

**History**  
**of the**  
**U.S. Food and Drug Administration**

**Interviewee:** Betty L. Jones

**Interviewer:** Robert A. Tucker

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**Place:** Rockville, MD

Interview with Betty Jones

December 28, 2004

TAPE 1, SIDE A

RT: This is another in the series of FDA taped oral-history interviews. Today, December 28, 2004, the interview is with Betty L. Jones, Deputy Director, Office of Compliance, Center for Drug Evaluation and Research (CDER). The interview is taking place at Montrose Metro II, which is the Office of Compliance for CDER, located at 11919 Rockville Pike, Rockville, Maryland, and is being conducted by Robert Tucker of the FDA History Office.

Betty, as we begin these interviews, we like to start with the person's personal history, where you were born, educated, and, when you entered the employment field, where you worked, if somewhere besides FDA, and then get into your FDA activities.

BJ: Okay.

I was born in Brownsville, Tennessee, and I went to school at M.I. College [Mississippi Industrial College], where I received a bachelor's of science in biology. My first encounter with federal employment was with the Internal Revenue Service.

RT: Is that right after your graduation from school?

BJ: Right upon graduation. IRS was the very first agency to contact me, and I needed

a job.

RT: That would have been when?

BJ: Nineteen seventy-two.

RT: You did mention your college. Would you repeat that?

BJ: M.I. College.

RT: Where was that located?

BJ: It was located in Holly Springs, Mississippi.

RT: Thank you. Please go ahead, if you will.

You then began with . . .

BJ: I began with the Internal Revenue Service as a data transcriber, which simply meant that you took all the information from the 1040's, 1040A's, and entered it into the computer. I quickly determined that that was not a good fit for me because it was actually a large room that was sectioned off, and you came in at eight o'clock and you did not get up until ten o'clock, when a little bell rang, and then you had to take care of every need that you had between ten and ten fifteen. Then you sat back down and you

worked until lunchtime, and the same thing all during the day. I quickly went home and said, “Dad, I know you said if you stay here, you have to have a job, but this is not the one.”

RT: It wasn't giving you much application of science, was it?

BJ: Right. So shortly after that, I got calls from the Department of Commerce, Department of Education, FDA, and Education. This time when I talked to my dad, he said, “We're going to make a better choice than we made the first time.” So I went on interviews, and by the time I finished the interview with FDA's Consumer Safety Officer Bleu, I had determined that FDA was the place that I wanted to be. He completely sold me on the mission, the people, and the public health benefit.

RT: What was his first name?

BJ: I'm not sure of his first name.

The interview took place at Cleveland. I had taken the summer off and I was determined in September that I would find a job, and FDA called me while I was visiting family in Cleveland. They tracked me down, so the interview was held in Cleveland, Ohio.

RT: I think his name was John.

BJ: I think it may have been John.

RT: Because I was at the Indiana State Board of Health, and Cincinnati district had a resident post in Indianapolis, and they were quartered at the Indiana State Board of Health. I shared a room with the FDA resident, so I knew this gentleman from there.

Where did you report for duty?

BJ: When I left Cleveland, I thought that I was going to Atlanta. That was what I had been told during the interview. When I went home to pack up for my first real career move, FDA called while I was home and said, "Report to Orlando District."

RT: That was a pretty good place, wasn't it?

BJ: Yes. It worked out fine.

RT: Who was the district director then? Do you recall?

BJ: Actually, at that particular time, they didn't have a district director. It was a newly formed office, and it wasn't a district at that time. It was a section.

RT: I recall that now.

BJ: Ernest Lloyd Bush was our head resident in charge of the particular section.

RT: I remember that Doug Tolen later was there. I don't know whether he was the first director.

BJ: No. The first director was Adam Trujillo.

RT: Oh, sure.

BJ: Mr. Bush was there for a very long time, just he and the employees before Adam came on board.

RT: What was your entry level?

BJ: I was a Consumer Safety Officer, GS-5.

RT: That was the usual entry level?

BJ: Right.

RT: Was that an upward step for you from the IRS position?

BJ: Yes. I got to use science, it was a challenging job and a learning experience, which was quite different from IRS, where the job was just simply entering data.

RT: A field investigator gets into a lot of different areas, and I'm sure even your early career, you probably got into quite a few different industries.

BJ: Yes. I conducted inspections and investigations in foods, drugs, cosmetics, clinical investigator, sponsor monitors, narcotic treatment programs, and Current Good Manufacturing Practices.

RT: I assume, as often is the case, you started out in food inspection as a trainee?

BJ: Right. All of the entry-level people always began with the food inspections, and as you progressed and as your supervisor felt that you progressed, you moved into specialty areas. I moved into the specialty areas of bioresearch monitoring and drugs.

RT: Well, again, your science education prepared you for moving that way.

For a time, you probably were accompanied on investigations by older or senior personnel. Is that correct? Or did they just turn you out on your own?

BJ: No. They had a very good training program when I started. In most cases, you attended training, and after that, you kind of learned on your own. Occasionally they may send two CWO's together, but for the most part, we didn't. It was a newly formed section and we didn't have any older investigators. We were all new at the same time. Mr. Bush was the only one who had been with the agency any period of time.

RT: At the time you entered, were there other women involved in the investigational workforce?

BJ: There were a few. In fact, as a part of Project Hire, that was probably the real first influx of female investigators in any large numbers, and even then, the numbers were small.

RT: Did you encounter, at that early juncture, any, oh, I won't say prejudice, but . . .

BJ: There was a little bit of male chauvinism.

RT: That's what I was really asking.

BJ: There was a little bit of male chauvinism, but we quickly overcame that because the women taught the men. I think in the beginning, they felt that we were going to be a burden because we weren't going to be able to lift the fifty pounds. We quickly showed them that we were capable of performing the job, and once we did that, we became a well-oiled team. The guys really wanted to go out with us. In the beginning, there were a few problems, because I think that they thought if you went out as a team, they were going to be the ones that ended up doing all of the heavy lifting.

RT: Sure. We've interviewed some of the pioneer women in the workforce, and they,



of course, experienced probably more of this reluctance of acceptance by men than you may have. But certainly women have proven themselves at all levels of the agency.

BJ: Well, I think we had a different mindset. The women that were there were all kind of strong-willed and we were determined to pull our own share of the load, so we really didn't experience that for very long.

RT: That's good. As you became more experienced, how long were you at the GS-5 level before you had a chance for a promotion?

BJ: If I remember correctly, I was only at that level for about a year, and then I received my 7, and then it was probably another year and I received a 9, and about a year and a half between the 9 and the 11.

RT: Did you make that progression all at the Orlando?

BJ: Right.

RT: As you progressed grade-wise and responsibility-wise, do you recall any particular regulatory issues or problems that you dealt with which might be mentioned here that you were involved with, in terms of regulatory activities at the field office?

BJ: Well, I can remember a couple of things kind of distinctly, but they go back to the

foods area. In fact, they both involved seizures. One was a mass seizure of a warehouse, and the other one was of orange juice.

RT: Orange juice.

BJ: It was orange juice, yes.

RT: Was that product adulteration?

BJ: Yes, the firm was saying that it was produced from concentrate, but they were adding things other than the concentrate.

RT: Did the warehouse have a rodent-infestation problem?

BJ: No. This one was the seizure of the product simply because they were adding ingredients. They were adding sugar and other ingredients to the product, and they were claiming that it was being reconstituted from concentrate.

RT: Right. That was the orange juice, but the warehouse, were there any rodent problems with it?

BJ: The warehouse, yes. It was rodent infested and had termites. In fact, I had gone out with James Casey. who is a now-deceased FDA supervisor.

RT: Yes. I remember him.

BJ: We were walking around the warehouse. I'll never forget this, Jim and I were upstairs, and the floor gave way, and I went through the floor. Jim caught me and pulled me back up through a hole in the floor. The termites had eaten away the underside of the floor.

RT: Those kind of experiences are something you don't get in the written history, but come out in the oral history of the agency.

Yes, Jim Casey was later chief inspector, as I recall.

BJ: He held a high position in the Atlanta district office. He was the executive operations officer for Atlanta District.

RT: Yes, that's correct. In the situation of the warehouse, was there an injunction there?

BJ: We got a mass seizure and the U.S. marshals boarded, posted signs, and shut down the whole warehouse.

RT: Did that facility later shape up and resume operations?

BJ: They eventually went out of business.

RT: In Orlando, those are two situations you recall.

Are there others as you progressed on? Because you were getting into some broader fields of experience now. How about these other areas like, some you had mentioned?

BJ: Bioresearch monitoring, yes. At that time, there were a lot of clinical trials being performed, and we had a lot of devices for which the manufacturers were making claims to cure diseases, so we seized some of those devices. We don't tend to do that quite as much anymore because it's resource intensive, but we would actually go to doctors' offices and collect the device that they were using at that particular time.

RT: Was that coincidental with the development of the device organization in headquarters after the device amendments had been enacted?

BJ: Yes.

RT: So that was a period of quite a lot of explorative surveillance of the industry.

BJ: Right. I also made undercover buys in the area of veterinary drugs in rural Florida. There were pharmacies selling prescription veterinary drugs over the counter without prescriptions.

RT: Was there a practice of selling those for human application?

BJ: In some instances, we suspected that they might be because sometimes the drug was penicillin.

RT: I just wondered if, as an investigator, you would ask the store or the pharmacist for something for a human condition which was really a veterinary preparation.

BJ: Most of the time, we went in and stated that we had a farm and we had a cow or other farm animal that was sick and wanted something to treat the animal. We described an indication, and they would give us the drugs without a prescription.

RT: So you'd close out after, what, two or three buys of? How many did you usually need before you closed them out?

BJ: Well, we would go in as teams. One group would visit and buy drugs, then another team would visit and buy drugs to establish a pattern that they were routinely selling drugs without a prescription and that this was not just an isolated incident.

RT: Okay. Now, as far as clinical investigators, that would be investigations of human drugs. Is that correct?

BJ: Right.

RT: What kind of activity did you get involved with, or what kind of practices did you investigate in that area?

BJ: Okay. In the clinical investigator area, we would visit the investigators and check data by reviewing records and verifying that they performed the assigned studies, that they had a sponsor monitor, and that these were well-conducted studies. They are using that data to submit to FDA for either their pivotal study or for the approval of a new drug.

RT: When you got into that work, that is a more sophisticated level of investigation.

BJ: Yes, it is.

RT: What grade level had you attained when you got into those activities?

BJ: I was a GS-9 and 11 when I started doing more specialized work in drugs.

RT: That usually is something more experienced people are responsible for.

BJ: By that time I had gone to basic drug school in Rhode Island and spent a month there, and I had a good understanding of how drugs should be manufactured and the Current Good Manufacturing Practices.

RT: In Orlando's jurisdiction, did you have any human drug or pharmaceutical manufacturing firms that you recall?

BJ: There were very few. We had more device manufacturers, veterinary drug manufacturers, a lot of food manufacturers and food warehouses, and drug re-packers.

RT: You were checking them on the accuracy of labeling and good quality-control practice.

BJ: And the conditions under which they were holding the drugs.

RT: I believe you mentioned that you also got into surveillance of narcotic treatment programs.

BJ: Right.

RT: What was the nature of your work in that field?

BJ: At that particular time, the narcotic treatment programs were still under FDA's jurisdiction, and that was more of a records review. You would actually visit the programs, examine their records and make sure that they were complying with the regulations set for the 295.505, which is narcotic treatment regulations. That was an area

that we regulated with DEA [Drug Enforcement Agency] and the state methadone authorities.

RT: Was that during the time in FDA when the Bureau of Narcotics, pardon me, the Bureau of Dangerous Drugs Control (BDAC) was in operation here? Of course, BDAC later went to DEA.

BJ: Right. I'm pretty sure that initially it was, and then FDA started interacting directly with DEA because narcotic treatment programs have to register with the DEA and the state, and then they send in this information to FDA, and we give them an approval.

RT: The Office of Criminal Investigations was a later development, wasn't it?

BJ: Right.

RT: So you were doing that work with more or less general training, not specialized for that activity?

BJ: Right.

RT: You also served in that office as a consumer complaint coordinator. Did anything of particular interest occur, which happened in that activity?



BJ: Well, probably the most interesting thing about the consumer complaint program was that establishments also used it to report what their competitors were doing. FDA became aware of a lot of activities that were in violation of the law because competitors would call in and inform us through the consumer complaint coordination function that their competitor is doing this or that and it would alert FDA of the activities.

RT: It was a good outreach, certainly. It was beyond probably the agency's ability to discover in many cases.

Then you were the recall and emergency coordinator, which is an important role. What extra effort or specific experiences did you have in that area?

BJ: Those are almost too numerous to even remember, because at the CSO level in a district office, you are dealing with every kind of recall that the centers eventually hear about. You hear about the foods, drugs, human and veterinary drugs. They are all received by the recall coordinator. It's almost overwhelming, and it's a full-time job, because you have to interact with each Center on their particular recall, and every Center handles it differently.

RT: Of course, in ORA or EDRO, as it was earlier, we had an emergency operations group. I think Dick Swanson was the head of it for a time. Did you channel through ORA's headquarters office some of this information, or did you deal more directly with the Centers?

BJ: Well, we had to deal with EDRO also, but the one incident that I remember most vividly is the botulism case. I did not get a chance to stay on the recall desk with that. I was a consumer safety officer and everybody was on the road, out in the field, traveling, going to every place that the product had been received, removing it from the shelves, and making sure that it had been removed from the shelves.

RT: For our record here, the botulism incident related to what product or what category of products?

BJ: I want to say it was a soup.

RT: That wouldn't have been Bon Vivant's vichyssoise soup.

BJ: I think it -- yes, that's the one.

RT: That was the major one.

BJ: Yes, that was the one. It was a soup.

RT: It certainly required a lot of field activities.

BJ: We were literally living in the cars because every person in the district was in a

car, and you had a list and everybody was filtering either north or south, hitting every facility that had received the product.

RT: That may have varied with districts. Some of the Western districts earlier in our history used to require a lot of road time, if you will, in the field. Orlando being a smaller area, perhaps that wasn't as great a concern.

BJ: No. We spent about two weeks out and two weeks in, and on an average, you could travel up to three weeks out of a month. Every Monday morning, at least ten people would leave, going to Miami, maybe two or three to Tampa, one to Tallahassee, one to Jacksonville, sometimes two.

RT: Now, regarding Orlando, was the jurisdiction entirely in the state of Florida?

BJ: Right.

RT: So you didn't have to go into other parts of the region.

BJ: Right.

#### TAPE 1, SIDE B

RT: I believe, in Orlando, you also served as Acting Supervisor/Consumer Officer and

Acting Head Resident in charge of a resident post. Now, where was that resident post located?

BJ: I acted as head of resident posts in a couple of places: Miami, Jacksonville, and Lexington, Kentucky.

RT: Now, those particular posts, were they relatively small in staff? How many investigators would you have had to manage in those particular posts?

BJ: Miami wasn't relatively small. In fact, Miami had a group of full-time people that were assigned there. I'm trying to recall, because by the later years it was quite large. But initially, I would say it was probably maybe about five people. You had an import section there in Miami, which was very busy, and then you had CSO's assigned to the Miami area. That's why they would send ten people down sometimes at one time going to Miami.

RT: What would have been the highest grade level at the resident post operationally?

BJ: Probably a supervisory CSO.

RT: At what grade level? Nine or higher?

BJ: No. They would have been at least a 12 or a 13.

RT: My question was somewhat a leading one in that I was going to ask you, when you were assigned to those details or assignments, what would have been your grade level then?

BJ: I would have been a 9 or an 11, and usually when you got assigned to those, the actual supervisory CSO might have been on a detail or on leave, and you were there to fill in for them during that period of time.

RT: So, in a way it was . . .

BJ: It was an acting assignment.

RT: Was it a management training opportunity for you.

BJ: Right.

RT: I think we've discussed a number of things you were involved with in Orlando. You later got a transfer to the Bureau of Biologics. How did that come about? Was it one you sought? What were the circumstances of your moving there? I assume it was a promotion opportunity?

BJ: Well, it was something that I sought, and it was basically after talking to my

supervisor and their saying, “You know, you’ve got greater potential than here.” In the earlier years, they did not give you promotions at the same place above a certain grade. You usually had to move to get additional promotions.

RT: That’s true.

BJ: And so, after talking with my supervisor, I said, you know, maybe it’s time to move. If I have the potential to do more than what I’m doing here, perhaps I should start thinking about going to headquarters or to some other place.

RT: That was a good manager who had the staff’s interest at heart.

When did you make that move, Betty?

BJ: I think I made it in October of 1978.

RT: You then came into the Bureau of Biologics.

BJ: The Division of Biologic Evaluation.

RT: Who was head of the biologics operation? Was it Dr. Henry Myers?

BJ: No. At that time it was Dr. Sam Gibson who was the head of it, and Madge Crouch was the deputy.

RT: Did you say Madge Crout?

BJ: Crouch.

RT: Okay. Not the same name as Richard Crout, who also was at headquarters.

BJ: No.

RT: As you moved into that area, it was a new level of experience for you. How did you get going there? Did you have enough background experience so you could move along easily, or did you have any special guidance, counseling, or training?

BJ: Well, by that time I had moved into the bioresearch area, so I was quite familiar with that area because I did a lot of the work in it. Being one of the more experienced CSO's, I was doing a lot of work with clinical investigators and sponsor monitors. Essentially the only area I hadn't been in at that time was the Institutional Review Boards, so it was a very easy transition to move into their bioresearch monitoring group.

RT: I seem to recall early on the bonding between that bureau and FDA's enforcement units was sometimes not smooth in the way enforcement or regulatory process decisions would proceed. Was that resolved by the time you came there? In other words, as I recall -- and correct me if you recall differently -- there was sort of an FDA regulatory

tough-minded approach, whereas I think in the Biologics group there may have been more of a let's educate and get cooperation.

BJ: Right. I think Biologics probably wasn't as much in tune with the rest of the agency in how they handled things. I think it was partly because, at Biologics, there was this feeling that they did have an additional hammer and they didn't have to be nearly as enforcement conscious as science conscious.

RT: What was the additional tool or hammer?

BJ: The licensing of biologics products.

RT: I don't want to get too far afield from what you were doing; however, the Bureau of Biologics had persons who worked from headquarters. Did they have also field bureau people or was it all operated out of headquarters as far as the field activities were concerned?

BJ: Most of the things were operated out of headquarters.

RT: So they would have to travel substantially.

BJ: Right. We made most of the determinations from headquarters. In fact, the Bioresearch Monitoring Program for a very long time retained headquarters approval,



whereas a lot of the other programs delegated authority to the field and the field made the calls and just submitted them. But in most instances, in bioresearch monitoring, the reports were done in the field, but they were sent to headquarters for classifications and determinations of the appropriate course of action.

RT: So, the licensure of any operation was contingent on an acceptable investigation and assurance of competency or adherence to the applicable rules and regulations.

BJ: Yes.

RT: Were there any requirements comparable, in principle at least, to good manufacturing processes or procedures?

BJ: Right.

RT: But was there something of that nature?

BJ: Well, they had good clinical practices, but they didn't call them that at that particular time. Those determinations were made by the people in the headquarters unit.

RT: So the persons who did the evaluations of the reports were you and your associates in their particular part of the operation.

BJ: Yes.

RT: Some of those reports were quite complex, weren't they?

BJ: Yes.

RT: Did that evaluation require quite a bit of time? As you know, the clearance of new drugs sometimes requires a very prolonged, protracted process. Was biologics review and licensure a more expeditious kind of review, or was it also very time-consuming?

BJ: I think that it probably was just by virtue of the fact that Biologics was smaller than Drugs. If you worked in that area, you essentially worked with the other units, and there was probably a more cohesive relationship, and you talked about things. For the most part, we were located close together, so there wasn't a problem, because my office was right next door to licensing. If I had any questions, I could just walk out of the office and walk next door and talk to somebody.

RT: That was a good arrangement.

The universe of biologics manufacturers, processors, or distributors, whatever, was that a relatively large inventory nationally? I'm sure it was a smaller one than drugs.

BJ: It's a relatively small number, especially if you compare it with drugs.

RT: Did it tend to be geographically centered, or was it across the nation, biologics, that is?

BJ: I think it's across the nation, but it's almost like drugs. You'll have little pockets where manufacturers tend to set up, and then you'll have other parts where there are almost none.

RT: In drugs, for example, there's quite a lot of activity in Puerto Rico, as I recall.

BJ: Yes.

RT: Is there a similar higher population of biologics firms down there? I guess the pharmaceutical manufacturers have their own rationale for being there.

BJ: Not unless they're companies that are doing both. For the most part, drug manufacturers tend to like Puerto Rico, New Jersey, New York, and the northeast.

RT: There are firms that are in both drugs and biologics. With regard to the oversight of the investigational responsibilities, has there ever been any problem with drug people and biologics people investigating the same place? Do they do their thing separately or together and do they get along, or have there been some problems there?

BJ: Well, I wouldn't say that they did it together. Usually, if you had a specialty in drugs, you probably weren't also a specialist in biologics, so it would probably end up being another person.

RT: And the industry doesn't have a problem with that?

There's been sometimes a feeling on the part of some in industry that the FDA comes in and the state comes in and somebody else comes in, and maybe another federal agency comes in . . .

BJ: Of course they have problems with that.

RT: Each doing their own little thing.

BJ: Of course they have problems with that. They felt we were in there too much, especially if they manufactured both product categories and it wasn't covered all at one time with, by one investigator. They often felt they were being targeted.

RT: In the Biologics Division or Bureau, you also got into matters, I believe, of the regulatory process, preparing for court cases and whatever. Were there any kinds of cases that come to mind which may be worthy of mention here, or any results of such court actions which may have been taken?

BJ: I'm sure there were some, but I don't remember the particulars quite as much as I

do the drug cases. But I'm sure that there were some instances of falsification of data or data integrity.

RT: The documentation for biologics approval, was that less onerous on the industry than drug approval?

BJ: I would say yes.

RT: Not as much?

BJ: Right.

RT: Tremendous volumes of records being submitted and so on.  
I think you then did get into the Bureau of Drugs.

BJ: Right.

RT: When you were at Biologics, what level were you grade-wise? Had you stepped up from 11?

BJ: I think I was a GS-12 at that time.

RT: Did you get a promotion by going to the Center for Drugs?

BJ: Yes.

RT: What led to your decision for that move?

BJ: Well, a couple of things led to my decision.

Actually, I got a promotion when I went from Biologics to Drugs, but shortly after that, the two merged. I remember when it became Drugs and Biologics. I was working with some of the same people that I had left. But then, at a point in time -- I don't remember what year it was -- they split, and you got an opportunity to choose. I could have gone back to Biologics with the promotion, but I chose to stay at Drugs. I went to the Center for Drugs, and other people went back to the Center for Biologics.

RT: Who was in charge of Drugs at that time? Do you recall? Was that Dr. Richard Crout?

BJ: Yes, it should have been Dr. Crout.

I stayed with Drugs and I went to the Division of Scientific Investigations (DSI).

RT: The primary work that you did there was of what nature? Scientific investigation, of course, is a descriptor, but what more specifically?

BJ: It was, again, bioresearch monitoring because it was clinical investigators,

sponsor monitors, IRB's, Institutional Review Boards, narcotic treatment programs, adverse drug reactions, and regulatory case management.

RT: Was there more regulatory case management work in the drugs than there had been in biologics?

BJ: Yes, far more.

RT: Now, Betty, while you were in the Bureau of Drugs, Scientific Investigations, you again had opportunities for initiatives. I believe you might have developed some regarding investigations and so on. Would you care to elaborate a little bit on that work?

BJ: Well, when I went to the Center for Drugs and DSI, it became a little bit more specialized, because I actually got into case management, which meant that all of the cases regarding clinical investigators, IND's [Investigational New Drugs] sponsor submissions, Institutional Review Boards, non-clinical testing, were filtered into DSI. I was in the Regulatory Management Branch at that time. All of those cases were filtered in for us to review, evaluate, and determine if the regulations or the statute had been violated, and the appropriate courses of action, which could range from consent agreements to prosecutions. I also got a little bit out of the realm of the Food and Drug, FD&C Act because I handled Title 18, which was falsification.

RT: Falsification of data?

BJ: Of documents, data, records.

RT: That's Title 18 of the . . .

BJ: USC [United States Code].

RT: Do you recall at this point, Betty, any particular cases that came to fruition through the courts and resulted in principal penalties? There are probably lots of them.

BJ: Yes. There are lots of cases. I can think of one. It was Dr. Kostas, and that was a strictly Title 18 case because he claimed that he conducted a study and he had falsified the data. We investigated and found out that, in essence, some of the patients didn't even exist. We went to the Department of Justice and went forth with a case under Title 18.

RT: What kind of preparation was involved there?

BJ: We had to write up the complaint and actually sell the assistant U.S. attorney and present the facts in a manner that interested him in pursuing the case.

RT: To my use of the term preparation, you responded very appropriately/ I really should have asked maybe, what kind of a product was involved, or therapy?



BJ: Now, that does escape me, what the actual product was.

RT: That's okay. I just wanted to put it in the record.

BJ: The main thing to us was that he made the submission to us and it was false. The integrity of the data had been compromised and Dr. Kostas was promoting a study to FDA upon false data.

RT: Now, as far as firms are concerned, there have been a lot of cases -- and I hesitate to name them because they may be out of context with your time there -- but, you know, like generics and other kinds of violations of that nature. Do any of those come to mind?

BJ: Well, the generics scandal was going on around the same time, but I don't have any personal knowledge of that. I mean, it's more about what I read and not any firsthand knowledge about it.

RT: Sure. That's okay.

BJ: At that time we were also doing adverse drug reporting, and that kind of relates to the same thing because when drug companies find out that there are significant events that relate to the drug, they're supposed to notify us of that.

RT: Wasn't there an adverse drug reporting program set up?

BJ: Yes.

RT: Was that an operation that you were personally involved in?

BJ: Yes. In fact, I wrote one of the first programs that monitored ADE's [adverse drug experiences], and I also managed one of the first convictions of a foreign-based company and an individual for violation of the Food, Drug and Cosmetic Act. The firm was fined \$200,000 and the individual was fined \$2,000. That was the maximum fees that could be imposed in both instances, and was the first of its kind. It was brought because the firm failed to report adverse drug reactions.

RT: What was that firm name? Do you recall?

BJ: That was Hoechst AG, H-o-e-c-h-s-t, and then A-G. I think it's German.

RT: The adverse drug reporting program continues to exist to this day, does it not?

BJ: Right.

RT: Generally speaking, does the agency have a good level of confidence regarding cooperation with that program from physicians and hospitals?

BJ: I think for the most part, yes.

RT: How about industry? Are they generally responsible?

BJ: In most cases. We have a few instances where we've had some problems.

RT: Currently we're hearing quite a bit about failures of the agency and/or pharmaceutical firms from one of the whistleblowers of the day. We've had whistleblowers in drug regulatory operations in previous times. Dr. John Nestor was one that I recall.

And now there's a gentleman, Dr. [David] Graham, who is speaking out adversely regarding some of the procedures. What is the general perception of these allegations coming from within? Do you believe this is a genuine problem -- and I'm not trying to get you to make a judgment here. Let me rattle on a minute. I wonder, is this a person who really believes there's failures, or is he possibly a person who's in some manner unhappy personally and taking the pulpit, so to speak?

BJ: I think Dr. Graham believes what he's saying, but I don't know that it's a completely balanced perspective.

RT: Well, sometimes it isn't.

BJ: But I do believe that he believes what he's saying.

RT: That's interesting. I'm not trying to put you on the spot, but there's a lot of things in the press, you know, and I suppose we'll have congressional oversight interest too, as we've had in the past, when circumstances of this nature arise.

You've had some experience being a presenter of testimony before the Congress. It seems to me I recall that you presented some testimony. Was it before Congressman [Charles] Rangel?

BJ: Yes. I've, actually had the pleasure, I guess, of doing this twice, once with Charles Rangel . . .

TAPE 2, SIDE A

RT: Betty, you were starting to speak of your experience as a presenter of testimony at congressional oversight, and you mentioned Congressman Charles . . .

BJ: Rangel.

RT: What was the issue involved in that hearing?

BJ: Well, at that particular time, there was an issue about narcotic treatment programs and their value to his constituents. Congressman Rangel didn't really like the idea that there was a treatment program across the street from his office in New York, and he

wanted to find out more information about it. He called FDA and DEA to New York for a hearing. I think Dr. [Stuart] Nightengale also attended.

RT: So the hearing was held right in New York City?

BJ: Right.

RT: What committee is he chairperson of? Do you recall? That's in the House, isn't it?

BJ: Yes, it is in the House. I'm not sure what committee.

RT: We can perhaps add that later.

BJ: But primarily he wanted to talk about the use of methadone in New York and inspections of narcotic treatment programs by the agency.

RT: Would you say that was an adversarial type hearing?

BJ: Very.

RT: You got grilled a bit, I suppose. Were there -- well, Dr. Nightingale was with you.

BJ: Well, DEA was also present with FDA. Congressman Rangel wasn't very happy with, I guess, the idea of narcotic treatment programs in general and their value. What I remember him saying to us was more like you're substituting one drug for another drug.

RT: Methadone in particular, I suppose, rather than really taking the clients or the participants off everything, which is probably a big, and maybe very difficult step.

BJ: Right.

RT: Okay.

BJ: The second time that I had the opportunity to testify was before the Subcommittee of the Committee on Government Operations of the House of Representatives, and that was in May of 1987, and that one was chaired by Congressman Ted Weiss.

RT: Oh, yes. Of New York again?

BJ: I don't know if he's New York, though.

RT: I believe he may be, but that's irrelevant.

BJ: That was regarding the drug Suprol, S-u-p-r-o-l (generic name suprofen).

RT: What would be the primary application of that drug?

BJ: Suprol was approved for relief of mild to moderate pain and the treatment of dysmenorrhea.

RT: Was it a narcotic?

BJ: No. It's not a narcotic. The real issue with Suprol was adverse drug reactions. Prior to the approval of the drug, there were very few reports of adverse effects associated with the drug, and then after the drug was marketed, FDA received numerous reports of adverse drug reactions.

RT: I see.

BJ: So it was post-marketing reports of problems with the drug.

RT: That identifies the focal point of the congressman's interest.

Now, when you appeared there, did general counsel have a representative with you, or were you representing the agency alone?

BJ: No. I think it was Dr. Bob Temple, Dan Michaels, and myself.

RT: You were the principal presenter with Dr. Nightingale.

BJ: Yes.

RT: You were the point person?

BJ: Dr. Nightingale was with us, and he was heading up most of the activities in the area of narcotic treatment programs from the Commissioner's level.

RT: We mentioned a few moments ago some of the publicity that is occurring now about some products where there's concern there hasn't been good safety data. I have a list of some of them here.

Currently there's quite a bit of press coverage, at least, about so-called risky-drug clearances as related to Vioxx.

BJ: Right.

RT: By Merck. And Celebrex and Bextra and Crestor are others that seem to be getting attention, maybe Botox as well. Is there anything the agency can do to blunt some of those criticisms? Are we satisfied that as far as agency oversight is concerned, we've done as well as is possible?

BJ: Well, I think we have the greatest system in the world. We are the gold standard.



However, we can always do better, and probably we would be able to avoid some of the criticism if we were more transparent in how we go about doing our work, and maybe getting the advisory committees a little bit more engaged along the way.

RT: I think you have struck the right note there, because no doubt many of the consuming public don't really understand the process or complexities involved in reviewing and approving these products. The adverse reporting, adverse reaction reporting system may not be generally known as an agency activity.

BJ: Right.

RT: Possibly more initiatives to communicate that fact to consumers is needed, maybe through our consumer specialists, although they only reach a limited clientele, of course. We're seemingly on the defensive right now, and that's why I raised the question.

BJ: But I think that if we were more transparent and probably if there were some way to simplify some of the things that we do, because I'm sure, to the industry and to consumers, it probably seems that the activities and operations that we're involved in are very complex.

RT: Well, of course, a lot of folks either don't know or don't recall when our system prevented Krebiozen -- not Krebiozen -- but thalidomide is the product I was thinking of, from being marketed. It was in general use, I guess, in England and Europe, and,

fortunately, our system had committed people, like Dr. Frances O. Kelsey and others, who stopped it from being marketed here before a tremendous tragedy occurred.

BJ: I think that they do not realize that in the pre-clinical and clinical stages, not everything shows up because it's not being tested in all populations. And sometimes, the reason that comes to mind is Suprol, the drug I was talking about earlier, was originally tested in healthy young individuals. I want to say that the indication that caused problems was as a painkiller.

RT: Well, it seems some of these products we've just mentioned fall in this category. Now, of course, the press and others are taking the agency to task because they didn't anticipate the problems, and taking the industry to task for not having done better pre-approval studies.

BJ: And then you'll find that when you move to distributing the drug when it's available to all the consumers, that you may find out in certain populations there are new reactions associated with its use.

RT: Which really can't be anticipated until there's a general marketing and use of the product.

BJ: Right.

RT: Another issue that seems to be eliciting a lot of interest and support is why drugs that are exported to Canada can then be obtained back from there at lower cost. The agency takes the logical position that we can't assure the authenticity and safety and efficacy of all imported drugs that may come in. It seems to be a continuing issue. Do you have any sense of how that might work out?

BJ: Well, I can understand consumers wanting to pay less for prescription drugs, but there are some inherent risks because you could be buying counterfeits and there's no way that the average American would know that it's counterfeit. The counterfeiters are very good at what they do and the products they make look almost identical to the real products, and you may purchase something and not have the drug that you were trying to buy.

The real problem is that we don't have the resources to really look at the number of imports that come into the United States. The numbers are increasing in leaps and bounds, and we look at less than 5 percent of what's coming into the U.S. It can have terrible consequences if you need diabetes medicine or if you need heart medicine, and you purchase a drug and it's not the drug it's supposed to be.

In other cases, the downside of it is that some drugs that don't claim they're a drug have actual drug ingredients in them. If you're reading the label and thinking that you're being safe, take it and it interacts with another drug you're taking, it could be life-threatening.

RT: Certainly the agency is responsible in trying to hold the position that our system

shouldn't be circumvented, and not all the public seems to understand.

BJ: No. I guess one of the things that brings this to mind is a dietary supplement type product which tells you, take this and you can stop taking your diabetes medicines, and it turns out that it actually has drug ingredients in it. The labeling, in some instances, indicates that you could take it along with your medication, and people then are having problems with their blood sugar dropping too low.

RT: Well, you've worked for some time in the agency, and under a number of different administrators both in the field and at headquarters. Do you have any recollections about any particular Commissioners, District Directors, or supervisors who impressed you as being very good for the agency or for the program you were in, more than others?

BJ: Yes.

RT: Do you care to comment in connection with any of them?

BJ: Well, the first supervisor that I mentioned, Ernest Lord Bush, was just exemplary in leadership, and he's exactly the type of individual that motivated and shaped people and could understand potential and employee needs. He did a wonderful job, because when he was first there, he had roughly thirty-five to forty people. It was just him, and you're talking to youngsters that were right out of college. He not only was a

consummate professional, he was a person that made you aspire to be better yourself.

RT: That's very good. There are a number of individuals like that in our agency, which I think is why people who come into the agency have such a commitment, an esprit de corps, or whatever you want to say.

BJ: I saw it again when I went to work for Dr. Sam Gibson, same type of thing, leading by example, the type of person that you admire both professionally and personally.

Again with Ross Laderman, who has now left the agency and now works for Biostrom in either North or South Carolina.

RT: At the top level, we've had different Commissioners, more changes in Commissioners since Dr. Goddard, beginning with Dr. Goddard, than we'd ever had before. It used to be that the Commissioner had quite a long tenure and tended to be somebody who had worked up through the ranks. You could argue it could be either way, I guess. Some of those people might have a deeper commitment to the agency than those who are more transitory in tenure.

Changing philosophies or changing management styles, has that, in your view, advanced the agency or had other effects? We've changed from the strictly "gotcha" regulatory style to cooperation and voluntary compliance.

BJ: Well, I'd have to say some of that started in the field, and I don't think that really

comes from the Commissioner's level. I saw some of that changing back with Paul Hile, but maybe not to the point that it is now. That's another person that I admire because I feel like he led by example.

I saw some of the adversarial things starting to change back with Mr. Hile. But there was a cohesiveness, when he was here, between the Centers and ORA that I don't think has been there since he left. I really think that we were a little better as an organization when Paul was here, because we all worked together better, and one Center or group didn't get out ahead of the other, and we were more uniform in what we did.

RT: Do you think that the policy board concept was a helpful element in that?

BJ: The Policy Council, yes, because it has not been the same since Paul left.

RT: That prompts me to recall, along your career track, the opportunity you had for management skills development. I believe at one time it was called the Executive Development Program. Wasn't that something where were assigned to headquarters and then to various parts of the agency for career development?

BJ: Yes.

RT: Not with a guarantee of a job promotion, but it usually gave opportunity for subsequent career advancement.

BJ: Yes. In May of 1985, I was selected. At that particular time it was called the FDA Mid-Level Program, and then they changed the name to the FDA Executive Development Program.

RT: Was that a positive experience for you?

BJ: That was a very positive experience for me. In fact, I think that was when I really found out that I enjoyed working with and for people, and through people. I don't think until that point I had any real aspirations to be a supervisor. And, again, it was a supervisor that sat me down and said, "Okay, it's time. You have potential that I see that's being wasted sitting here doing reviews and evaluations. You should apply for this program."

RT: That was good. Currently you're the Deputy Director of the Office of Compliance in CDER. Do you feel your executive training helped you to acquire that post?

BJ: Yes, I do.

RT: Prior to your current appointment, you had been in the Center for Drugs.

BJ: Right.

RT: How did it come about that you had the opportunity to become Deputy Director in Compliance? Was that . . .

BJ: Okay. I was selected for the program, which is a year-long program where you are detailed throughout the agency and even outside of the agency to different places. Inside I had the opportunity to work directly with Paul Hile. I worked with Merv Shumate; Jake Barkdoll; Caesar Roy, who was a Regional Director of New York; Lloyd Claiborne, the Regional Director, I believe, in Chicago at that time. I did details throughout FDA and outside of FDA.

RT: That certainly gave you an enlightened and broadened sense of the organization, of the agency.

BJ: Upon completion of the FDA Mid-Level Program, the position for Chief of the Regulatory Management Branch was announced. I applied for it and I was selected for that position. I stayed there a number of years, where I did bioresearch monitoring, narcotic treatment program, adverse drug reactions, and at that time Ross Laderman was the Deputy Director. Ross decided to take a job on the outside; he counseled that, "It's time for you to move on. You need to start applying for other things."

RT: In your deputy role, were there any unusual or noteworthy experiences you'd like to mention?



BJ: Oh, they have just been so numerous that I honestly don't know where I would begin.

RT: I know you've gotten a number of awards along the way. But I just wanted to know if there was anything in your more recent career that . . .

BJ: Well, yes. I can talk about the fact that in '93 or somewhere along there, GPRA [Government Performance Results Act], was created by Clinton and Gore. Because I've always been kind of performance-based in how I go about doing things, performance-based and results oriented, I was asked to head up a task force to put together our first performance-based plan for submission to Congress. That was quite challenging. I was assigned to that for probably about nine months.

RT: I see.

BJ: Other things of note.

I was part of FDA's Y2K rapid-response team and CDER's Y2K task force, and it was to meet the computer IT needs for 2000, and as a result of that, I got recognition from John Koskinen, who was the chairman of the President's Council on Year 2000 Conversion, and I received a letter of commendation and a cash award from Dr. Jane Henney for participation in that endeavor.

RT: Very good.

BJ: I also received an award for being innovative. This was when I was heading up the narcotic treatment programs. I initiated the first consent agreement that required a narcotic treatment program sponsor to use third-party experts to certify program compliance and established an escrow amount of \$100,000, which directed funds to be paid to FDA to cover inspectional costs for noncompliance.

RT: Interesting. You've been busy.

Have we covered most of what you've accomplished? We've hit a lot of highlights. Is there anything else you'd like to add as we near the end of the interview?

BJ: Yes. My time at FDA has been wonderful. I think I made the right choice thirty-three years ago. I loved it then and I still love it today.

RT: I might ask, since you've mentioned several times that someone else has said, or you realized, it was time to move on.

#### TAPE 2, SIDE B

RT: You have now decided to move on -- you're going on to retirement. Do you have in mind continuing a professional life, or are you going to enjoy your freedom from it for a while?

BJ: I'm just going to enjoy myself for a while. I think FDA is in good hands. It doesn't mean that I won't do anything, but I think it'll be just like back when I started. It's finding the right thing to put my efforts in. I think I still have my best work ahead of me to be done, so it's just finding the right thing to put all of that energy toward.

RT: Well, that's a good way to leave the agency, certainly a right spirit. I wish you, as an interviewer for the History Office, happiness and success in your retirement. And thank you very much for this interview.

BJ: Thank you.

END OF INTERVIEW