants up in Nebraska that manufactured needles and cannulas and that sort of thing. It's just like I did inspections of canneries before we had the LACF regulations.

And actually, I was involved in reviewing some of the infant-formula regulations when they were implemented, because we had, in Springfield and in Cabool, we had two -- and, actually, there's another one up in Eldorado Springs that we had . . . We had three of the larger infant-formula manufacturing operations in the country. They were contract manufacturers for Bristol Myers, and so I had had a lot of experience early on in doing inspections of that industry. Maybe I had a little input on some of those infant-formula regulations.

We've talked about the better side of the manufacturers, but I had some memorable worst-case scenarios that I have gotten involved in in the foreign inspections.

RT: Please continue, Ted.

TLA: Well, you asked about some of the experiences that weren't quite so positive in my foreign trips, and I did inspect a company in China that was wanting to market a veterinary antibiotic added to feed. I don't remember exactly which one it was. But they had developed a process whereby they were able to eliminate one of the isomers of the drug, and nobody else in the world could do it, so they had a competitive advantage. That part of the process involved China's Nuclear Regulatory Commission.

And so I went over there, and it was a fermentation/chemical purification process. The initial stage was a fermentation, but then the key purification steps was where I liked to focus my inspection. So, before we did the fermentation part, I said, "Let's cut to the

chase here. I want to see the key purification, the first purification step after you've isolated this compound from your fermentation process."

And they said, "Oh, that's a trade secret. We can't show it to you."

And I said, "Wait a minute. You want to sell this product in the United States, you have to pass inspection. I look at trade secrets all the time. I've got to see the key part of the inspection."

They said, "No. We'll show you everything we do after that, we'll show you everything we do before that, but it's trade secret."

Well, it's kind of ironic because they don't respect anybody else's intellectual property, but they were not about to let me look at this part of the process.

So I said, "I'm not going to do the inspection unless I see that."

And I thought at the time, gee, maybe I'm going out on a limb here, but I'll be darned, I was not going to set the precedent of allowing them to refuse a critical part of the inspection process and still let them ship their product to the U.S. I said I couldn't do it. And I figured I would take the heat if I had to when I got back to the U.S., but I said, "Let me make sure that you understand what the ramifications are here." I probably insulted them culturally, but I said, "You check with your boss and see if you want to refuse to let me look at this process."

Well, they disappeared for a while, and they came back and they said, "Not going to happen."

Actually, the night before, I'd had a dinner with the deputy mayor of Guangzhou. She was a card-carrying member of the Communist Party, and that's what it said on her business card. I thought, gee, if my dad had seen that I was having dinner with a

communist, he'd probably roll over in his grave. But that really didn't have anything to do with the issue.

They decided that, no, they weren't going to show me that part of the process, and so I said, "Okay, I'm out of here." I turned around and walked out.

I went back to the hotel. They had put us up in a five-star hotel in Guangzhou called the White Swan Hotel, and it was really a nice hotel. I'd left my computer in my hotel room and it never worked right after that, and I think they'd gone in there and tried to steal software off my computer. I have no proof of that.

Since we couldn't do the inspection, this whole trip was, well, it was one of the trips from hell.

I had another assignment up in northeast China. I think it was Northeast Pharmaceutical Factory #6, in Shenyang, and this was in January. Shenyang is not far from Siberia. I had been warned by the U.S. agent that they would not have any power on, any heat on in this factory. They weren't actually manufacturing, but, to save energy, they wouldn't have any heat even in the conference room. I was going to have to wear a hat and coat, even in the conference room. I bought some expedition-grade long underwear, and I wore that underneath my suit, and we went up there and did the inspection. Sure enough, there was snow on the ground, and it was just as cold as you could imagine. The U.S. agent had a big old long, wool overcoat on. He couldn't stand it any longer.

About a half-hour through the inspection, he says, "We can look at records in the office. I'm going to go back to the office. I can't take it anymore."

So I said, "No. I've got to look at the equipment."

So he went back to the office. And I was comfortable because I had that long underwear on. But the poor Chinese folks that were with me, they were shaking like leaves, and they probably thought I was made of steel or something, since I didn't look like I was getting cold. But I had to look at all the equipment.

We were due to have lunch about noon, and so they had ordered lunch from a local restaurant, I guess, and so we were sitting around the conference table and we were ready to eat, and lunch didn't get there, and it got to be about one o'clock, and I started looking at some records. And they were so embarrassed that the lunch wasn't there that they all left the room; all the Chinese left the room. So we were just sitting there with the U.S. agent and a translator, and they had lost face because they didn't have lunch. So they finally got us some lunch. It was cold.

But then we heard screaming out in the hall, and it was one of the employees who hadn't gotten paid, and she was really upset with them, and they had to physically restrain her and wrap her in a blanket and take her off. But there was no heat in that thing. And most of those people were riding bicycles, and the streets were all snowy. I saw them crashing on their bicycles. They'd have a little metal milk crate with a few pieces of wood in it, and they'd be standing around on the street corners trying to keep warm. It was really a Third World deal.

When I went to leave Shenyang, they had a deal where they wouldn't let you off at the terminal; they let you off the taxi about 500 yards from the terminal. They had some young Chinese kids there that were porters, and that's how they made an extra dollar off of what little tourist trade that went through there. They figured who's going to haul their luggage 500 yards to the terminal (even though there was a drive right up in

front of it). Well, that kind of made me mad, so I just said, "The heck with you guys," and I carried my luggage all the way to the terminal.

We were supposed to leave on a one o'clock flight, and we were getting ready to go, and they couldn't find the guy that had the key to the jetway. So everybody was ready to get on the plane, but they couldn't get the jetway unlocked. We stood around for, it must have been a good half-hour before they finally found the guy that had the key. So they unlocked it, and we finally got on the plane. This was China Northern Airlines, with the world's worst crash record on that airline, and I knew it. They don't have assigned seats, so it was like loading cattle. Everybody was just jammed in there and it was first-come, first-serve on the seats.

I got in there and sat down, and they took lunch orders. They had a beef dish and they had a Chinese dish. Well, I was one of the few Americans, and maybe the only American. I'm sure I was the only American on that flight. So I ordered beef because some of that really authentic Chinese food doesn't suit my palate.

We took off, and the stewardess came down the aisle, and they looked like they kind of had an attitude. They would just give out unopened cans of soda and give you a glass, and here you opened your own soda. One stewardess dropped a can of soda, and she just picked it up and gave it to one of the passengers. Well, he set it in his seat there, and once we got airborne, he decided he'd open that soda can that she'd dropped. When he did, that thing exploded, and it was literally raining soda from the ceiling of that airplane, and those two guys that were sitting there were just covered with sticky soda.

Then they came by and said, "Well, we're out of beef.: Everybody wanted beef because nobody ever got beef in China, apparently. So all they had was the Chinese

stuff, and I could not eat it. They had some spoiled egg dish. I mean, it was fermented. It was really rotten. So I couldn't eat it. I didn't have any lunch there; I just couldn't.

From Shenyang, we were flying into Hong Kong, and they had a rare winter typhoon that day. The Chinese pilots are mostly former military fighter pilots. At that time, Hong Kong Airport was right in the middle of the harbor, or next to it, and the plane ride was so rough. It was the roughest ride I've ever had, and nobody thought that we were going to make it alive. He came in for a landing, and I looked up and I could see the tails of the jets parked on the runway, and we were still at about a 45-degree angle going down, and all of a sudden he just pulled back on the landing gear. We went right back up in the clouds. Oh, I thought I was going to die.

Then they wouldn't let him land, and they sent him to a little town about an hour away. By this time, it was about five o'clock in the afternoon, starting to get dark. We landed in the rain way up on the runway, and they wouldn't let us off the plane. We said, "We want to take a bus to Hong Kong. It's only an hour away. We want off of this!" Nobody wanted to go through that again. We didn't trust that pilot, and they would not let anybody off the plane. Somebody came out on a bicycle in the rain, and they finally explained that since it was Hong Kong, it was not a Chinese territory there. It was an international flight at that point, and they didn't have the right "chop" or stamp on the passports to let us get off the plane and go to Hong Kong by bus. So we sat there on the runway. Of course, since they had run out of food, there wasn't anything to eat. They didn't have anything but a little bit of water. The Chinese people on the plane were arguing with the crew, and finally the flight crew retreated to the front of the cabin and everybody just sat there. We didn't take off until about 8:30 that night, and I hadn't had

any lunch because they were out, and we didn't have any supper, and they didn't bring any food, and they had no drinks or anything.

We finally got into Hong Kong, and I got off the plane, and there's a McDonald's in the Hong Kong airport, and I was never so happy to see hamburger and french fries in my entire life. As soon as I got through customs and all that, I got a hamburger and french fries and something to drink. By this time, it was almost 11 o'clock.

I hailed a taxi and went to the hotel, and I went to check in, and they said, "Well, we're all booked up. We sold your room."

I said, "Well, I had a reservation."

They said, "Well, you were supposed to be here by six o'clock because you had a five o'clock flight arrival."

And I said, "Well, we got diverted and ended up someplace else."

I was starting to get mad at that point, and I thought, well, I'd better not get too mad because he's going to find me a motel room here in Hong Kong for tonight. So I kind of calmed down, and he said, yeah, he'd called around. He found another hotel. It was about six blocks away. And I said, "Well, call me a taxi."

He said, "It's just a few blocks away, and the taxi drivers will get mad if it's just a few blocks' ride."

I was about to lose it at that point anyway. So I just grabbed my luggage, I walked out the door, I hailed a cab. I didn't care if it was going to make the cab driver mad. It was raining, and I'm not going to walk six blocks in the rain dragging my luggage so I won't offend a Hong Kong cab driver. I don't think so.

Anyway, so it was a nice hotel.

The next morning, I fired up my computer, and my computer was not working, and that's when I realized that, I thought that maybe the Chinese had tried to download some software off my computer. I called the U.S. and I had them Fedex me my backup computer to Singapore, my next stop.

I had to go back to China on Monday morning, since I had another inspection in China.

The next morning, I found out that DEIO had issued me a single-entry visa, but since I had spent the weekend in Hong Kong, that was one entry, so I had to get another visa. Well, it was Saturday morning. I found out where the visa office was, and I got over there, and it was just about to close. It was only open till noon, and it was just about to close. I got on the elevator to go up there, and the elevator got stuck. It went about three feet and got stuck. So we were able to pry the doors open to the elevator. I kept looking at my watch. I thought, I'll just take the stairs. So I ran up the stairs, and I got about to the fifth floor, and there was an iron gate across the stairs and you couldn't get up there because it was their embassy.

I ran back down the stairs, and the only other elevator happened to be working, so I got on the elevator. I went up there, got in line, and I finally got to the visa window. They said, "Well, we can issue you one on Monday."

I said, "No, I've got a train into the interior of China the next morning."

They said, "Well, we can get you a commercial visa, not an official visa." They said, "That'll be 640 Hong Kong dollars."

I said, "I don't care what it is. Get me that."

They said, "Okay. But you've got to have a visa photo."

I'm saying, well, you know, here's about 20 minutes till the office closes. So I had to go find a photo place, and then I had to stand in line. I finally got a visa picture, came back about five minutes before it closed, and was able to get my visa.

The next morning, I was supposed to meet a U.S. agent at the train station, and I could not find the gate at the train station where my train left from. Well, as it turned out, they were doing some construction at the train station, and that gate was now outside, so I had to go outside, around, and wait in a big, long line, and then I had to go through customs again. I finally got on the train.

I did the inspection, took the train back to Hong Kong. I got out to the airport a little early, and I thought, well, if I can get an earlier flight to Singapore for my next inspection, I will. So I was able to get an earlier flight to Singapore, so I got on a flight to Singapore and got into Singapore okay. And there was my computer at the desk when I checked in the hotel.

By that time it was 6:30 at night, and I was exhausted. The bellboy took my stuff up to the room. I got up to the room. No computer. So I ran back downstairs, and there it was sitting in the lobby. The bellboy had just left it sitting there in the middle of the lobby.

Got my computer, got back upstairs, went to sleep.

Had a phone call the next morning -- it was the quality-control manager from the factory I was supposed to inspect, and he was supposed to have met me out at the airport, so he was at the airport at midnight. My flight was supposed to get in about 11 o'clock. I had neglected to tell them that I'd gotten on an earlier flight because I hadn't looked at my paperwork until the next morning. So here I'd left them stranded at the airport

waiting for me at midnight. Of course, the airlines wouldn't tell them if I was on the plane or not. They finally called the hotel and found that I had checked in. But that was kind of embarrassing, that here they were out there to meet me and I hadn't told them I was coming early.

RT: That account certainly documents that making foreign inspections isn't quite as easy as accessing domestic facilities.

TLA: It certainly wasn't. Not only that, I was booked back home on an American Airlines flight, and I saw on the news that American Airlines pilots were going to go on strike, so I didn't know until I left whether I would actually be leaving or not because of the airline strike.

That was sort of the trip from hell. Everything that could go wrong went wrong, but we managed to survive it.

RT: Are there any other experiences in that, activity that you care to cover?

TLA: Well, let's see.

The trip I had to India, I had a chemist with me, and they'd been having some civil unrest there.

RT: This was an FDA chemist?

TLA: Yes. This was Michele Obert from the Kansas City office.

We were going to go out and get in the car for the ride to the factory, and there was a guy standing there with a machine gun out there where the taxis load, and it was the body guard for this guy that had just pulled up in his car. Apparently, Michele didn't realize what was going on, so she just made a beeline. She walked right by this guy towards the car he was guarding, and I said something to her about it, and she realized then that maybe she ought to make a little detour, because the guy with the machine gun was looking at her like, what are you doing here, lady?

He was hanging around the hotel most of the time we were there, and you could see him with his Uzi, lurking in the background.

TAPE 2, SIDE B

RT: Just a minute. The recorder cut off. It's resuming now. Go ahead.

TLA: Okay. Let me see. Anything exciting happen to me in Europe? Not that I can recall.

RT: Europe probably is generally a less hostile environment than the other side.

TLA: It was easier to get around. More people spoke English. It was particularly tough in some of the outlying areas of China, for example. But that was probably about the

most unusual experience, other than spending five weeks on one road trip. It seemed like that was the road trip that would never end.

Other than that, the inside of those factories looked just about the same regardless of where in the world you are, so that was kind of one constant that gave you a little bit of familiarity, because when you see a reactor vessel or a centrifuge, and you're looking at the data, and the chemistry is the same. You find the same problems as you do in the U.S. In a lot of ways it was a challenge, and it was much more difficult when you add the travel problems.

One of my hobbies is doing triathlons, and I did some of the Iron Man distance triathlons. That's a 2.4-mile swim, 112-mile bike, and a marathon. I had a trip to Japan and New Zealand one year, and I decided to do the New Zealand Iron Man Triathlon at the end of my trip, so I took a couple days' vacation at the end of my trip.

I had a huge bicycle case. I took my bicycle with me in addition to my luggage and my computer. And traveling in Japan with that, I had to run to the top of the stairs at the train station and leave my luggage, run back down and get my bicycle case, and just kind of bumped up the steps till I got to the top, and then I try and load everything up and run and get on the train to go from point to point. That was insane. I know I'll never do that again.

We had to go through the train station in Tokyo at rush hour, and that is, you know, you see pictures of the conductors stuffing people into the trains to jam them full. That's how full they are, and it's just a beehive of activity. And trying to figure out where you were supposed to go to catch the next train. There's about four different levels in that train terminal, and it's always just really busy.

So here I was with a computer and a suitcase and my huge bicycle case, fighting my way through the crowds in the train station, and then trying to get this stuff on the train. I took up enough room for about four people, and I know folks were looking at me like, what is this crazy American doing here with that huge luggage?

RT: You had to probably plan a little advance timing for accomplishing all that, too, didn't you?

TLA: I did. But I was able to find places to swim in Japan. After work, I'd either ride my bicycle or do a run, or both, and I was doing a swim workout. My swim workouts were about an hour, hour-and-a-half swim without stopping. I was in the indoor pool in Japan. Everybody was swimming laps in there and it was all very regimented. And so, fine. I found a lane that was about the right speed, and pretty soon I was the only one in the pool. I didn't really know what was going on, but I knew that I'd only gone about 45 minutes or so and I still had about another 45 minutes to swim, so I just kept on. Finally one of the lifeguards tapped me on the head, and he couldn't speak English, but he would point to his watch. I shook my head no. I still wanted to swim some more, but he kept shaking his head. He made me get out of the pool.

Well, I learned they had a rule over there that you had to get out and rest 15 minutes of every hour, so everybody had to get out. They'd blown a whistle that I didn't hear, I guess, and everybody got out of the pool except me. So I finally realized what was going on.

I don't know where everybody went, because they weren't around the pool. Maybe they went back into the shower room or something. Here I was sitting by the pool by myself for 15 minutes, and then I had to get back in and do another 45 minutes on the workout.

RT: When you do foreign inspections, do you have to observe the same protocol of introduction as in this country, that is, give a notice of inspection and show identification and so on?

TLA: Early on, when we first started the program, we never issued a notice of inspection because that was a legal requirement for the United States, and we had no legal authority to be over there. Initially, we didn't even carry our badge and credentials, and part of that was for security purposes so that we wouldn't get kidnapped, basically, in some of these countries. Initially, we just presented business cards.

In Japan, that was a big deal. They have a very formal system. You present your business card, holding it facing the individual that you're giving it to, and you hold it with both hands, and you present it to them. Part of the protocol is, they take the business card, they look at it, and they compliment you on how well-designed it is. In Japan, there was always a crowd with me during my inspections. I think my record was 36 people that were in the introductory meeting who were to accompany me during the inspection, and I gave 36 business cards to those 36 people, and they gave me theirs. A lot of theirs were totally in Japanese, which I couldn't read anyway.

But it was kind of like dominoes, you know. When I was going through the factory and I would stop, everybody would just kind of jam up behind me. When I'd look at something, everybody would look. It didn't bother me that there were 35 people with me, but it was almost comical.

RT: Were some of those industry folks who accompanied you taking notes on what you were doing as well?

TLA: Yes, they were taking notes. There was usually always somebody, in Japan particularly, taking notes.

RT: Did they ask to film you?

TLA: Once in Japan, they wanted to videotape me, and basically I told them I would prefer that they didn't.

Another time, they had a little microphone on me, and everybody had earphones and they wanted to record everything I said, so I said, whatever, "It's okay with me," and their point being, ostensibly, that they wanted to make sure that they understood the questions that I was asking and that they gave the proper responses. There are a lot of nuances in the Japanese language that don't always translate specifically to English. So they did that. They put a recorder on me the first day.

The next morning, when I showed up to start the second day of the inspection, they decided that they weren't going to do it the second day. They said the first day I

asked over 200 questions, and they just weren't able to get everything translated, apparently, so they decided that wasn't going to be a good game plan. So I guess I cured them of trying to do that.

RT: Some of these folks actually asked you why you were looking at or examining certain equipment or procedures? In other words, asking, if you will, for justification of what your inspection involved? Or did they pretty much accept that as a necessary if they wanted to do business?

TLA: No. Most of the folks knew why I was there and what I was doing. They just didn't know how I was going to go about it. The extent that I was going to look at things.

For example, some of the Japanese would bring all their records into a big room, and so there'd be a room just lined with their batch records and their documents and their procedures, and I could just pick and choose. Well, what I liked to do is I like to go out and see what they're doing, see if they're doing the documentation concurrently with their manufacturing procedures, check the times and things like that on the documents as in real time, so I think that was a little bit different.

I spent most of my time in the factory. I'd be out in the plant and I'd say, "Do you have a separate hose for transferring this drug from this vessel to that vessel?" and they'd say, "Oh, yes, we've got it," and they'd send somebody off to bring it. Well, I did want to see the hose, and I wanted to see where it was stored. So a lot of times I'd ask them for something and they'd try and bring it to me, and I wouldn't let them. I'd follow the guy who knew where it was because I wanted to see where it was stored, how it was

labeled, how it was handled, how it was cleaned, and that sort of thing. A lot of times I'd be taking off, following this plant guy, and everybody else would be standing around wondering where I went, what I was doing. That wasn't unusual, but I didn't want them to do things specially for me. I wanted to go see it.

This one plant in India brings this to mind -- they had a real poor water system, purified water system, and, in fact, it was so bad that it was leaking. You could see it spraying out in the manufacturing area. The plant manager went over and stood in front of it, hoping that I wouldn't see it. But I saw it before he even did that, and I politely asked him if he would move so I could go see the leaking pipes, and that was an item on the 483.

RT: Well, I suppose we've pretty well comprehensively covered that part of your career.

I noticed in some retirement information that circulated that apparently, on the domestic side, you apparently were also active in intergovernmental relations with some of the state, and perhaps county, counterparts of our staff. Is that something you would like to comment on?

TLA: Yes. Being stationed in a Resident Post, I thought it extremely critical to leverage our limited resources with our state and local people, and I think that sometimes this wasn't recognized quite as much at the district office level. I spent a lot of time cultivating my relationship with the state people, not only in the Health Department, but the State Board of Pharmacy, the city health departments, the State Department of

Agriculture, and the local agriculture department feed inspectors, for example. Cultivating those relationships paid dividends many times over.

In fact, an example is the Joplin City Health Department. I gave them basically a modified complaint form, and explained to them what kind of complaints I would be interested in following up that involved products under our jurisdiction. They would take the information, and then just fax it over to me, and if follow-up was necessary, I could do that. They would do the initial investigation, which saved me about 140-mile round trip to go and actually look at the product or do the initial investigation.

Also, the Springfield, Green County Health Department laboratory had a micro lab, and they did some helpful things. They looked at some of the complaint samples for us and saved us shipping them overnight to Kansas City when it was just something initial. On an initial screening complaint, verifying the complaint, particularly on those where I thought that it was maybe kind of iffy.

RT: In this district, was the commissioning authority used to convey to cooperating state officials some FDA investigative authority?

TLA: Yes, we did that, particularly in the milk area. We commissioned some of the other folks.

Down here, for example, in the feed industry, we did all the medicated feeds work ourselves because we didn't have an agreement with the State of Missouri.

The State of Missouri did have a micro lab here, and I would use their facilities to sterilize my sampling equipment, for example, rather than shipping it to Kansas City or

someplace else and having it shipped back. I could just go over and have the state health department run it through their autoclave for me.

RT: In regulatory cooperative actions, what, if any, were advantages of state participation?

TLA: Well, the big advantage, obviously, was the state could embargo something and tie it up immediately without having to go to federal court with a TRO [temporary restraining order], and that's a time-consuming process when it is imperative to get something to protect the public, to get something stopped right at the moment. We'd use both the state and the local folks with their embargo authority to facilitate that.

When I first came down here, our relation with the city health department had been pretty strained. One of the previous Springfield Resident investigators had been notified that there was some lettuce out at one of our very large grocery warehouses that had some pesticide residues in it. He asked the city health department to put an embargo on it, and a seizure, and so they did, and it took a long time for the seizure papers to wend their way through the federal legal process. Well, lettuce is a highly perishable commodity, and it sat there and sat there, and it started to liquefy and decompose and make a mess. By the time we were able to arrange for seizure action to proceed, we were told that, well, the product wasn't sellable any more, so there was no reason to seize it, and so we didn't seize it. That left the city holding the bag, and they were threatened by the company with the cost of this material since they were the ones that had actually

embargoed it, and then we let them down. So that was a sore point with the city that we eventually had to get ironed out.

RT: That always was an issue in many locations and occurred not infrequently, of course.

Are there any other comments or observations you'd like to make before we close our interview?

TLA: I think that covers some of the highlights. I've seen a lot of changes in my career from when I started out. A lot of regulations were not even in place, like there were no device GMPs and no blood bank GMPs and no infant-formula regulations. It was interesting to have played maybe a small part in the implementation of some of those requirements and the resulting increase in the level of consumer protection that resulted from those.

RT: In terms of staff performance appraisal, we have gotten into the management-by-objectives system. Was that problematic in being, shall we say, fairly evaluated when you were frequently on overseas duties, or could your objectives be defined well enough to result in a fair and equitable appraisal of your performance?

TLA: Performance appraisals have never been any kind of an issue to me. The foreign inspection reports, of course, went to my supervisor even though he didn't do the recommendations, so he knew what I was doing. I kept him informed. I always tried to

run the office with the least amount of hassles for my supervisor. I would just get things done and not ask him about every little issue that came up. I would just do it and apologize later if I was wrong, and most of the time I didn't have to apologize. Like when I walked out of the Chinese plant because they wouldn't show me a critical part of the process, I never, ever got any criticism from anybody in FDA, and I really felt like I went out on a limb, but I had gotten support and I appreciated that. But the appraisals, I mean, if you work hard and do a good job, people recognize that, and the appraisals take care of themselves.

RT: Well, Ted, I want to express appreciation to you for this interview. We've covered some experiences that really aren't in the agency's oral history record, so you have made a significant contribution. Thank you.

TLA: Thank you. It's been my pleasure.

END OF INTERVIEW