

History
of the
U.S. Food and Drug Administration

Interviewee: Connie H. Guerra

Interviewers: John P. Swann, Ph.D.
Robert A. Tucker

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Interview with Connie H. Guerra

June 5, 2008

TAPE 1, SIDE A

RT: This is another in the series of FDA oral history interviews. Today, June 5, 2008, we're conducting an interview with Connie H. Guerra, who recently retired as Director, Office of Information Technology, for the Office of the Commissioner. The interview is taking place in Rockville, Maryland. Conducting the interview are Dr. John P. Swann and Robert Tucker.

As we begin the interview, we'd like, Ms. Guerra, if you would introduce us to your first employment with the agency, and then we'll go on through various points in your career. You might also tell us where you were born and educated, and how you came to the agency initially.

CHG: I was born in San Antonio, Texas, and moved to the D.C. area in '72. I was educated there, in San Antonio, and went to Our Lady of the Lake University -- in San Antonio.

I attended Montgomery College in Rockville, Maryland. My initial thrust was to go into genetics. I was married with two small children and needed to start my career, so I attended Montgomery College and took math and computer courses.

RT: Your earlier degree from . . .

CHG: I did not get a degree.

RT: I see.

CHG: I did not complete my college education. But I focused on going into computer science, and, therefore, took all the math and computer science courses required toward a computer science degree. So I would have needed to go back and take non-computer college credits to finish.

I attended many computer and management classes during the course of my career.

RT: What year was your graduation from Montgomery College?

CHG: I did not graduate from Montgomery College either. My focus was the math and computer classes in order to begin work as soon as possible.

JS: If I may ask, what got you interested in computer sciences? **Note:** I think JS asked something like “since it is so different from genetics”?

CHG: Yes, it is different; there is a big difference between going into genetics (I was taking pre-med courses) and a computer curriculum. I had always been very good in math and had taken quite a few math classes in school. In fact, I was the only girl in my

upper math classes (elementary trigonometry and analysis, etc.) in high school. So, it was something that I was very interested in early on, but genetics was really my first choice.

When I moved here -- and I had two small children -- I waited until my daughter was in first grade to start working full time or to start looking for full time work. I actually had been quite interested in something that would get me into the computer field at that point. It sounded like an up-and-coming career. I also wanted something with the government because, truthfully, it was very family-friendly. I wanted to be able to be home early enough to take care of my children. Plus we lived close to Parklawn, which made it very convenient. At the time, my husband worked at Parklawn too.

JS: For FDA or for another agency?

CHG: For another, for the National Center for Health Statistics. Since then, they have moved and I stayed at Parklawn.

I decided to try and get my foot in the door and then get into computer work. The way I did that was to get a position as a clerk typist. I started out as a GS-4 clerk typist.

The reason I applied for the position to start with was they'd mentioned on the announcement that there would be some data entry work, so I figured it was a good way to get in.

Well, when I started, I found that the work was not computer work. It was typing and auditing travel documents. However, I did end up going to class for what was the United Airlines Computer System at the time. This was in the very early stages of the

computer work that FDA did with the airlines. I worked in the accounting group, in the Division of Financial Management, and made the travel reservations for the agency via the United Airlines APOLLO computer.

JS: For airline travel?

CHG: For airline travel.

There were two computer systems at the time that were in place. One was called SabRE that most of the other airlines used, and another one was called APOLLO. Two of us went to class for this, and when we came back we began making the airline reservations online.

JS: At this time, the agency was making its own reservations.

CHG: Absolutely.

JS: For travel by FDA officials.

CHG: For everyone.

JS: For everyone, as opposed to the situation probably not too many years later when we, of course, relied on travel agencies to do that sort of thing.

CHG: Yes, and we actually did the whole ball of wax, made the reservations, asked for whatever they needed, got the visas and passports for them, handled the imprest fund, which was to give out money for travel, and other local travel. It was an interesting office because it handled all travel-related work. There were three people in the office, and sometimes we shared a chair because we were doing work on typewriters still, and also on the computer, and then we would jump up and go pay out the money in the imprest fund, because we had a certain amount of money in there to pay to travelers. Everyone went through that imprest fund for any kind of local travel or anything like that, because that's how the money was disbursed at the time.

JS: This was starting in 1979?

CHG: Right.

JS: Nineteen seventy-eight.

CHG: Seventy-eight.

I was sort of in between a couple of different offices. I was doing travel audit work and reviewing travel vouchers that FDA employees would submit. Now, FDA has a computerized system that travelers are directly entering information into.

Well, at the time, it was all manual, and so the travel vouchers would come in and people would audit them, we would audit them. And there was regular local travel and

travel for domestic travel, international travel, and change of station. And there's also the travel that's different for Commissioned Corps. So we did all of that and we'd work directly with FDA travelers. It was like a mini-IRS for travel.

CHG: And at the time, believe it or not, there were calculators that we had to use, and they were these big black calculators that you would hand-crank down that you see now in old movies. I mean, this is in '78. It wasn't that long -- I mean, I know it was a long time ago, but you would think that it would have been a little bit better at the time, but it wasn't. So you would get this big, long tape, and, of course, if you made a mistake, you had to start all over.

We handled many phone calls to answer questions and provide assistance.

RT: I traveled quite a bit since the early '60s, and I recall your operation and going to that little desk.

CHG: And then talking to you.

RT: Yes, that's right.

CHG: Right. I also worked in other portions of the accounting organization.

I was trying to get into IT (information technology) -- it wasn't called IT at the time; it was called ADP, automated data processing at the time. In order to prepare for a

computer position, I was attending Montgomery College and taking math and computer classes.

JS: Just let me interrupt for a moment.

Did the agency subsidize any of that education?

CHG: No, none. No, this was all on my dime and time.

I noticed that some of the things that were being done in the accounting arena really could have been done a little bit better with computer type stuff.

Now, the accounting group had a computer group that was doing some work using a precursor to Oracle called Datatrieve, and it did some work with that. They had some VAX mid-sized computers that mainly handled accounting work and managed their own financial management system. They began working on a system that was to be used by the Centers (at the time they were bureaus). It was called the, I believe, the Financial Management System. The computer group used Datatrieve, IBM on the mainframe, and VAX computers.

RT: Was Ronald Chesemore in that operation?

CHG: Yes. Ron Chesemore was my Division Director at the time.

By the way, the United reservation system was called the Apollo computer.

JS: The Apollo computer.

CHG: I actually started working on the analysis of distributions of data on cash awards for Gerry Meyer. At the time these folks needed information for management decisions, so I created statistical reports and graphs for distribution agency-wide on whatever was needed. I believe he was the Associate Commissioner for Management Operations at the time.

Because most of the work was manual and there was no computerized way of getting reports out, I realized early on that there was a huge need for FDA-wide reporting. There was no automated way to report on trend analysis, personnel, and other management data.

JS: Your sense at the time -- to the extent to which, for lack of a better term, the agency was computerized -- you mentioned that Financial Management was operating on sort of a database system: I'm sure that the Bureaus must have had some means of using information technology to make their work and product approvals and so on more efficient. Is that fair to say?

CHG: Yes. They had actually some minicomputers. There was a large network of VAX minicomputers out there. So quite a bit of this work was out there at the Centers, but they were specific to the Centers' missions and being worked at that level.

JS: Did they have their own staffs dedicated to IT issues?

CHG: Yes, and there was work being done out there. But I wasn't involved that much with the various Centers except as it related to accounting.

At this point, I was an accounting technician. Most of the accounting folks wanted to get into accounting but I wanted to get into computers. So in 1983, I took a position, still with the Center for Foods, which was Bureau of Foods at the time, as a computer systems analyst.

JS: Now, when you got there, what did you do when you first started there?

CHG: When I first started there, I actually spent quite a bit of time just getting to know the computer systems that they had. But what I did find was that not everyone had a computer. This was before PC's (personal computers), so all they had was hardwired mainframe terminals, and not everyone had one. In order to get the work done, they would have to go to a computer room and use the computer terminal to actually do their work. In fact, they actually had punch cards and card readers at the time. The programs were typed into the keypunch and then put through the card reader. Of course, each computer program consisted of large stacks of computer cards, and if you dropped one, you were in dire straits.

At the time we needed to know something called JCL, called job control language, which told the computer what the program was going to be and how it provided instructions on how to process the program. Many of the programs ran on an IBM mainframe computer.

They also had a Data 100, which was, I believe, like a minicomputer. They also had a system called animal history on paper tape. It consisted of a long piece of paper that had holes punched in it to store the data.

JS: You said animal histories?

CHG: Animal histories.

RT: Was that experimental test animals?

CHG: Probably test animals. I don't know the background, but there was a lot that they did with animal testing.

I worked downtown in Federal Building #8. Did you ever go down there?

JS: Oh, yes, yes.

CHG: Well, you probably know, then, that was the only animal laboratory in D.C. They did experiments there with the animals, testing, like you said. It was an old building and not very well ventilated. Interesting smells.

JS: Awful, awful in many ways, I think.

RT: I guess that's why they eventually moved clear out.

CHG: Maybe. There were white mice running around sometimes.

RT: I was one of the first, my group was one of the first to move into FOB8.

CHG: Really?

RT: It seems hard to believe that it's an old, antiquated building now, because that was state-of-the-art at the time we went in.

CHG: At the time, yeah.

I didn't dislike the building because we were a computer group and had a glass door that insulated us from the labs. So we didn't get the smells as bad as some of the other folks did, even in the offices. I mean, they were almost right next to the labs in some cases. I suppose it was to keep things clean for the computer equipment. When I think about it now, there were a lot of people that smoked and you could see the smoke residue on the computer equipment.

What I recall is that the hallways had showers that could be used in case of contamination.

But every once in a while, what I understand and I can't say for a fact, but I was told that the intake and the outtake were right next to each other, so the smells would come into the offices.

JS: You mentioned . . .

CHG: Now I'm off on a tangent.

JS: No, no, that's okay. This is part of the working environment.

But you mentioned that there was tape, paper tape with animal experiment results. Was this somehow put into the IT system?

CHG: Yes. They had a paper tape reader, but I can't recall what it looked like. Reports were generated from the data.

The computer room, we had, like I said, housed the terminals, and large IBM computers. People had to change the tapes on it, you know, reel-to-reel tapes, and we had big printers that would handle the large print jobs.

But shortly after, and I would say just a couple months after I got there, we actually got terminals at our desks, which was wonderful. Because before that, in order to work on a program, you had to go to the computer room and do your work, and you were vying with everyone else to get your work done.

In fact, there were some folks in the labs who got pretty proficient in some of the computer languages in order to do some of their graph work for the labs, so they were using things like SAS/GRAPH and SAS, Statistical Analysis System. They also used FORTRAN.

But some of the work that we did was using a COBOL-like 4th generation software called Mark IV at the time.

JS: Did you say Co . . .

CHG: COBOL.

JS: COBOL-like.

CHG: Yeah, COBOL-like. It was an easier method of using COBOL.

JS: Can you just say something about COBOL?

CHG: COBOL was, is a business programming language. It's very structured. It is used for business and administrative applications.

RT: Is that C-o-b-a-l-t?

CHG: C-o-b-o-l, COBOL.

A lot of the large companies used COBOL because it's very efficient for transactional work. It ran on the IBM and supported large quantities of records.

That's some of the first-generation type of programming that I used.

I was a systems analyst and certainly collected requirements and did the analysis, but I also did the programming, testing, training, and maintained the applications we created. We did it all, including setting up computer equipment, providing customer support, and coordinating the data maintenance and outreach for our systems. I used to set up printers and troubleshoot hardware and software problems. But I drew the line at laying cable.

JS: It was in this position, I believe, that ARIES comes into the picture, the Administrative Resources Information and Exchange System, that you became very involved in. Could you discuss a little bit about the history of ARIES and its function and what came before it, what it replaced, how it improved life at FDA?

CHG: Well, when I first started working for the Bureau of Foods at the time, I came over working on the financial management system and helped them to get some of that going for the Division of Financial Management, so I was managing the pilot there for the Bureau of Foods. Because I had worked for financial management and I already knew the system, it was a good fit for me to go in and pilot the system at the Bureau of Foods.

Because of the pilot work, I started working on accounting, business, and administrative systems. At the time, the Bureau of Foods, now named CFSAN (Center for Food Safety and Applied Nutrition) had put together a system that was doing some reporting and using some of the information they were actually keying in from personnel information in order to produce management reports to analyze trends, etc. It was early

on, and they had people actually keying personnel information into the system. So I got involved in that, working as a team with my Branch Chief at the time, George Brindza, and another person -- I don't know if you want names.

JS: Sure.

CHG: Ruth Byle at the time -- she's McCarthy now. Ruth and I worked together on this system. There were reports that coincided with some of the accounting data that was needed, such as personnel information. Once the data were matched up, reports were made available such as how many awards people received; how many females in the agency, etc.; thus many questions were able to be answered. It was beneficial to EEO and FDA management to get that type of information.

FDA personnel data was being keyed into the HHS system. Even though it was being keyed into a main personnel system, we couldn't get back our own information. So we worked with the department, and actually going through the chain to actually get that information back. And that is still the case in some instances that you may have a larger system, like HHS, that data goes into but you can't get it back at a level where you can report on it.

JS: Why is that the case?

CHG: Mainly because the focus in many cases has been the transactional pieces, getting the personnel records data in, getting your OPF (Official Personnel Folder) information

in, putting it all in. Even though they know that they need it, that's sort of secondary in many cases because they're trying to get the work and transactions done. It's understandable, but there's a big benefit of getting these reports out.

Anyway, that was kind of the beginning of it.

But the jumping point, I believe, was when we had Brian Hill, who was the head of Property Management. He handled the rooms' moves and, therefore, the phones and other property for the Bureau of Foods. He came running down the hall and said, "They're going to change all our numbers. Nobody's going to know how to contact anybody. What can you do?" They really didn't have anything automated. They would type everything, so they had no electronic directory at all.

We already had personnel information for the Bureau of Foods, and the base information had data in there such as the person's name, all of that type of information, and it was a good core of data already. So all we had to do was attach location information. So this became my system that I worked on. So we took the location data, linked it to the core data with the key as the name, and boom, we had an electronic directory. No big deal. So we had an automated directory almost immediately. We were provided some folks to key it in, and so that really helped to maintain the Bureau of Foods Directory.

The Bureau of Drugs at the time asked to come on board, when they became aware of the automated directory. They started using the system, and other Centers were interested in differing degrees.

Then, in 1985, Commissioner Young at the time initiated a task force to look into systems that could be extended agency-wide.

JS: Do you know of anything in particular that prompted the development of this task force, anything . . .

CHG: Specific? I think just, in general, there was a lot of things that he saw that were probably not as efficient as could be, and it was a way to do some reengineering. He named Brad Rosenthal, who at the time was the Office Director for the Center for Foods, Office of Management, to be part of the task force. And as a result, he called us in and said, "Well, let's look at the system."

TAPE 1, SIDE B

JS: You were discussing the task force in implementing this system.

RT: The system we were talking about, really, I think fits the acronym of AIREs, is that right, A-I-R-E-S?

CHG: No. A-R-I-E-S.

RT: Which stands for the . . .

CHG: Administrative Resources Information and Exchange System.

JS: Right. So this actually, ARIES, changed in many ways the way FDA was doing its business on many levels, in moving us from a paper institution tracking so many of its key functions, key administrative functions, to an information technology-based system.

CHG: Automated system, yes.

Previous to the automation, the directory was managed by an entire division that would once a year call out for people to send in a paper form with their location information. Then they would print a telephone directory. By the time the phone directory was printed, it was out of date. So the system allowed for more up-to-date data.

The big issue was not the system. In many cases -- and across the board for almost any system that we've ever put together or that I've worked on -- is getting the information in, and whose job is it to maintain that data. So in a lot of cases, what we tried to do was extend it out as far as we could to the point of who is responsible, in other words, to have levels of and degrees of responsibility. At the end, it would be the person: "I moved, here's my information." But then there's administrative officers and other folks who are tied to that process. So it has grown, it has grown.

Well, when I actually put it together, I sort of got my hand slapped a bit -- and I'm not sure if we want to put that in here -- because it wasn't my business to create directories for the agency or for the Center.

RT: Who was the impetus or the originator of the idea that we need to change? Did that come from the Commissioner level or from operational?

CHG: No. It came up -- you mean the directory itself?

RT: Yes.

CHG: It came from a specific requirement. I mean, we actually did this. It wasn't our job to do this, but we had a need, and the need was that the Center for Foods' phone numbers were changing, and so we put it together.

JS: Did any other Bureaus or any of the major Offices in the agency have anything remotely like this?

CHG: No, they didn't.

JS: Yet they must have experienced the same kinds of problems and inconveniences with constant changes, particularly with the Office of Regulatory Affairs, where you have a national system of offices, and I would think that would be even more of a problem.

CHG: Well, what actually grew out of this was the organizational data also. That also did not exist. And the organizational acronyms -- you probably see it today on your reports and other communications, for example, OC/OM/OIRM -- guess where they originate from? Because it didn't exist before. So we made a database that had this

information, with the key being the administrative code, which brings it to a level that the personnel system uses.

JS: When you say the administrative code, is that what we often refer to as the mail code?

CHG: No.

JS: This is a different code.

CHG: Totally different one.

The administrative code comes from the personnel system, and the personnel system has in it the person's Social Security number, their name, a lot of identifying information, and something called an administrative code, which is a code that places you in an organization within HHS.

However, that code doesn't necessarily give you enough information to tell you, unless you're an administrative officer, to know that this is the Center for Foods, the Office of the Commissioner, you know, the Office of Information Management.

So what we did was take that administrative code and attach to it the acronym, which we use in the government all the time, and also the name, and that links to the person. So guess what? You can now create reports on people within their organization. So you can cut up the pie by center, by region, by district, by resident post. That was very useful, because once you had that, you can also run reports on how many people in a

resident post or a district. How many GS-9's here? All of that information is now available, reported to by organization.

So, like I said, that did not exist anywhere. In '85, we extended it to the entire agency.

JS: Well, that's what I'm particularly curious about, because you kind of mentioned this jokingly before, but I am curious how, to what extent this was embraced and to what extent it was maybe not so warmly embraced by the agency. Now, I trust in the Bureau of Foods, this was implemented, and maybe gratefully. So I don't know. But maybe elsewhere within the agency, also within the Department, how was this received?

CHG: Well, the Department sort of didn't really look at it that much, to tell you the truth. Initially, we had trouble getting the data from the Department, for the personnel data, which was the core data that we used. But once we did get that, it was okay with them.

Now, the main thing we had to do was keep the data secure, and we always managed to keep it secure. We had levels of security within the system. Certain people only could see Social Security numbers, only certain people could see grade or certain things that were in that record, and other things we didn't even use. So we kept it all secure. We had it isolated from the directory, because anybody could see the directory information, but those folks were not privy to the other, so we had levels of security in there. As long as we kept that, the Department was okay with what we were doing.

Because the Commissioner gave us the okay to move forward, it allowed us to extend the system agency-wide.

I was sitting at the Bureau doing this agency work, and there were a lot of folks who did agree with what we were doing, but there were some that were not pleased.

Like I said, it was a team effort; I worked with Ruth Byle, and we had our management in great support of this also. And even though it was agency work, my Division Director, Charles Exley, still supported it because whatever we did for the agency also matched up for what we could do for the Center. So, you know, you get a big bang for your buck on this one.

I spent time mainly at Parklawn extending the ARIES system to the various Offices within the Agency. I spent a lot of time on outreach actually going to the administrative officers, management analysts, and the directors of the Centers and Offices and saying, "Here's the system. We can do this," because everyone had their own little system, but it was only for their Center. And it was different. Most of them keyed in their own data. They didn't get it directly from the Department like we did. So they already had reports. Some of them had their own needs. Again, it was only for their organization or at an Office level in some cases. It wasn't necessarily at the Center level. And so I spent a lot of time analyzing their specific needs.

To date, it was always still a lot of work getting people on board, using the system.

RT: You mentioned in the information you gave us that there were a number of systems that you did develop, and I'm wondering if that's of what you're speaking of

now. You mentioned that you developed, implemented, and fashioned online applications using Model 204.

CHG: Right.

RT: You mentioned several other systems like Mark IV, MVS, TSO, and so on.

CHG: These are programming languages -- software. TSO is Time-Shared Option, on the IBM Model 204 was the programming language that we used.

RT: So were these systems, your mentioning of these, a precursor to the ARIES?

CHG: No. Those are programming languages. ARIES is a system. The ARIES is an application. We used the programming language Model 204 to program ARIES.

In the backend, you use, in the backend to the transaction, we'd bring in the files and massage the files using Mark IV in some cases on the mainframe, because the Department used mainframe data files. So we took those and loaded them into a database called Model 204.

Model 204 is an easy-to-use database management system. It was a precursor to quite a few other databases. It is still in use, but FDA now mainly uses Oracle.

With that core information, I think what you were getting to was we did add a lot of other things. Once we had the core data, we could just build on it.

We also created the performance awards system. In fact, we were able to transmit that data directly to the Department and key it in only one time instead of the Department having to key it again. So we saved a lot of money there also.

Anytime we needed another system or some other need came up, another requirement, all we needed to do was attach those few data elements or fields to that core data, and then we had another subsystem that we could report on.

Yes, there were several things that we were able to do with that.

JS: With respect to ARIES, how long did it take the rest of the agency to implement it? Was it done quickly, or in fits and starts?

CHG: Fits and starts, fits and starts. But there were some things that actually pushed it along. We had a need to manage the directory services and things like that. When the awards were needed, everybody needed to use it, and it was a directive from the agency to use ARIES for this, and so it was done. So because of HHS requirements and directives, it was pushed along.

What always was a problem was the maintenance of the data, keeping the date up to date. That was difficult.

JS: Did you rely on the management offices in the Bureaus and, later, Centers for that function?

CHG: Yes.

JS: So this was maintained by, well, this was entered by them but funneled, obviously, in to you.

CHG: Yes. Well, funneled into the main file. The core data, such as pay plan, grade, even information on race and all of that, Social Security, name, everything like that, came directly from the Department. There was no rekeying of that at all. In fact, we had it set up so there was no touching of that data; you couldn't change it.

The only thing they had to do was attach the other information, location data, room number, the information needed to manage the agency.

JS: So that core personnel information came from the Department.

CHG: Yes.

We did not rekey it. It was very efficient in that regard.

JS: Were the Bureau of Management offices the ones supplying that to the Department, the personnel information? Where did that come from?

CHG: It came in when a person came in to be hired, and they would fill in those forms, and then it would get keyed in.

JS: So, one time.

CHG: One time, yes. It's still being done that way.

JS: I want to talk about the FMDB.

CHG: Okay. Let me finish this one piece because at another point, I did a lot of work for and worked with the Director of the Parklawn Computer Center, Tom Redden. He at the time sort of held two hats. He was the Director of Parklawn Computer Center.

He was also a precursor to a CIO. He was the Director of the Office of Information Management. They didn't call him CIO at the time, Chief Information Officer, but that's basically who he was. So he actually was the head of IT at the time.

He requested that I work on putting together some information to put together white pages. It was requested by HHS to put together white pages, and we needed to put something together for FDA, to put all this information together. The white pages were going to be a directory. So we did put that together; we had it already. We didn't have to re-create the wheel, we already had it. All we had to do was communicate and send them the files, and we set it up on automated transmit to get them, HHS, the information for location directory, every day, thus keeping it up to date.

After that, we also needed, at the time -- and this was later on -- to communicate via e-mail when e-mail began. What we had to do in order to communicate, because everybody had e-mail information at a very rudimentary level, and we could communicate, but it was machine to machine in many cases. You had to have that person's e-mail address, which was this long address (series of numbers and letters) that

had a name, a machine name, all of this, no standard, no nothing. So mainly just the IT people could communicate from machine to machine, and you really needed to know this long address -- it's called an address -- in order to communicate with them.

Well, no one really could use it because there was no way to know that, and you typed it in and people had to know all these instructions.

Well, here at FDA, we also had non-standard software for e-mail. The Bureau of Foods used IBM PROFS. Some people were using the VAX itself; other Bureaus/Centers were using All-In-One, Banyan, and Pegasus. I don't know if you recall any of this. There were different computer software systems to communicate via e-mail, and it wasn't an easy task to communicate.

JS: If you wouldn't mind, what period are we talking about here when the agency starts implementing a real e-mail system, even if it's a matter of communicating with a long-string address?

CHG: When did that happen? I was still at CFSAN when we were doing that.

JS: So, early '80s maybe?

CHG: Yes, probably, because -- probably mid-'80s. It was after this. I don't have an exact date.

JS: That's all right. Our sense is that it took place in the mid-'80s.

CHG: Something to that effect. We started doing some rudimentary work on the web also, to put things out there. In fact, we put the directory out there on the web, but it was very rudimentary, very rudimentary at the time, and it wasn't pretty, definitely not.

Anyway, we had all these different systems, and everybody had their own software, but they couldn't communicate. Even if they could, the e-mail address was so long, or the directory, the address itself was so long.

So HHS came up with the possibility of using a software package called Softswitch, and what this allowed HHS to do was to take whatever the address that went in and to convert it and make it a standard, semi-standard, shall I say, and then we could communicate from one e-mail software package to another. I was part of that task force, the e-mail task force. With ARIES, I was able to convert all of the agency's addresses and put something together for Softswitch so the communication could be done, because I had already started to enter e-mail information from the various Centers in the Center level because each Center had their own standard or semi-standard, and it had the Center in there. Then we changed it so that then we could communicate with this software translator called Softswitch in order that all of the FDA could communicate. So, again, ARIES was used to accomplish this.

JS: Prior to Softswitch, so the Centers could not necessarily communicate with one another. What about the ability to communicate with the outside world?

CHG: Not really, not easily. I mean, we were sort of looking for HHS mainly, you know, to start with.

Because we had that already automated, we were able to come up very quick on this, whereas the other agencies didn't have the same thing, and they had to start it from scratch.

Actually, we were the only -- and I don't know if FDA us still the only ones that are actually using the core personnel information to manage their location and e-mail directories.

JS: Our fellow agencies at HHS and others really lagged behind FDA when it came to implementing something like this.

CHG: Now, CDC (Centers for Disease Control) actually did do something very similar. They had a system similar to ours. Some of the other agencies actually had to start from scratch.

It actually paved the way to start communicating, even before we went to a standard e-mail system, because FDA did not have a standard e-mail system for a long time.

JS: There was another program you were involved in for the database, when you were at CFSAN in this period, and that's the Food Monitoring Data Base, the FMDB, for which you were a project officer. I wondered if you could elaborate a little bit about

what FMDB was all about and how it facilitated, I guess, integration of data between the agency and the outside world.

CHG: The Food Monitoring Data Base was the Center for Foods system that provided a way to analyze health information from disparate data sources.

JS: Do you know what kinds of information? Was it pathogens or something, or what?

CHG: Yes, but most of it was related to food. There were various studies such as the USDA Nutrient Data File; Total Diet; NHANES (National Health And Nutrition Examination; and the Hanes Surveys.

JS: The reason I'm curious about this is that the agency I think was operating out of the Kansas City District office -- Bob, correct me if I'm wrong -- a sort of a total diet study, a kind of a market-basket survey of foods, of food purchasing habits, I suppose.

CHG: Yes, and that was one of the data sources.

JS: Was that an element of the data base?

CHG: Yes.

JS: Okay.

CHG: The FMDB incorporated various CFSAN information systems. CFSAN maintained a Thesaurus that contained terminology on foods, such as its components, various names, and other scientific and related information. There was also information on chemical compositions (CAS numbers), and CFSANJ maintained procedures for the creation of a food-factored vocabulary called LANGUAL. All of these systems provided an avenue to link diverse food- and health-related databases via a food source. This was important because the food names in the various data sources had different names (sometimes in foreign languages).

CFSAN kept that Thesaurus going for a long time. The Thesaurus was a data driver that served as a core much like the ARIES core information for personnel.

RT: During this period in your career, you were, I believe, a computer systems analyst.

CHG: Yes.

RT: You had risen to a GS-13 level from your earlier work. So, I believe you then moved on to another phase where you went into an EASE [Enterprise Administrative Services Environment] kind of activity.

CHG: Yes.

RT: I think in that position, you were the EASE systems administrator. Would you give us a little information on what was involved in that activity?

CHG: Yes.

FDA was basically . . .

TAPE 2, SIDE A

RT: I believe when we changed tapes, we had just started to discuss the EASE system, and I believe at that time you had also become the Information Systems Security Officer. Both those responsibilities were a move forward in your career, I'm sure.

CHG: Actually, I was the Information Systems Security Officer for the Center for Foods also.

RT: I see.

CHG: The Agency had just started to really have designated security officers for each Center and for the agency. We initiated the groundwork for the security programs to conform to HHS and NIST Computer Security Requirements. I transferred to the Office

of the Commissioner to implement a system to automate time-and-attendance for the agency. It was called EASE.

JS: EASE stands for?

CHG: It's the Enterprise Administrative Services Environment.

We often labored to come up with an acronym that was catchy and meaningful. And I have often said that we were really put on the spot to implement something as difficult as time-and-attendance with a system called EASE.

And then the project itself was the Automated Systems . . .

JS: Administrative -- I think you have it here, ASAP.

CHG: Yes. Administrative Systems Automation Project, ASAP. So not only did it have to be easy, it had to be done ASAP, so it was a challenge, for sure.

I was called upon to work on this mainly because of my background in ARIES.

JS: Walk us through a little bit about time-and-attendance issues, you know, prior to EASE and how things were managed and where the need for EASE . . .

CHG: Came from.

First of all, it was a directive from the Department. "You must automate time and attendance." Something had to be done. Each Office, in some cases Center, had their

own method of collecting and managing time-and-attendance. Timecards were filled out and mailed, keypunched, typed forms were collected, and then either keyed into a system that a Center had and then transmitted over to the Office of Financial Management -- I don't remember if it was DFM [Division of Financial Management] at the time; or key directly into DFM's system. Then it would be transmitted separately to the Department. Please don't quote me on that one because I'm not exactly sure of how that was done. But I believe some Centers, like the Bureau of Foods, I think directly sent it to the Department and maybe bypassed DFM.

It was done in different ways. That was the key. Some used the timecards with a time clock; and others would fill in the time card manually. The timekeeper would collect the information and keep the records manually of how much leave was used and remained.

So it was a struggle to get timekeeping done; there was a lot of time spent on this.

The Department was implementing a system. They had something already in place that would allow people to key in the information and put it together and then -- I called it "sneaker net," because what they would do is they would have it on a disk and then they would walk it somewhere else, so it wasn't really automated.

So our group was pulled together with Ray Russo heading up the project ASAP. He had also come over from the Center for Foods at the time and asked me to join him on the project. We spent a lot of time looking at what was out there, you know, what other systems were out there, looking at things that other agencies had, plus we analyzed the Department's system. We didn't feel that it would be beneficial for FDA to use the HHS

system at the time because it wasn't truly automated yet. Plus it did not meet FDA's complicated time-and-attendance requirements.

What we were looking to do was to put this system together that would truly automate time-and-attendance and be able to transmit it all in one fell swoop to DHHS.

What we did at the time was to take the core information, again, that I had been using at ARIES and to use it over again to be the basis for the information for time-and-attendance. Again, I had the name, the Social Security number, what pay plan they were in, what their tour was, all of the information needed for time-and-attendance except for the hours that they would be working. So there were some key fields that needed to be added to the database. It wasn't as easy to do this, because at the same time we were moving the database to another software package. We moved it from Model 204 to Oracle to start that process, and it was quite a bit of work to get that done because it's not a one-to-one change.

We had a lot of joint sessions with the users to see what they needed, because we were not just looking at setting up the time-and-attendance -- that was our ultimate goal -- but we needed to set up the system so that everything that was being accomplished in ARIEA could still continue to be used. We couldn't break it because the agency depended on it to support a variety of personnel and administrative functions. So it was a total transition over to another database. At the same time, we were looking to automate other agency requirements.

With the EASE system we implemented and automated the time-and-attendance system.

FDA actually has one of the most complicated time-and-attendance systems because of the fact that we have almost every imaginable type of time-and-attendance category used. We have ANY80, ANY8, and Maxiplex. All of the requirements for the various categories are very different. FDA is very flexible in its time-and-attendance system.

JS: So these are all ways that employees and . . .

CHG: Users.

JS: Can account, not account for their time, but spend their time on their job, whether it's here or any 80 hours during a fortnight, during an 80-hour workweek, or working here, working at home, working somewhere else and so on.

CHG: Absolutely.

JS: Don't you think other agencies have this sort of . . .

CHG: Now they do.

JS: But we were leading the way?

CHG: Well, we were at the time. We were looking at others to see what they had. And,

again, the Department had what I mentioned before, and CDC had something that they were also using, and we looked at that. But it was also used in an older system database. So we were looking to upgrade it to a new platform, Oracle, and bring it state-of-the-art and bring it up to that. The CDC didn't have as many flexible leave categories as we did.

JS: Did the Department ever try to impel its will on one system which would be applied to everyone?

CHG: They didn't do it in quite that way. They were quite democratic about it, and I'm not sure that was necessarily the right way to go, but, you know, this is the way they operate. They would say, "Here's this, and you can use it, or you can have your own, but you have to transmit the data this way." So they didn't mandate it. It may have been for the better, you know, to do that, but they weren't ready to take on, either, the work that would be involved to allow all of the changes maybe that were needed. So we didn't do that. I mean, the choice was made to, you know, and management, of course, agreed to do this, and it actually did work quite well.

The plan was to start out with allowing the timekeepers to do the work, because the timekeepers were the ones that were currently managing all that. But we didn't have the manpower to train people, because our staff was small. We had to train people; we were doing train-the-trainer to implement this.

The initial thrust was to get the timekeeper to do the entry of the data for timekeeping, and later on to pass it on to the employee. Well, we never got the funds to move it forward, to make the changes to get the employee to enter the information

themselves or to add other things such as automated leave slips, so that never got done.

Today, I believe FDA is changing over to the NIH (National Institutes of Health) system, which is going to be, hopefully, the Department standard.

RT: This acronym, Oracle, I don't think we've defined it.

CHG: Oracle is a programming language.

RT: It's just a program language.

CHG: Yes.

RT: It doesn't stand for any particular system.

CHG: Nothing. It's called Oracle.

RT: Thank you.

CHG: It is software. A database management system.

JS: This was, EASE was your primary responsibility in this position.

CHG: Yes, in that position, yes. As such, EASE then also took on all of the transitional

changes that, moving the ARIES system over to EASE, so the things that were being done in ARIES moved over to EASE, and so that also was part of that.

JS: What portion -- I want to make sure I understand what you're saying, that elements of ARIES were incorporated into the EASE system. Correct?

CHG: Yes. Actually, it's been said that EASE is the daughter of ARIES.

JS: Right. You probably should be using sort of the Greek mythology acronyms here for these systems and how they tie into one another.

CHG: Well, actually, we tried at one time. We just couldn't come up with something that would signify that.

But the other impetus at this time was the Y2K. I was part of the FDA Task Force to review FDA systems for Y2K compliance. Y2K also brought into play the fact that, what are we going to do took into consideration changes and Y2K issues so that we did not break anything? It was also a way to look at some of our older systems and say, do we still need them, and move them into this new platform and make the required changes, or are we going to leave them behind? So Y2K actually gave us a way to look at these systems and to say these systems may break -- and note the "may" with big quotes around it, because we didn't know for sure. We knew that some systems were using two digits instead of four for the year, and so with Y2K, some of those were going

to break. And so the question was, did we want to spend time on upgrading this one or put a new one in?

We spent a lot of time on EASE itself, and moving the things that we needed from ARIES over to EASE, because that was being put together so it would not have a Y2K issue either.

There were some things that were left behind that I think probably should have been moved, but, you know, with money and restrictions and the need to get the time-and-attendance done, the effort was put on there.

Actually, we looked at ARIES, and it still ran after Y2K.

JS: Now, this is interesting, and we have to talk a little bit about this too.

As the year 2000 approached, was there any sort of sense of, well, we'll see what'll happen when midnight strikes?

CHG: We were actually here; we actually did.

JS: But was there, I mean, was there an element of doubt . . .

CHG: That anything would happen?

JS: That something would happen that we just hadn't prepared for?

CHG: Yes, yes. I mean, we tried very hard to review all our systems. I mean, you've

got millions of lines of code, and we spent time going through the programs, we did a lot of analysis to correct any issues. This was done agency-wide. All the IT folks were doing this. Of course, I was looking at this because our systems and data had been built on a two-digit premise. And we had to look at everything and hoped that we basically took care of it and did a lot of testing. We ran tests and backed up and fixed again, ran more tests, you know. We did a lot of that.

The task force was very well organized, going through all the systems we had agency-wide.

JS: Agency-wide.

CHG: Yes, defining and tracking them all. You know, I mean, you turn around, you turn a rock over and you go, "Oh, another system!" you know. We didn't think about this. It might have been a very small thing, but something that was needed.

It also allowed us to know where we were at the time, and that was important, to actually be able to say, "This is everything we have, and this is what we need to do." Yes, we spent time there. We didn't celebrate New Year's Eve with our families. Most of us spent our time on call or actually in the computer rooms.

JS: Well, I imagine a lot of people were just kind of holding their breath.

CHG: Yes, yes. And we did very well, we did very well.

JS: I mean, overall.

CHG: Overall, we did very, very well, just a couple of hiccups, but for the most part, everything ran. FDA did a very good job.

JS: But we also spent a lot of time preparing for this, didn't we?

CHG: Yes, yes. There was a lot of time spent.

JS: The task force had been put in place when?

CHG: God, I mean, it was maybe a year before. It was a long time. It was very important. I mean, it was definitely a security issue. There were people who thought maybe we wouldn't get paid, and that some of the mission-critical systems may not run. There were just a great deal of processes and people involved in the Y2K initiative. It was an interesting time.

JS: One other question I wanted to ask about this, particularly this period.

Obviously, in the wake of 9/11, we're very concerned about -- and we were before, as you've mentioned -- about computer security issues, but particularly after September 2001.

CHG: Yes.

JS: I assume we started reevaluating our computer security procedures and securing data and so on. Can we kind of characterize how that worked in your corner of the agency with the EASE system, and if it necessitated even stricter security with EASE and the other systems you were involved in?

CHG: It didn't necessitate, necessarily, tighter security within the system because the system already had a lot of controls.

What it did necessitate was a bigger awareness of the role of the security officer and security in general for our systems across the board. And what that means is access controls (who can get in and what they can do, what happens when the system goes down, and what are our contingency plans. So the big effort really was, what is our contingency plan for keeping the agency running, because you can't depend on the cell phone, you can't depend on all systems being up. You must have a place to store your data; another, you know, what systems are absolutely required? What are our mission-critical systems?

Even though EASE is important for pay, we have a contingency for that. If we don't get paid through the transmit of the data from EASE for time-and-attendance, there's a default payment that can be processed based on tour. That contingency process is available at the Department already. So that sort of process is already in place. EASE is not a mission-critical system.

But there are systems, you know, such as food or drug safety or anything to that effect. These mission systems have to keep running so we have to have a contingency for them. There was time devoted to these efforts.

The other thing is the management for the continuation of operations. Who is critical to the agency running? Certain IT folks might be critical; surely the upper management, upper management; and how do they go about doing this? Looking at who are the critical folks, and that changes constantly.

Actually, I was working with some of the folks who were putting these plans together to look at using the EASE database for tying in that type of information. It never actually got done, but there's still an effort to look at that and how they're handling it today.

The thing about the EASE database is it's got directory information, it has who the folks are, and it refreshes itself daily. If a person leaves, like myself, it's already off the rolls; a person who comes on board is on the rolls. So it can be used as a basis for person-related data, not necessarily the end-all, because there's more information that needs to be added to it.

But the big key was to manage and look at who those critical partners were and key individuals for keeping the agency going -- again, mission-critical system, mission operations and programs.

RT: I presume that before the 2001 incident, we hadn't really done much in that way.

Is that true?

CHG: Well, there had been probably different levels of that at different Centers. There was across-the-board a need, and always was, and we did work with the security folks to make sure that we knew who the critical people were. Depending on the Center, they managed it at different levels.

RT: As I recall, during the Cuban crisis years ago, there were plans then for evacuation of key personnel, so I guess it's been going on for some time, but it's probably much more sophisticated now with automation.

CHG: You would hope.

Again, it's more complicated than just who, because, for instance, if you have systems or projects, you also need backups on these. So if you have somebody that . . . And one of the things that was being looked at was the avian flu plan. If someone gets the flu or if there's some sort of a problem where people are getting sick, it's no longer the IT system that's the problem. In other words, it's not an emergency where we're being attacked and our systems are going down or something to that effect. It's the people who are no longer able to work. So one of the things that was being looked at is, can we work at home so that we don't pass a virus or whatever back and forth, or can we then also set it up so that we have backups, so that if this person doesn't come in, we have others? In most cases, for most of our systems, we have a procedure for backups, one, two, three, four deep, depending, who can take over and handle these things, or someone else, and that's very, very important, and this was being done also.

JS: So the system would identify this kind of, I won't say redundancy, but this sense of people who cover, or who could cover for other people in the event of some calamity.

CHG: Right.

JS: Okay.

CHG: That was being done a lot in the IT organization. It would happen especially where a system would go down and somebody else would need to take over. It would happen. It was happening more and more across the agency, and being looked at to make sure that everything was covered, and if people were to get sick, then what contingency we would have for that. This was a different orientation, you know, not the machine so much, but then the people.

Again, I'm not the expert on this. I worked with the folks who were working on this project.

RT: You, I think, were promoted to Acting Director of the Office of Information Technology, Office of the Commissioner. That was in 2004, I believe, wasn't it?

CHG: Yes.

RT: You mentioned that you met frequently with the Commissioner, Office heads, and

other officials regarding strategic goals and so on. Was that also part of the planning process for the agency?

CHG: Yes, it was. I didn't meet directly with the Commissioner. I met with mainly other IT directors, the Chief Information Officer, the Office of the Commissioner itself, the Associate Commissioners and directors of the various offices. This was a new position, actually. Each Center had, for some time had a director for IT. They may not have been called directors of IT at the time . . .

TAPE 2, SIDE B

RT: I think you were then a GS-15 in the position we are now speaking of.

CHG: Acting, yes. I actually was Acting for a short time before I became permanent.

But in this capacity, this was a new organization. As I mentioned before, the Centers had IT directors before, and Offices, for that. The Office of the Commissioner is truly not a Center, it is an Office of Offices, but very loosely tied, in fact. They're very autonomous. They would, within each Office, have direct communication to the Commissioners in some cases and have their own mission, so they're almost like mini Centers, if you think about it, each Office within the Office of the Commissioner. They really are not a cohesive group in the same way that the Centers are. And so since an IT director for the Office of the Commissioner had not been in place before, they sort of

took their lead from the Office of Information Management or the CIO as helping them out.

There's very specific needs that each Office and the Offices within the Office of the Commissioner have that are different than the Centers. They are the same in many cases, but they're different in that they work very independently, not as a group. So it was a big challenge.

I worked with each of the Office managers to see what their needs might be, and their needs were not something that was easily translatable to every other one. They had very specific needs. They were, I believe, 30 or 31 Offices in the Office of the Commissioner.

When I did get the job, I was given a lot of congratulations, I think, or some sympathy in some cases. It was a challenge, but it was good.

There were quite a few things that were needed. There were hardware and software requirements that each of the Offices needed. They didn't have a voice in the same way as the Centers did in many cases, and so I was helping them, to lend them a voice, to be able to say, "We need this in the Office of the Commissioner," or "We need that." When certain things were needed to be implemented across the agency, rather than each Office having to handle their own IT piece, I was able to help them to put something together for the Office of the Commissioner.

It was a challenge, but it was also a great learning experience for me because, although I had worked with the entire agency for many years, since back in '85 . . .

JS: Well, even with CFSAN, you were working . . .

CHG: With CFSAN, I was working with the agency. So I had a lot of knowledge of the organizations, all of them, and how they operated -- not necessarily their missions, not their programs as much, more at the administrative level.

In this position I got to know the program issues and what IT needs they had. Even though I did know the CFSAN program area, I didn't know the ones from the Office of the Commissioner as much.

There were various initiatives that needed to happen, and the work we had done before, as I was also the Security Officer for the ASAP project, we were moving towards a single FDA sign-on that would allow users, the general FDA employees, to sign on one time and not need to keep track of multiple passwords and ID's. This was something that we were really trying to move forward.

We were also working on the Internet and the Intranet inside FDA. I was a working member of the project representing OC. The inside FDA project was working on modernizing the FDA Intranet to make it more efficient and user-friendly. I focused on the various offices' requirements and what would be helpful for the Office of the Commissioner.

JS: I know you said you were meeting with the Commissioners themselves directly.

CHG: Directly.

JS: But you must have a sense with the Commissioners or Acting Commissioners

during the four- to five-year period that you were in this position, either Acting or as Director, of the extent these people had to take an interest in ideas, whether it's the systems, the Internet/Intranet issues, and so on? Did they have much of an interest?

CHG: Some more than others. They absolutely were interested because some of the work we had to do was to put together the business plans for the IT information systems that was submitted to the Office of Management and Budget. It was important because the IT money we got was based on our supporting business plans. There has been a need to upgrade the IT infrastructure and some of the agency applications to keep the agency systems current and running properly. The infrastructure needs also included a PC refresh process that would get new PC's or laptops to FDA employees.

We had initiatives coming down from the Department on things that needed to be done IT-wise, such as, we had to move our e-mail system over to the Department system, and that was a huge initiative. I oversaw the implementation for the Office of the Commissioner, which, again, with so many deputies, it was a challenge to meet the timeline. In many cases there was quite a bit of negotiating required. Because e-mail access had to be suspended to convert the system, it was difficult to find a time that was agreeable to all. So there was a lot of coordination required to minimize the downtime for the Commissioner, Associate Commissioners, and other critical staff.

There was the conversion of the FDA accounting system to the department system. We provided IT management support on this and several other IT initiatives that were put into place during my time as OC IT Director.

As far as the Commissioners and their interest, they were interested in the mission systems and all the goals and missions, so, as such, they knew that IT was important. But I'm not sure that they all realized to what degree the IT systems were depended on and how badly infrastructure updates were needed. The Bioinformatics Board FDA has instituted is bringing to the table management from different centers to discuss the IT needs for each project and system. They're not really looking at IT itself; they're looking at the program needs, and IT then will work with them to come up with IT requirements.

JS: That's the way it should be.

CHG: Absolutely.

I think this is really good, because there's open discussion now and people are coming to the table with their needs, and it's being looked at in a way that's across the agency rather than just at the Center levels. They're also looking at the IT needs for scientific missions.

JS: The Board -- was the Board established before you had retired?

CHG: Yes.

JS: Okay. Do you want to talk about your involvement with the Board?

CHG: I sat in as an IT Director, as a bystander, if you will, because the Board was to be

composed of the Center office program areas and not IT per se. The CIO was at the table but the IT directors were there to gain insight on the process, to answer IT-related questions as needed, and because our IT staff would be involved in the various support groups that were reviewing the systems, which ones could be used to satisfy an initiative defined by the Bioinformatics Board.

JS: But, of course, they have to have, you say bystanders. But, on the other hand, one has to deal with the realities of what IT can and can't do with respect to program needs for the Centers. Right?

CHG: Yes.

JS: So, having experts like yourself and the others in the Centers would seem to be an important part of that deliberation.

CHG: Absolutely. And, again, the working groups were looking at that and providing feedback. They were categorizing groups for this and working towards goals that were for the agency, which I believe is a very efficient way of managing the FDA initiatives because you're looking at the monies, and if you split the monies up so that you have an IT system that is only being used by the IT Center instead of something that can be used across the agency, it's not very efficient.

Again, I'm not sure exactly where it's at right now, but they had been making quite a few inroads. The new CIO was introducing some new IT programs to start

looking at agency-wide approaches to software development. This was the approach I had been working on for a long time.

I left at a time when I was really getting excited about the work that was being done in the CIO's office. There was a focus on reusable, sharable code and software tools. This, in conjunction with the Bioinformatics Board encouraging the use of shared Agency data and standards, made it difficult to stick to my plan to retire. These are initiatives and approaches and I had been working on throughout my IT career.

RT: As I recall in your background information, you also served as an Acting OBES Director during the Director's extended absence. What does that acronym stand for?

CHG: The Office of Business Enterprise Solutions. Prior to my taking on the position as IT Director for OC, I actually worked in OBES.

The OBES was actually the organization that grew out of ASAP (Administrative Systems Automated Project). The Internet organization was also under OBES, and the Intranet got started there. The various entities within OBES collaborated on a variety of IT initiatives. I also managed the Business Objects infrastructure and reporting requirements for the Agency.

Business Objects is the reporting tool that allows reporting on a variety of databases and data sources. It provides reporting capabilities for detail and summary reports including color charts. It's a pretty user-friendly software package. During the Y2K analysis, one of the big emphasis was to provide generalized reporting for ARIES data. ARIES contained both current and historical data. In fact, ARIES had historical

data starting in 1982 for CFSAN, '83 for Drugs, and '85 for the entire agency, up until today. So that's a lot of trends analysis, if you can go back and report on who was where, what was going on, FDA and Center-level losses and gains, all types of personnel and payroll data.

With the Y2K coming and the need for reporting within EASE, we also needed a good reporting tool. Well, the one that we had in ARIES was one that we had written ourselves.

Well, Business Objects allowed that, but it also gave you more. You could also use it to report on other databases agency-wide, not just EASE. So we set up an infrastructure for this reporting tool for agency use and invited the Centers to use it. We put it up and kept it up to date, and it actually became the reporting tool for the agency, and a lot of the Centers were using its capability. OBES managed the Business Objects Infrastructure and the EASE system.

RT: You mentioned, too, that you implemented IMPAC II for grant management. Explain it a little bit more, please.

CHG: Well, there was a requirement for the agencies to go into this initiative. It was headed up by NIH, but the Department required that everyone get on IMPAC II for grant management. We worked with the office that handled grants to make sure that they implemented it. We oversaw the management and the accounting but we didn't manage the system itself. That was handled by NIH.

RT: The agency does have a few grants, is that correct? At least we have contract programs with other government agencies.

CHG: Yes, they do. But, again, I didn't get into the program area. We just oversaw the implementation of that system and making sure that they abided by the DHHS requirement.

One of the things which changed quite a bit throughout my career was that we had a lot of oversight by OMB in the latter years in managing the IT budget. Previously we managed the money and handled it more at the agency and Center levels. We now had to provide IT budget and Business Plans to OMB. There was much more documentation and stringent reporting requirements.

JS: When did that seem to start noticeably?

CHG: I'm not great with dates.

JS: Since 2000, the 1990s?

CHG: In the 1990s. It seemed especially so the last maybe five, six years.

JS: Why do you suppose they took a much greater interest?

CHG: Well, understandably, a lot of it is to make sure the IT systems are efficient, that we're spending money wisely, and that certain directives and standards are being followed. Also, there were the OMB, HHS, FDA, and project goals that had to be supported. In other words, you know, if you're going to set up a system, it should be a system that follows the goals of the Commissioner and the needs of the agency; the Department; the President's goals. It was a way of making sure that these directives were followed and that you were budgeting properly. It's a good thing, but it's difficult for IT folks to do while supporting all that IT encompasses since it was very time-consuming. So there was a lot of time spent on managing the programs and projects. Basically it helped to establish a standard methodology to manage projects.

There was a requirement that IT staff managing projects complete project management coursework. We took the classes to make sure that we all knew the project management terminology, and how to implement it. Those of us that had come through the ranks knew about this, how to do it, but the terminology was different, because it was structured in a different way. So it was important to attend the classes, especially for the IT staff. Plus it all plays well with the Bioinformatics Board's project management and initiatives.

But it's difficult for some of us to necessarily do that because, as IT folks, many times you see things as programming, running them and solving problems, but then you have to document. Documentation is sometimes difficult to get to, especially within the new guidelines. But it's a necessary evil, and a very good one, actually.

RT: You were also involved in the technical development setup of the Hyperion implementation.

CHG: Hyperion.

RT: Can you tell us what it is?

CHG: Yes. The Office of Financial Management uses Hyperion to run accounting reports, and they manage the budget using it. They get data from the Centers, the Centers use it, and Financial Management runs reports on the consolidated data.

Hyperion is actually a tool, much like Business Objects. It's a reporting tool that focuses on accounting reports. OFM (Office of Financial Management) had implemented the system quite a few years back, and it was definitely due for an upgrade. Computer upgrades can be quite challenging. There's the data, the hardware, the software, and all the requirements that have to be addressed.

RT: Is that a system common to other agencies, or it was just an FDA system?

CHG: Well, Hyperion itself is a tool. It's like a programming tool, but it's a reporting tool. The data that was being used was financial management data. I'm sure other agencies were using it also. The upgrade required that the data be reviewed, all the interfaces that were in there be analyzed, and the contractors that were working for the

Financial Management group were doing a lot of that work, but the database administrator, the enterprise architect for the Office of the Commissioner, and the security officer for the Office of the Commissioner all were working on my staff. My staff was working with OFM and their contractors to analyze and facilitate the upgrade.

Part of the difficulty in completing the upgrade was getting the work done by the infrastructure group, the Office of Information Technology Shared Services, OITSS. One of my jobs was to negotiate timelines for OC initiatives. Setting up the hardware, bringing up the application, and implementing it was still in the process when I left FDA.

RT: For the period 2005 till your retirement, I believe you were Director of the Office of Technology and a supervisory IT specialist. Your involvement in a number of things there were at the culmination of your career. There's one thing that you had mentioned: You set the groundwork for standardization and automation conducive to SOA [service-oriented architecture] and consolidation efforts. What is SOA?

CHG: SOA is Service Oriented Architecture.

RT: I just thought that researchers might not be familiar with the term.

CHG: Well, basically SOA uses the enterprise architecture, which is a setup of the various infrastructure pieces for IT, such as the software, the hardware, the business requirements, the data itself, and all of that infrastructure tool sets. The enterprise architecture has been worked on here at FDA for quite a while. FDA pulled together

information from all the IT systems, brought it into the database, and generated models to analyze how the infrastructure could be used within the enterprise to further IT. HHS has also emphasized the enterprise architecture and in fact has mandated that all agencies enter the data into the HHS Enterprise Architecture System.

RT: Thank you.

CHG: Service-oriented architecture is not a new concept. It's been around for a while. But the technology advances have made it easier to implement. The idea and the approach of service-oriented architecture can provide greater efficiencies because you're looking at creating a service instead of just a program that does specific things.

A service can be something as simple as the retrieval of location information. A service can be something like that, where you put in a name, you get a location for somebody. That's a service at a very rudimentary level. But there's so many of these that we can do across the board, and if you do that service once, you don't have to do it again at each different system. You could just call that service and say, "Give me this information."

It can be implemented in different ways and at different levels, and allows for diverse platforms to communicate.

IT has grown and changed a great deal since I started working with computers.

As we go through IT, many times I have seen concepts go totally around and come back to square one again.

For instance, when I started with CFSAN, we were using the mainframe and using hardwired terminals linked up to the mainframe. A terminal located anywhere in the country could still be connected to a mainframe database.

TAPE 3, SIDE A

CHG: What I have seen is that initially we were using terminals, and then we started using PC's. With the onset of PC's, the programs and data were on the PC itself. The emphasis was for people to run their own programs and keep data close. Somehow the need for procedures and data to be handled at the enterprise with standards got lost. Whereas before you had one database with standards and connectivity to a particular platform with different systems and applications that didn't necessarily communicate with one another. So there were limitations and the user interface could be tedious.

The PC had some great capabilities and allowed the user to have more control, and it also brought in some wonderful capabilities for the user interface, meaning what you saw, color, visual things, easy to use, using the mouse, not having to use the keyboard. All of that was great, but you lost the computing power of the larger systems.

What I've seen is that we've gone full circle and now we have systems being connected via the Internet. And the enterprise approach is alive and well.

So you see something that had been done many years ago being repackaged and called something different. The basic premise and approach is the same, but with a new face to it and a brand new name, if you will. But the basic premise of IT is still there.

RT: You've covered a very interesting career, and we appreciate your taking time with us to record it.

Is there anything else that you'd like to say in conclusion?

JS: Or what have we not covered that we really should cover?

CHG: You know, I don't know. I, again, didn't really look at this that much to see what I may or may not have done.

What I can say, though, is I've seen a lot of changes in IT throughout my career. Like I said, when I started, we were using punch cards, paper tapes, dumb terminals sitting in a shared computer room. That changed when we had our own PC's. We went from what they called dumb terminals at the time to then we began using PC's and Mac's with easy-to-use interfaces. We went from actually doing all the coding (programming) yourself to a click of a mouse where the code was generated for you. And our means of communication changed. Our means of communication had been through the phone, and then we started using the computer to communicate through e-mail. I've seen a lot of these changes. I've worked with FDA management and staff to implement these changes from the beginning to now, where everybody's communicating through e-mail.

Another change was the Internet. When I started working on the Internet, we were putting the FDA directory up and I was working with some IT staff from CDER (Center for Drug Evaluation and Research) to set up some very rudimentary procedures. The information was black and white, not pretty, on the Internet at the time. Mainly

academia and some government agencies were using the Internet at the time. We put the Fish List on the Internet that was created at the Bureau of Foods.

RT: What is the fish list?

CHG: The fish list was a list of all the fish and their regional names. A fish name in one part of the country can be different than in another part of the country for the exact same fish.

There was some other information that we put up for the Bureau of Foods, but it was difficult to do. I mean, you had to write a program to get it out there. Now you can just click on it, just cut and paste, so it is very, very different.

All of these changes have been wonderful, and have allowed us to do so many different things now that are much easier. But the IT folks now have to still know the concept. They may not have to do as much back-end programming as we may have done at one time, but they have a totally new set of challenges. With IT there is always something new to learn and implement.

I think the other thing I see is, I'm not sure as many women are coming into the information technology or computer science as had been before, surely not very many Hispanic women. I believe I was, and I am so far the highest-ranking Hispanic woman in FDA's IT. I would like to see this change. So I'm not sure why that's happened, but I think there is a need to get more women in IT management; actually, in FDA management in general.

RT: Well, we hear an awful lot today identity theft protection. In these systems, is there pretty good security in terms of information that isn't really public?

CHG: Yes. We're very careful not to allow access to such things as Social Security numbers or any other sensitive data. I have worked for years very closely with the EEO folks because there are restrictions on what can be put out there as far as race categories, things like that, which is confidential, private, and should not be out there. There's definitely that. FDA has a strong security plan and takes it very seriously.

JS: I want to bring up something to follow up what you said earlier.

What's your sense for how many Hispanic women are in executive-level positions in this agency?

CHG: I can't think of very many, I'll tell you the truth. I know that there was an EEO director; Rosamelia de la Roche was an SES'er. Like I said, I became a GS-15. But I don't know.

Now, that is some information you could directly get from the EEO group.

JS: Thanks to ARIES, right?

CHG: Thanks to ARIES and also from other FDA and DHHS systems.

Now they're able to run some reports, I believe, from the main personnel list. They've made some very good inroads. In fact, I've worked with a lot of the folks at the Department, too. When they implemented the PeopleSoft system, which is the main personnel system now, I helped work on the FDA implementation of that, and they were also looking at using Business Objects that we implemented here at FDA to do some reporting on personnel data. I don't know if that actually occurred or not, but they've made quite a few inroads on getting some of that out.

JS: Kind of another just sort of broader observational issue, if you'd like.

To what extent do you think the IT systems, both the ones that you've been intimately involved with in your career in the agency and also others in the Centers that you know about, to what extent have they kept pace with or failed to keep pace with the agency's mission?

CHG: I think that they've kept pace with the mission as best they could based on the amount of money that was allocated to IT. And that's been kind of a difficult situation in some cases.

But now the Center IT organizations are joining forces. This will help IT become more efficient. Say you have a Center requirement that can be extended to the agency and shared with the Centers.

There's quite a bit of need in the scientific arena to help scientists with their specialized computer needs. The Bioinformatics Board should help to address both agency and Center-level needs provided funds are available.

What I can say, though, is I think the agency has fallen behind on infrastructure. Keeping up with technology is difficult because it is constantly changing. Plus those Center/Offices that have money are able to upgrade and the others are left behind. So working as a team, an agency team, not just a Center team or an Office team, will help FDA to keep pace. I believe that the culture has started to change. I see that with the Internet/Intranet working group. The IT directors are getting together under the CIO and looking at new approaches and tools with generalized and shared code.

JS: Well, thank you very much.

RT: We appreciate very much this interview, and we'll get a copy to you for editorial review.

CHG: Okay.

RT: Well, you're another one of those very remarkable people, I think, Connie, that took the opportunity to come in at a low-grade salary, low-grade position, clerk-typist. I've known a number of people that have done that and ascended right on up to the top like you did. That's great.

CHG: Thanks for the opportunity to answer your questions.

END OF INTERVIEW