History

Of the

U.S. Food and Drug Administration

Interviewee: John L. Kunkel

Interviewer: Robert A. Tucker

Date: June 19, 2006

Place: Minneapolis, MN

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

CASSETTE NUMBERS: 1

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

DATE: June 21, 2006 PLACE| Minneapolis, MN LENGTH: 65 Minutes

INTERVIEWEE:

NAME: John L. Kunkel
[redacted]

INTERVIEWER(S):

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

FDA SERVICE DATES: FROM: August 20, 1972 TO: May 30, 2005

LAST FDA POSITION HELD: Director, Information Technology, Central Region, Field Servicing Center, Office of Shared Services

INDEX

Interview with John L. Kunkel

June 19, 2006

TAPE 1, SIDE A

RT: This is another in the series of FDA oral history interviews. Today, the interview is being conducted with John L. Kunkel, former Director, Information Technology, Central Region, Field Servicing Center, Office of Shared Services. The interview is taking place in Minneapolis, Minnesota, at the Minneapolis FDA Field Office. The date is June 19, 2006.

John, we like to begin the interviews with a brief review of your personal history, your education, and where you might have worked professionally prior to joining the FDA, and then, of course, move through the increasing responsibilities you had with FDA. So would you like to begin in that way?

JLK: Sure.

I was born in Milwaukee, Wisconsin, and raised there. I went to school for my college degree to the University of Wisconsin in Stevens Point. That was the first attempt or the first college experience I had. I also went to the University of Minnesota later in my career with FDA, and

what is now Century College, to obtain experiences with computer science. At that time it was known as management information systems.

At the University of Wisconsin, I received a biology degree; and from the other two, I got the management information systems.

RT: Your degree at Wisconsin was received in what year?

JLK: I received my degree from the University of Wisconsin in 1971, and I started with FDA in 1972.

Between my graduation and my actually beginning with FDA, I worked as an exterminator in the city of Milwaukee, which is a whole ‘nother story of itself.

RT: All right.

Where did you first serve the agency?

JLK: I began my career at the Food and Drug Administration back as part of Project Hire in 1972. I was called by the agency and asked whether I’d be interested in working for the agency out of Detroit. I initially turned that position down. They called back and asked whether I’d be willing to work out of the Indianapolis resident post, which I did agree to take that job, and I started with the agency in August, actually August 20th of 1972.

RT: And you were interviewed at the Detroit office then?

JLK: No. My interview for the position took place in Milwaukee, and I was interviewed by the individual who was then the Resident-In-Charge, who was then Walt Stauffacher.

RT: All right. How do you spell that last name?

JLK: I believe his last name was spelled S-t-a-u-f-f-a-c-h-e-r, and that's just from a recollection. I may not have that perfect.

RT: Sure, that's okay. Okay.

And then you were recruited to go to Indianapolis. That would have been out of Detroit District at that time, wouldn't it?

JLK: That's correct. Indianapolis a resident post, the largest resident post Detroit District had, and we did virtually all the type of work that's normally done by an FDA resident post. We did the Foods, Drugs and Cosmetics . . . It was primarily drugs down there, as that's the home of Eli Lilly, and so we did a lot of drug work at Eli Lilly.

RT: What was your entry level grade-wise?

JLK: I started as a GS-5.

RT: And you remained at Indianapolis for how long?

JLK: I stayed at Indianapolis until 1976.

What had happened is that we had a large number, as everybody is aware, a large number of employees who started under the Project Hire umbrella, and by the time they had reached four years of experience, there was very little promotional activities or chance to be moved around within the agency, as there were just so many people. So the agency decided they would try a pilot program with myself, another individual from the Indianapolis resident post. We were given the opportunity to be transferred, to transfer to any of the offices we wanted to at FDA. I chose to go to Minneapolis for no other reason than that I heard it was a good place to go. So I decided at that point that I'd move out of the resident post and go to the Minneapolis District office, and so I moved to Minneapolis in 1976.

RT: Now, during your tenure in Indianapolis, as you just mentioned, that's quite a center for drug and pharmaceutical manufacturing. Did you get some experience in that field there?

JLK: Oh, yes. I, we did -- in fact, I was doing primarily a lot of drug work in Indianapolis at the time. I was also heavily involved at the time with the federal-state program with respect to medicated animal feeds and worked quite closely with the Indiana state counterparts who were under contract for FDA to do feed-mill

inspections. We did a lot of that work together. So it was primarily drugs, both human and animal type drugs, that I was involved in while I was in Indianapolis.

RT: So, in that particular experience in the feed mills, what were you looking for there? Were you looking for pesticides, or what was the focal point?

JLK: The feeds that we were looking at at the time, we were primarily interested in the drug mixing of the medicated animal feeds, the drug levels, and ran them. And at the time, we were also very interested in some of the illegal drugs, the DES and some of the other things that were coming along at that time as far as their usage within the animal feeds. They were supposedly banned at that point, but yet we had a number of individuals in the state who were still obtaining the feeds, the illegal drug combinations or what have you, and adding them in, so we spent a considerable amount of time tracking those individuals down and putting an end to that practice.

RT: You, of course, made the inspections of farms or, pardon me, mills and took samples. Was there any particular effort made toward the peddlers to farmers of some of these drugs where off-label use was promoted?

JLK: There was some. We found, though, that for the most part, most of the distributors were very cooperative

with us at that point in time and were providing us with the information. It was primarily the larger farms in southern Indiana, where they were ordering the product for usage with one type of animal and then switching it over for a type of animal for which the drug was legal yet, and then switching it to another animal [sic]. So most of our work had to do with both feed mills that were producing it and then the actual farm inspections.

RT: Well, Indiana isn't particularly a mecca for meat packing, although there's some of it there. Was any regulatory attention given to tracing residues in human food, for example, in meat?

JLK: Sure. The primary problem, the biggest problem at the time probably was in hog farming, and I do remember going a number of times to USDA slaughtering facilities and bringing back tissue samples, which were then overnighted to one of the laboratories for analysis to determine what the levels of the medication or whatever in the feed, or in the tissue actually was.

RT: Had, at that point, there been specialization of laboratories for this kind of work, or did it, did these samples really go to Detroit's laboratory?

JLK: No. The laboratories were somewhat specialized. A lot of it did go to Detroit, but the laboratories were

able to go ahead, and some specific samples went to other laboratories that were more capable of running that particular analytical method. I don't remember anymore, though, which ones went where or any of that. That was a long time ago, and it was only four years out of my career.

RT: Well, you spent some time in Indianapolis. While you were there, did you have opportunity for promotion, or was the transfer the vehicle to be promoted?

JLK: No. I began, as I said, as a GS-5 with the agency, and by the time I left Indianapolis, I was at the GS-12 level, I believe, if my memory serves me correct [sic]. So I came up to Minneapolis as a GS-12.

And as I had had a good deal of drug experience when I did move to Minneapolis, I did the [unclear] number of drug manufacturing facilities here, but also became very interested at that time in the medical device industry, which was quite, there was quite extensive inventory of medical device manufacturers in the Minneapolis area, and that is what eventually led me into computers then, was the medical device field.

RT: Now, was the burgeoning device field, attention to that drawn by the enactment of the Medical Devices Amendment, or was this prior to the congressional enactment of that amendment?

JLK: No. I believe that we were doing device work at that time under the amendment, and we were, again, this area being heavily into pacemaker manufacturing and the major device development, of not just syringes but actually the biggies, it was quite prevalent in this area.

RT: Okay. Then you mentioned that more or less led to your interest or work in computers. Can you kind of relate how the two relate to each other?

JLK: Sure. As I said, I transferred to Minneapolis in 1976, and by about 1979 or 1980, it was becoming more and more apparent at that time that the microcomputer, the small chips, were starting to be used more and more in the manufacture of medical device products as well as other commodities that we regulated as well. At that point, they were primarily being used in the quality assurance aspect of the industry, where they would hook up their analytical instruments using microcomputers, and in some instances, such as pacemakers, they were beginning to implant microprocessors right into the pacer.

Well, what happened is that in about that same time frame, 1979, 1980, the agency decided that the number of investigators that it had was quite large and that it might consider downsizing somewhat, and there was a lot of

discussion at the time about reducing the force through either a RIF or a voluntary reduction in staff.

I took a look around and realized that when I had started with the Food and Drug Administration back in 1972, I had elected to start in August, which was the very last group of individuals to start under the Project Hire program. And the way the RIF would work, they would start with the last would go first, which meant that I was very high or very close to the top of the list that would be RIF'ed if that were to occur. And realizing that this might be a problem, I decided I'd better find myself something besides just a biology degree, because they were a dime a dozen.

So what I did is I elected at that point to go back to school on my own and start studying computers and computer programming just to see if I had any interest in it, as I had seen a number of them already in the industry and I found that I was drawn to them as I did the inspections, and I wanted to learn more about them.

So I went back. At that point, I started at the University of Minnesota and started taking classes there and just fell in love with computers. I thought they were the neatest things.

So I came back to the agency and told my boss at the time, who was George Goers, and he was the Director of Investigations Branch, and Henry Roberts, who was the Director of the district office, that I had been pursuing this on the side and that I found these computers most interesting, and that in seeing that they needed to have, that we didn't have any expertise at all in the agency, in the field force, that is, in computers for inspectional activity type thing, I told, I volunteered to go back to school and pursue computer science with the intent of coming back and bring that knowledge back into the agency.

At that point, the agency had a long-term training program, and so, with their help, George and Henry's help, I put together an application and applied for [unclear] to a long-term training program and was accepted with the intent of or with the idea that I would pursue a course of study in computers -- and, as I said earlier, management information systems is what they were referred to at that time -- and learn more about them in order to bring that knowledge back.

So I think it was in 1981. I think I spent the year 1981 in long-term training and then came back to the agency with a good knowledge of computer systems, programming languages, and overall quality assurance aspects for

software development, which I then brought back into my career.

RT: So initially, of course, you were doing that at your own expense, and then later, the agency assisted in the cost of the training.

JLK: That's correct. When I first started out, I was definitely paying for this with my own expense and on my own time, and realized quickly that it would be a better idea to let the agency pay it, and so that was one of the reasons also that I pursued the course here with the agency.

Now, the interesting thing is, is that when I came back to the agency, I came back in the middle of what was -- the programs or the assignments that were given out to the investigators were given out either on a monthly or bimonthly, or either monthly or twice each . . . Let me rephrase this. They were given out so that you either received assignments that were four weeks long or eight weeks long, and I came back kind of in the middle of this. And so, as a result, when I came back, I first arrived back after attending school and getting this education, what was given for assignments was pretty much just the runt of whatever was left over in the box that hadn't been assigned to somebody else. So I came back with all this computer

knowledge and found myself back doing grain elevators and warehouses and what have you. Computers were the furthest thing from the list of products or items that they had on hand.

I did this for the first assignment period, figuring that it was just because I had just returned. But when I came back, when I found that the next assignment period that rolled around found me doing the same old stuff that I had been doing before I left the agency, I realized that this wasn't going to work. Now I had all this knowledge, all this desire, and no place to go with it.

As it turned out, I was very fortunate, because about the time that I was reaching the end of my rope with this, Bill Clark, who was the Regional Food and Drug Director at the time, happened to be visiting Minneapolis, and so I arranged a meeting with him and the District Director, where I sat down and explained to them that I had gone off to school and obtained all this great knowledge, and that I thought it was kind of being wasted in the fact that we weren't utilizing it to determine just how well the industry was adhering to what were considered then by the collegiate group, anyway, to be standard practices.

Bill was very good along this line, and he took copious notes during our talk and he agreed to give me six

months to do whatever I wanted to do with respect to inspections and focus on any part of the industry I wished in order to see just what was happening.

So I did that. I spent six months. Well, actually, I never even made it through the full six months. I spent probably about four months out in the field doing inspectional work and started writing my reports on what I was finding with the computer systems, at which point Bill came back to Minneapolis District, sat down, and we started talking, and it was just overwhelming what I had found, the number of facilities that simply had no control over the computerized quality assurance systems or either the computerized aspect of their product they were producing.

Bill took him back with him then, back to Rockville, to the Parklawn Building, and sat down and talked with them back there. And the next thing you know, I was full time and, to my knowledge, the very first computer system specialist that the agency had in the investigational branch. And from then on, I went around and started doing nothing but inspectional work on computerized systems.

RT: Now, during this period that Mr. Clark gave you to do some self-generated-initiative work, was the agency at that time on the management-by-objective performance appraisal system?

JLK: Oh, yes.

RT: And was that a problem in terms of your evaluation and being measured against maybe some intangible?

JLK: It might have been if that had gone on for much longer. But what was happening is I was finding so many significant problems in the industries that it was shotgunned from a very small aspect of my job and what I was doing to doing it full time as a test period, to suddenly be doing it full time and this is your assignment; this is what you're going to be doing.

I was also helped because it was shortly thereafter that word of what I was doing and some of the inspectional reports that I had written and some of the findings that I had come across were eventually brought to the attention of the Commissioner. And so I was receiving, then, calls then from the office of the Commissioner dealing with issues that were coming up to his office in other parts of the country dealing with computerized problems.

RT: Who was the Commissioner at that point?

JLK: I believe that was Frank Young at that time.

And what happened after that was that, the next thing you know, I was moved out of the District -- or I was still resided in Minneapolis and did throughout my entire career,

but my obligations and responsibilities suddenly extended from coast to coast, and I suddenly found myself working very close [sic] with Frank Young's office and becoming a consultant, almost, for him, and traveled with him quite a bit to different seminars, speeches, and presentations where I would give a bit on computerization and what the agency was beginning to do to look into it. So we did a lot of work or a lot of public speaking from coast to coast during that time. And at the same time, my travels also began to where I spent fewer, less time doing inspections locally, and I was no longer on the work plan for the Minneapolis District at all, and I was on a national work plan at that point.

RT: Did that pioneering work lead to training and inclusion in a larger cadre of folks?

JLK: Yes. It was a very interesting time. I mean, it was an absolutely fascinating time as I look back within FDA.

I had finished my education and came back and started this work, and within probably the next six to eight months, I learned of another individual on the West Coast who was also completed, just completed his education and had the same, essentially the same background as I did now in computers, and that was Martin Browning. And so Martin

Browning out of Los Angeles and I teamed up and became a team doing computerized work.

Shortly thereafter, then, we were on with a third individual who was from the East Coast, and that was Phil Piasecki. And so what we essentially did is the three of us were called back to Washington and we sat down and tried to decide how we were going to regulate this new element of the industries, and how we were going to get our investigators up to speed with respect to how to do inspections in this type of an environment.

So what we did is we, the first thing we did was we divided the country in thirds, with Phil taking the East Coast, I took the central states all the way down to the Gulf, and then Martin took the West Coast. And to this day, I still think I kind of got the short end of the stick, because they were going to places like San Diego and I was going to like Cleveland. So somehow or other, I don't know how that all worked out, but that's how it did.

But what we did is we divided the country up and then began doing inspections across the board. We didn't have district boundaries or even regional boundaries. We would go to wherever an investigator found a situation that they felt may be problematic, and we would come in and carry

that aspect of the inspection, the computerized aspect of the inspection, for them.

We quickly realized that we were traveling far more than we were home, and that this wasn't going to work out very well, and that our investigators also needed some basic knowledge on how this all comes together if they were to do a good inspection. And keep in mind, now, we're talking the early '80s here where microcomputers are just mushrooming all of a sudden and starting to pop up everywhere.

So what Martin and I did, with Phil's help, is we sat down and worked out a course that we would then in turn give to investigators throughout the country. And I wound up initially doing the training, and Martin and Phil did some as well, to the point where we were eventually doing it as a team.

And what we would do is we would go throughout the country and give classes on a regular basis. We started out giving them, oh, we started out -- I believe we were in Little Rock, Arkansas, for a while. We gave some down there. We gave them on the West Coast, and then some back in Rockville, those areas too. So we started training nationwide all the investigators and put together a computer training program for the agency that we built on

and continually modified, to the point where, in the end, after a couple of years, it was quite an extensive program, so much so that some of the other countries who had people who were visiting the United States actually, some of their investigators who were visiting actually started to take interest in it, and it wasn’t very long after that when I received a call from the U.K. asking me whether I would be willing to come over and teach a class for their investigators.

RT: About how long was the training course that you developed, in length?

JLK: There were several different levels of classes we gave, and each class was one week in length. We gave, primarily we had an initial class, which was just an introduction to microcomputers and how they work, and what you might find in doing your inspections. And then eventually we took that, then, to the next level and started teaching individuals how they could use computers in their inspectional activities to help them in the analyzing of data that was given to them or how they could actually, instead of inspecting the computer, they could use the computer themselves as a tool.

RT: And then there was a third phase then, did you say?

JLK: The third phase, well, the second aspect of this, how to use it as a tool, was then carried out to another level as well. Some people were able to grasp the idea of using a computer very easily; other people had difficulty with it. And as a result, those who grasped it very quickly and were willing to learn more, there was more, another course that was then provided for that as well.

If I remember correctly, there were probably throughout -- and this is over a period of time -- there were three different courses that were actually provided at different levels of education, and different aspects being covered, all strictly based on computers.

RT: About how many staff of the agency had the privilege of receiving this training?

JLK: Oh, hundreds and hundreds. We trained everybody that we could possibly train. We did this very extensively for the first few years. This is a good portion of our workload, was training others. I can’t even begin to estimate how many, but it certainly is in the thousands that received it, because not only did we train investigational staff, but we also wound up with individuals coming to us from the centers and participating in portions of the classes because they themselves needed

that type of education. And this was brand-new technology to the field, to the agency.

RT: So the training group was not limited to investigational staff. What would be the other categories of staff that would have received the training? Administrators or . . .

JLK: Not administrators, not in this particular program. This particular program was targeted at reviewers for the different centers and the investigators, so anybody who would deal between industry and the agency, in a regulatory aspect, those were the people that we in turn were training.

And we also were training the industry. That was the irony of it, is that we would give these classes internally to our own staff. And then Martin and I were very heavily on the public speaking tours at those times, and we were constantly being called upon to go out and give an hour, two-hour, three-hour presentations to different trade groups and different industry organizational groups that, where we would introduce them to the new role FDA was taking or the new perspective FDA was taking on computerized systems, and either embedded systems, which means that the computer itself is embedded within the medical device, or in quality assurance aspects where you

would have an external piece of equipment that you would use to test or measure the quality of your device or your finished product -- it could be a drug -- where you'd have a computer doing that. And we spoke to both avenues as to how they needed to police their own activities and make certain that the products that they were producing were sound and fit and produced in a good, using what were then good standards for the industry, as the good manufacturing practices at that time didn't really address clearly and cleanly computerized aspects of production or quality assurance. This was new to the GMPs as well.

RT: Now, the industry, did they sort of have a user fee or tuition? In other words, did the agency recover the costs of having given that training?

JLK: Actually, the way it worked is that most of these organizations were willing to pay our travel and expenses. But the agency, at the time, was interested in this information getting out to the industry as well. So it was pretty much a mixed bag as to who paid for what. Very rarely did we receive compensation from the industry. We, most often, the agency footed the bill because they felt it was as valuable to the agency to have the industry know this as it was for the industry to learn this.

RT: Commission Young, you mentioned, Commissioner Young had a lot of interest, much interest in a lot of things. Did he in particular kind of embrace this expansion of computer education initiative?

JLK: Oh, sure, absolutely. And it was well received across the entire agency. People were beginning to -- I mean, it was becoming so common to see these things in the field or in the industry as we would regulate it, and having no knowledge of it, no real working knowledge of how it worked, it was . . .

The interesting thing was is that this was a mystery to the agency as to how they worked, and it was also a mystery, in many respects, to the industry that was employing them. Most of the people in industry were quality-assurance orientated, had the same background, and many of them in fact had been FDA investigators at one time in their career. So what happened is that these devices were coming in and being sold to the industry by those individuals who had computer backgrounds and being told this was the greatest thing since sliced bread, and they were being readily accepted at that time as a computer, and a computer makes no mistakes, and so therefore it’s a great device to be using. After all, we’re computerized, so there’s nothing to worry about.

It was very interesting to see that the industry, when we began doing, when we were really doing these inspections and really going at the idea of reviewing and evaluating the way the devices were being operated or controlled, the number of situations we encountered where the devices were controlled by software that was just totally out of control; and to the point that the quality assurance people were as stunned as we were in many instances to see the status of their own documentation and controls that they had in place over the product they were producing.

I still recall very vividly one of the medical device manufacturers who had a very critical device that was ready to market, and we went out to take a look at it, give it a pre-market approval inspection, and they were so stunned . . .

TAPE 1, SIDE B

JLK: They were so stunned. We would ask the questions, and their engineers would bring back the documentation. These were questions that they themselves had never thought to ask. They brought back the documentation, and it was just helter-skelter, just chaotic, to the point that these quality assurance people

were just, in this particular instance that I recall directly, the individual says, “We’re not marketing this product.” They themselves withdrew and took an extra six or eight months to redo everything having to do with the computerization, the embedded computerization in the product, because they themselves saw what a mess it was. So it was amazing.

I went into one biologics facility, a blood banking facility, a great big one, and found that they had made in the past year, over a one-year period, they had made 247 changes to the software, all of them critical, and each change was made because the previous version didn’t work. Yet the blood was continuing to be processed by this software, I mean, handled by this particular system, and they weren’t stopping their release of the biologics, the blood. They were still sending it out even though the 247 -- that’s almost one a working day -- because of the fact that the stuff wasn’t working. And this was completely new to them, to the quality assurance people in industry, as it was to the FDA investigators.

RT: That’s interesting.

Now, I think, from something I’ve read about your career, you kind of became a consultant to the Commissioner in this area, didn’t you, [unclear]?

JLK: For a while. There was a short period of time, probably about a year, that I was called upon by the Commissioner's office to go with him and make speeches and presentations and consult. Whenever such questions came back to the Commissioner, they'd be sent to me and say, "What do we do? What do we think?"

That only lasted a short period of time, though, because I became, we became so involved in trying to teach our own internal staff and teach the industry that I simply didn't have time for the Commissioner. There wasn't time for that type of thing, and on a one-on-one type basis with an individual industry, instead we dealt with the entire commodity of industries.

So I would still get questions from time to time on a specific item, but more often it was, I'd get a call saying, "We seem to have a problem with this aspect of an industry, and we know they're going to have a seminar at such-and-such location. Could you give a three-hour presentation at that?" and I would take off with my slides and my speech and away I'd go and give it to there instead of on an individual basis back to the Commissioner's office.

RT: You know, the agency, in drugs, of course, and in foods, developed GMPs, good manufacturing practices. In this arena, that occurred too, did it not?

JLK: Oh, absolutely. In fact, that was one of the areas that we looked at quickly and saw that we were finding issues and problems within the industry, and we were having to more or less interpret or tweak the GMPs, the existing GMPs, to encompass those problems that we were finding. Or we had situations where the GMPs were stringent and prohibited things that the computer could do better.

One that comes to mind immediately is, had to do with the processing [unclear] of canned foods. For a long time, it was required that they had to have an operator on site who would be checking the mercury-and-glass thermometer every so often, and things like that had to be done, and there was no leeway where you could bring in any kind of computerized controller in order to oversee that activity, even though the computer, properly put together, would do a far better job on it than the individual. We just didn’t allow that in the GMPs.

So, many aspects of the GMPs, both foods, devices, obviously, medical gas, all had to be modified or changed in some degree to encompass the aspect of this new

technology, these computers. And what would happen is that many times they would write a draft of the GMPs and then they were sent to Martin and myself, and we would sit down individually and go through it and review it, make comments and notations in the margins or what have you, and then send those back, and then the individuals would then incorporate many of those into the final GMPs.

RT: Did those, then, as proposals, go through the Office of General Counsel for preparation of publications?

JLK: Yes, yes. It followed the same route a regular GMP would. The only thing we were is we were simply, we worked primarily as technical advisors to the various Centers, which was a little difficult at the time for the Centers to swallow.

There's often, or within the agency, there has [sic] always been the Centers and ORA or the Centers and the field. And some of the Center directors had some problems with the idea that they would be going to the field for input on the GMPs, because, after all, the field is supposed to enforce the GMPs that are put together by the Centers, not the other way around.

So the politics at the time were quite interesting. There were many times we just did a very soft, soft peddle

or soft, soft sell in order to get across something we felt was very critical, because we were, after all, the field.

RT: Well, some of the Centers historically, before maybe the development of the EDRO, the Executive Director for Regional Operations, as an overall coordinator of field activities, some of the field or Center, or some of the headquarters or Center directors used to kind of possessively feel that they had direction of the field activity, and you kind of had a lot of competition, which sometimes wasn't the most productive.

JLK: Well, I retired a year ago, almost a year ago now, and as of my retirement date a year ago, there was still some of that going on, and it hadn't necessarily changed all that much. And we were seeing that not only in -- I'm sure it still existed quite a bit within the aspects of the regulatory side, but it also was certainly present in the IT side of the agency. So there was quite a bit of, still quite a bit of you're the field and we're headquarters.

RT: I think earlier you might have alluded to the interest of some foreign governments in the training that was being provided for our own agency staff. Would you elaborate a little on that?

JLK: Sure.

We had given some courses, as I said earlier, to our investigators and to some of the Centers and people back in the Rockville-Washington area, and some of the Center staff as well. And word of what we were doing in some of the presentations that we had made had gotten out to the U.K. and to the European Union, which was just forming at the time. And it wasn't long after that I received a call from the U.K. asking me whether I would be willing to come and give the course that we were giving to our investigators to their staff. So I agreed with the, obviously with the agency's blessing, I agreed to do so, and wound up giving several courses over in the U.K.

The first one was primarily for the staff, the people within the U.K. that would be involved in regulatory activities; and the second one was for individuals from the entire European Union. Those were absolutely, those were absolutely fun. I mean, I had more fun giving those classes because those people, they had not encountered this themselves before, or they had encountered the new technology, were seeing it, but hadn't had the training at all before, and they couldn't get enough. And those sessions would go late into the day, and I had planned on doing sightseeing, but instead, there I was still teaching the stuff.

RT: Now, in the European Union, there probably were some countries that were not necessarily English speaking. Was that a problem of interpretation of a presentation, or was that . . .

JLK: I have a tendency to speak quite quickly, especially when I'm giving a presentation. I like to keep the class going and rolling, and so I move -- I don't stand at a podium, I walk up and down the aisles, I'm talking quickly in order to keep their attention, and firing questions at them as I'm giving the class. And I found myself having to slow down both so that they could understand me, but, more importantly, so I could understand them. It got to the point where I was having trouble interpreting some of their English, and so I would say, "Could you say that again?" or "Could you rephrase that?" or trying to find other ways to say, "What?"

RT: Well, it was a challenge.

JLK: It was. It was a very, very fun experience.

RT: And now, I think along the line, you actually developed, I think it was called a Blue Book, that became an industry standard. Would you like to elaborate on that?

JLK: Sure. The Blue Book was a most interesting event.

The origin of the Blue Book had been for one of the training classes that we were going to give for our whole staff, for all the FDA investigators. And one of the things that we realized in our own training was that we didn't really have a manual that we could actually follow or that they could take back with them. They gave the people who were attending our classes a lot of material, a lot of information, a lot of stuff ad hoc, if you will, but there was never anything that was really bound that we could follow page by page, chapter by chapter, right on through.

Well, we realized that we needed something like that, so we started to develop -- Mark, Phil, and I sat down and decided we would put together a book, a manual that we could utilize, and eventually the development of that manual fell on my shoulders.

And what we did is we wrote a book that was essentially going to be a training manual for our own staff. And we sent it in to headquarters and found out that there's, for political reasons, that we couldn't develop a book that was going to be used as a training thing for our own staff, that that wasn't allowed. What we could do, though, is we could probably develop something much smaller in scale that would be a publication that we

could pass out as a handout, but we couldn't call it a training manual for the staff. To this day I don't understand what that thinking was on that, but that's what it was.

So we took the book, which was quite large at the time, and cut it down a bit so it would be more of a pamphlet, and I think we went from a hundred-and-some pages down to like 50 pages, 60 pages. I don't recall. I still have the original drafts, though. I still have those, believe it or not.

And we developed this thing, and somehow or other, word leaked out to the industry before it was actually finished that this was coming out. And then all of a sudden there was all this ruckus about this book because the Centers hadn't developed it. This wasn't developed in the Centers, and yet here we were with, ORA was developing what was going to be their own regulations, and that wasn't the intent at all. The book was going to be simply a training aid for our investigators.

Well, the book suddenly reached proportions much grander than I ever expected. It wasn't, we never expected it to be an industry-wide publication, but it suddenly got mushroomed from a training aid into a publication, into an industry-wide publication known as the Blue Book by the

industry. And our book wound up everywhere. Even though it was never officially endorsed, never officially utilized in training by the agency, the book became a standard within many of the presentations and seminars and everything else were given on the FDA Blue Book, and that book was simply how do you build a computer system or how do you know if a system is built correctly.

It was a very fascinating way that this thing developed from seed to plant, and it wound up with a life of its own but became the Blue Book. And I feel kind of . . . It's interesting that I find myself in a situation where I can actually say I wrote the Blue Book.

RT: So is that online? Is that on the Internet?

JLK: You know, I'm not sure where the Blue Book is today anymore. The Blue Book was written back, oh, it had to be back in the mid-'80s that we put that together, the late '80s maybe. And the technology has changed and grown considerably since then as well. So to my knowledge, the Blue Book was never edited -- after my first version of it, was never re-edited or reviewed again. And I'd have to say that in today's world, that I don't think the Blue Book would hold that much value because the technology is dated and there's new ways of doing some of the things that are talked about in there that would have to be updated. Where

it is today, I don’t know, but like I say, I know where the original version is.

RT: All right. Let’s see, what else?

Now, you also, I believe, originated or developed the ORA, Office Regional Affairs, PC, Personal Computer Support Group. Can you describe that a bit?

JLK: Sure.

As you can imagine, the work I was doing in the investigational area, the regulatory aspect, between working with the various center staffs, the training courses, and the actual inspections, plus the seminars, I was traveling extensively, to the point where I was traveling some 30-some weeks out of every year. It was getting to be quite a burden. And I had young children at the time. And there came a day where I finally decided that I had had enough.

So what I did is I came in -- well, at that time, I was going back to Rockville. Probably one week out of every other month for certain, if not more often, I was spending back in Rockville. And so what I did is I went back and I told them I was quitting, that I was no longer going to do this, I was going to find something else to do in the agency. And I looked at various elements of what I could do, and, after all, I had the investigational

background, I wasn’t worried about being RIF’ed at this point, and so I took a look and decided that what I would probably do is come back and be a compliance officer or a supervisor or something along those avenues and fall back into the regular career path of a regular FDA employee.

Understand that to this point, my career path had been anything but normal. It had been an adventure, absolute adventure, absolutely fascinating time. I wouldn’t have traded that for anything.

So I told them I was going to quit, and I came back, and I sat down with the district director and, to be quite honest, I think it was -- I don’t really remember who it was at the time, but I think it may have been Burton Love. I mean the regional director; I’m sorry; the regional director. And what I did is I sat down with him and I told him that I wasn’t going to do this work anymore out of headquarters, that the travel had become just too extensive, and I was going to start something else.

And so at that point we developed or decided to develop within what was then the Midwest Region our own PC support group. At this point in time, we were starting to see personal computers were more prevalent, to the point where we were seeing them of them. Every district I think had one or two, maybe one in the laboratory and one in the

investigational group that were available for the investigators to use. But what we weren't seeing a lot of were the very early form of the personal computer being used for word processing within the secretarial pools.

So we decided what we would do is put together a program where we would begin training our own staff, not necessarily on regulatory aspects, but administration aspects using the computers. So I got involved with that and started the -- initially, I was the only employee of the Midwest Region's PC Support Group. And what I would do is I would teach the staff word processing and how to use computers, the actual hands-on aspect of using the computer.

What we did at the same time here in Minneapolis District that was kind of interesting is that there was such an interest in these things that we went out, and there was a company in town that dealt with surplus equipment, and I found out that they had 25 or 30 computer systems that were old IBM Model XT's, so they were the original desktop or the original microcomputer, desktop computer from the IBM era. And they had these things available in surplus. I think they were $150 apiece, if my memory serves me correctly, and that was a complete

computer. It had the hard drive, the floppy drive, the monitor, the keyboard, the whole works.

So what we did is we pooled our money in Minneapolis. The employees did this individually. We pooled our money and went out and bought all these computers and brought them back into the District office, and then, after 4:30 in the evening, because we couldn't do it during working hours, we opened up all of these computers, took them all apart, and rebuilt them. And it came out, of the 25 or whatever it was that we had purchased, with 15 that were working, and we took the other 10 back, then, as not working. And what we had done is we had taken all the broken parts, combined them into 10 computers, so there was no way in the world those things were ever going to work.

But then we took those 15 computers -- now they all belonged to individuals -- and we held afternoon and evening classes, brown-bag classes at lunch and stuff -- teaching the staff how to use their own personal computers.

Now, that goes back, that has to be in the early, very early '90s when we did that. And, ironically, it was just this past year I got a call from one of the individuals who had been a supervisor at the time here in Minneapolis and had swore that he was never going to use a computer. But he bought one of these and actually began working with it.

So in 2005, his IBM XT, the video card had finally broke. He no longer was able to do the video with it, and he wanted to know where he could get another card for that. Well, there's just no way that there's any cards available for that. But to think that one of those computers was still working all those years later and that somebody was still using it. It's kind of fun to think about that, too.

But the PC Support Group was initiated here. That's the type of thing we did or that I did. And we started, then, to also -- I started also working with the different districts comprising Midwest region in the purchase of additional computers, government-owned computers, for use within the District offices.

Well, as the number of computers grew, and as the employee knowledge grew to the point they were actually able to use them, the amount of work that we actually did or that I was actually getting called on to do was almost getting, again, to be as much as what it had been when I was working nationally.

So at that point, Burton agreed that I could hire a second individual to work with me, and I was very fortunate to find a very sharp young lady who came in -- her name is Charity Forar [note to RT: found name online in FDA Employee Directory] -- and Charity is still with the agency

today, but she came in as a very young lady into our office and was very good, very quick at picking up on how these computer systems worked herself. She came in, and she originally had been in data processing, but she quickly learned how to build them and went back to school and learned how to actually make them work. And to this day, she still is with the agency. She's currently working out of Minneapolis, but she is now one of the national directors for the computer systems used throughout the field, which makes me feel very proud to know that we got her started from data processing all the way through to the point where she is now one of three or four individuals in the country responsible for the network that runs the agency's computers. That's quite amazing.

RT: What grade level was she able to achieve in that?

JLK: She's now a GS-14, and I believe that when she started, she was a 3.

RT: That's quite an advance.

JLK: It is, absolutely.

RT: In your own case, Bill -- John, I'm sorry -- in your own case, John, how high did your work carry you grade-wise?

JLK: Grade-wise, I was only -- I was a GS-14. I had opportunities to go higher and I elected not to. I just

didn’t want to, at this point I decided that it was, it just wasn’t advantageous to my career to move anymore, and I decided to stay here in Minneapolis. And I was very, very happy with the work I was doing, and so I elected not to.

RT: Well, that’s a very important aspect of one’s career. I’ve known of a few folks that have gone into headquarters and gotten a grade who elected either to go lateral or maybe go back a grade and a happier environment for them in a field office.

JLK: Yes.

I enjoyed -- in fact, when we had a number of new employees come into the agency, I had an opportunity to speak with them at one point, and I told them that this has got to be the absolute best job you could possibly have -- not just my job, but a job with the Food and Drug Administration. And the reason I say that is that, look at my career. I mean, I started out doing investigational work in tomato canneries and drug manufacturers and feed mills, and it took me all over the world doing computers. I mean, it’s such -- you can do as much as you want in this agency, as much as you want to do. All you have to do is apply yourself to the job, and it’s the best job in the world.

RT: Well, that's the way I've always felt. I've always enjoyed my job and personally felt sorry for those persons that you run into who can hardly wait until retirement. And I would suspect you, like myself, had to think a little bit whether you wanted to retire or not.

JLK: It was, there were some aspects of my job that were absolutely fun, really, really fun, and this is not to dispel the work that's being done by -- I can't even think of what the correct acronym is at this point anyway -- but the criminal investigation group. But we used to do those, all the criminal investigations. And, in fact, not only did I do some of the criminal work for FDA, but I was also called on by the U.S. Attorney's office here in Minneapolis to do it for other agencies, from DEA to whoever, because at that point they didn't understand or they didn't know how to word or write a search warrant to encompass the computer, or how to seize a computer when they ran into one within a facility. I was very fortunate.

Again, there are so many different sidebars to my story that it's, many of them will be left behind. But one of the things at the time back in my career, the agency was looking at the Federal Law Enforcement Training Center, FLETC, down in Georgia for the idea of training investigators down there. And what they asked me to do was

go down there and actually, as somebody with a lot of computer skills and knowledge already behind me or under my belt, to go down there and essentially audit the training program that they offered down in FLETC. And so I did that and understood more than of the criminal aspects of how to deal with a criminal computer environment, that everything up to this point had been industry, which for the most part was trying to be on the up-and-up and aboveboard.

But what do you do when you have somebody who's using computers with criminal intent for the distribution of some of the illegal drugs that FDA deals with or whatever, and then has it all on a computer and wants to get rid of that computer when they get a search warrant, or whatever is issued. So because of my experience in having done that, I had the opportunity then to go on many of these searches with the different aspects, even of the new criminal investigations unit for FDA at the time. I would go out and do some of that work with them. So that aspect of it . . .

You asked whether I was willing to retire readily, and that aspect of it was a lot of fun. But as more and more people became trained, my role, as it should be, began, I began to take a step further and further back and let some of the younger people who started out, had entered the

agency with much more technology knowledge than I had originally had, let them take the forefront and let them run the program for a while.

Technology is something that is not stagnant. You've got to be on top of it all the time. I mean, I stayed with it and learned as much as I possibly could, and I believe I used it to a great degree to help the agency. But I realized as well that some of the younger people coming on board were born with these things. They teethed on them. And so, for them, they were already at my level when they entered the agency, and now they can take it to the next step. So I was willing to retire and step aside and let others take over that activity.

RT: Now, in your retirement, you're still actively involved in this area of activity, aren't you, perhaps in the private sector?

JLK: Yes, but it's not in any way that you would imagine.

As you can -- having had my name written up in many of the trade journals and publications -- and industry groups knew quite well who I was -- when I did retire, I did receive a considerable number of offers to come in as a consultant or to work for them, and I actually elected not to do that. And instead what I did is I took a job as a

volunteer teaching at a small school in northern Wisconsin, and I teach fifth- through eighth-grade computer technology. And those fifth- and sixth-graders, I've got to tell you, they keep you on your toes. And my seventh- and eighth-grade class this past year, by the time they graduated, they were building computer systems for use by the school. They built them from scratch.

RT: Isn't that something.

JLK: Yes. So just think what the next generation is going to be able to do. It's going to be absolutely astounding.

But I am having more fun with those kids. They're an absolute ball.

RT: Well, that's great. I recall my eldest grandson, when he just a little bit of a kid, visited, and he was playing a little simple game of aligning plumbing parts, but he was learning the valves. Now he graduated from Virginia Tech as a computer engineer or something and is really doing great. And I'm way back in no-man's land by comparison.

JLK: Well, see, you were with FDA in my period of time. You should have been coming to my training classes.

RT: That would have helped.

I made the error personally of retiring, I think, one quarter before general training was going to be provided to professionals.

JLK: Oh, okay.

RT: And it's really a turnaround, because when I first started, I used to like to do a lot of typing of drafts myself, and my boss would come by and say, "We're going to degrade you to a 3. You're not supposed to do any typing." Now everybody has a keyboard in front of them.

JLK: That was actually, now that you bring that up, that was a very, very important hurdle for us to overcome in that many of the managers that we faced at that time back in the '80s felt that the typing of anything by anybody, whether it was the entry of data for analysis in a computer or the typing of a report, that was secretarial duties, and that you don't take investigators and put them behind a keyboard.

RT: That was it.

JLK: But, you know, I believe they were wrong in their concept. But overall, when you look at where the agency is today, I kind of wonder sometimes whether the tail of technology is wagging the dog of the agency. When you look at how dependent we have become on it and how we seem to, when I left the agency anyways, speaking from that

perspective, how the agency was so focused so heavily on technology and the technical aspects of what we were doing, the computer aspects of it, not from a regulatory perspective but from an internal perspective, for numbers crunching, I wonder how much of our regulatory capability has diminished by the fact that we focus all of our time now not on the inspections or on the regulatory end, but on the computer aspect of how it's going to look in the report, and it's kind of a shame.

RT: Well, other interviewees we've interviewed have touched on that same point. I don't think we've ever interviewed anyone who was as knowledgeable as you are in this field, so we're very appreciative of getting this input for the oral history record.

JLK: It's been fun. It's been a great career.

RT: Is there anything else, John, that you would like to include, ancillary endeavors that you might have been involved in?

JLK: I just have to say that I've done it all. I've done everything from undercover investigations; I've chased people down the highway in the middle of the night, 100 miles an hour; I've been involved in police or where we had the state patrol block highways and stop trucks that we were chasing full of laetrile, the roadblocks. I've done

all of that, and wound up with technology as my background and ended my career there. And it's just been a fascinating, absolutely fascinating experience. I wouldn't have traded it for anything.

RT: Well, that's great, that's great.

If we've kind of covered it, I'll close with, again, a note of appreciation.

JLK: Well, this is the kind of an experience where on my way home in the car, I'll be saying, "Oh, I should have told him about this," and "Oh, I forgot about that." But I think we've touched on pretty much the high points, but I'm more than willing to tell anybody anytime about or talk to anybody anytime about what we've done and how we've gotten where we are, and it's been fascinating.

RT: Good. Well, we may want to take an opportunity to do an addendum to this interview when it's convenient.

JLK: That's fine.

RT: Very good. Thank you very much, John.

JLK: Well, thank you for the opportunity. I'm glad I get to share this experience with others.

RT: Thanks. That's great.

END OF INTERVIEW