

History
of the
U.S. Food and Drug Administration

Interviewee: Willie R. Bryant, Jr.

Interviewer: Ronald T. Ottes
Robert A. Tucker

Date: June 16, 2005

Place: Rockville, MD

Interview with Willie R. Bryant

June 16, 2005

TAPE 1, SIDE A

RT: This is another in the series of FDA oral history interviews. Today, June 16, 2005, we're interviewing Mr. Willie R. Bryant, Jr., former Senior Recall Officer, Office of Regulatory Affairs, Office of Enforcement, Division of Compliance, Management and Operations. The interview is being conducted by Ronald Ottes and Robert Tucker at the Parklawn Building in Rockville, Md.

Willie, we would like to begin with a brief review of your personal history, where you were born, educated, any employment you may have had prior to joining FDA, particularly any which is pertinent to your career in the agency, and then explore in some depth your experiences and work achievements in FDA.

WB: I was born in Portsmouth, Virginia, May 31, 1941, attended public schools there in Portsmouth, graduating from Woodrow Wilson High School.

I attended Frederick Military Academy for two years, my freshman and sophomore years of college. Then, the military academy expanded into a four-year coeducational school, at that time it was known as Frederick College, also located in

Portsmouth, VA. So I transferred to Frederick College in the junior class, and I was the valedictorian of the first graduating class of Frederick College in Portsmouth, Virginia, in June 1963.

In March 1963, we had a career day at Frederick College, and FDA's Norfolk resident inspector came out to the college to interview and recruit people for the Food and Drug Administration.

RT: Do you remember the resident's name?

WB: I don't remember, but I do know that I had never heard of FDA. I had no clue what it was about until this young man explained FDA responsibilities and operations to me and several of my friends.

He explained what FDA did, and it sounded very interesting to me. I liked the idea of being an inspector since I was getting a biology degree with a minor in general science. I had taken a lot of the courses required to be an FDA inspector. They called them inspectors in those days, not investigators as they are called today.

We had to take the FSEE [Federal Service Entrance Examination] in those days. I took and passed it. In April, I was contacted by Baltimore District Office personnel and offered a job, which I accepted. Two weeks after I graduated from school, I went to Baltimore and was sworn in as an FDA inspector by the then District Director,

George Sooy.

RT: What was your entrance grade level?

WB: As a GS-5, at a salary of \$4,565 a year, I remember very well. At that time, there were also about thirteen others who came into Baltimore as new inspectors, so we had a glut of new inspectors and the District didn't have enough senior personnel to train these new employees. Management decided to farm us out to the resident posts. One new inspector was sent to each resident post in the Baltimore District (Raleigh, Charleston, Roanoke, Norfolk, and Richmond) for basic training. I was assigned to the Norfolk resident post for ninety days.

RO: Didn't they also have a Washington, D.C. resident post?

WB: Washington, D.C., of course, yes. Bill Wobbleton was there in the Washington, D.C. resident post for a while, and so was Bob Rice.

The training in Norfolk included warehouses, a lot of pesticide usage work at farms, as well as sample collections, peanut shelling firms, and other small food firms of that nature.

RO: You mentioned that George Sooy was the District Director.

WB: Yes.

RO: Who was the chief inspector?

WB: Gordon Thompson, and Tom Kingsley was the chief supervisory inspector. Then, ultimately, Gordy Thompson became the Director of Compliance when Pat Ryan moved on to the headquarters Field Compliance Branch. Tom Kingsley then became the chief inspector.

RO: Where was the Baltimore District office located? Was it in the Appraisers Stores Building on Lombard Street?

WB: Yes, downtown. It was an interesting location. I remember so well, there were a lot of bums that were down there, and I remember coming back from an inspection out in Winchester, Virginia, where we had inspected an apple storage warehouse. The warehouse manager had given me this big, huge apple. It was the size of a grapefruit, a big red delicious apple, and I was going to bring it back and take it to my wife. As I was leaving the office in the afternoon heading out to my car, I passed one of these bums, and he said, "I'm going to get that G-D apple!" I thought, "Not on your life." So I walked a little faster and he walked a little faster. I took off at a jog to get away from this guy because I was saving that apple and taking it home.

One day one of the bums tried to sell me his belt. He wanted enough money to buy some little bottles of liquor, miniature bottles, I guess.

Within a couple of years after I started work at the Appraisers Stores Building, the Baltimore FDA Office moved

to 900 Madison Avenue.

RT: Was that when they built a new District building?

WB: That was a new facility which they built next to the State Office Building. It was a much, much nicer facility.

RT: What was the name of the new FDA building? Some new FDA facilities were named after some of the agency's important people.

WB: I don't think the building was named after anyone. It was just FDA.

I remember some interesting things that happened there.

We always had a morning coffee break at 9:15 in a little room upstairs, and some of the chemists were always up there playing cards for fifteen minutes or so every morning and afternoon.

The biggest problem we had there was with the concrete pillars in the basement garage, where some of the new inspectors kept crashing cars into the pillars. We had quite a few such accidents, fender benders, down in the basement before the cars got out on the street. I never hit one, and never had a problem, but it was amusing seeing others dent the cars.

RT: Did you have any sort of formal training as a new employee, other than on-the-job with a senior inspector?

WB: Not for the first eighteen months. It was all on-

the-job training with senior inspectors initially. Then I went to Basic Drug School in Providence, Rhode Island, which was my first formal training. I'm trying to remember if there was any formal training after that. Yes, I remember being sent to Battle Creek, MI to "bread school." That included several days training in inspecting grain elevators and cereal manufacturers.

RT: You mentioned doing apple processors. Did you get into any pharmaceutical firm inspections before your formal drug training in Rhode Island?

WB: I did very little pharmaceutical work in the Baltimore District. Do you remember in the early days anything about the John Companos Pharmaceutical Company? I went with a senior inspector on an inspection of the Companos Company. This was in '66, so it was three years into my career with FDA. I happened to mention to John that I was about to be drafted and was going to have to leave FDA. He said, "Drafted? You're not going to be drafted. I'll take care of that." He happened to be on the Draft Board in Baltimore, or had a brother or sister or some acquaintance on the Board. So he grabbed a phone and before I could stop him, and he started calling the Draft Board. He was going to get me out of the draft. But, unfortunately or fortunately, my Draft Board was in Portsmouth, Virginia, and he didn't know anybody down there, so that didn't

happen.

RO: His firm was primarily what, Companos?

WB: They had a small generic drug company, and were manufacturing some antibiotics. If I remember correctly, they had a lot of basic GMP problems.

RT: In Baltimore area was there any truck-stop surveillance work done regarding the illicit sale of "bennies" or similar drugs?

WB: We did a lot of that, not only with truck stops, but with some physicians as well. There were some older physicians in West Virginia who pretty much had abandoned their medical practice and were primarily just selling drugs out of their offices. We had a number of investigators who spent a large portion of their time just doing undercover work.

The first audit work I did was just going to drugstores and getting refills of prescriptions, illegal prescription refills.

RT: Did a number of those investigations result in regulatory and legal actions? Or, just a warning letter citation?

WB: I don't remember any of the undercover work that led -- I take that back. I did one situation which led to a court action.

I got called in by Tom Kingsley on a Monday morning,

and this was when I had been with FDA maybe a year with very little experience and absolutely no training in undercover work or working with the police. I was just fresh off the street, so to speak, with not much broad FDA training.

Tom called me in and said, "The Baltimore police need someone to work with them because they are aware of some people selling street drugs but they need a fresh face because the drug sellers know all the Baltimore undercover people. They need a fresh face to go in and make some buys and do this work." The police have asked us for help in making undercover buys, so I want you to work with them.

So I said, "If that's what you want me to do, I'll do it."

So I met two Baltimore detectives, who introduced me to a young lady who knew a guy who was selling drugs on the street.

Do you really want to hear this story? It's sort of interesting, but it's . . . Okay.

So they decided that I was going to be "Bill" Bryant from Weirton, West Virginia, and this girl was also from Weirton, West Virginia. She supposedly had known me out there in West Virginia. She was going to be the introducer to these hoods who were selling sets of drugs, I guess, one upper and one downer, and you could buy them in sets for so

much per set.

So she and I met this guy, Scott, one evening in a bar -- not in a bar, but in a pizza parlor. We chatted for a while, and I brought around the subject of uppers, downers, whatever. The bottom line is that we made an agreement that I was going to buy some drugs from him, but he didn't have any with him at the time. It was agreed that he would get the drugs and I would meet him there at the pizza parlor in the evening.

So the two police detectives, that I was supposed to be working with, were going to sit across the street in a bar and watch the pizza parlor door, to be aware of when I went in and when I came out. They were going to be my protection, because I had no protection. I didn't carry a gun and I had no experience in undercover work. I wasn't a karate expert.

So I went in, sat down and waited. Scott came in and he says, "Okay, I've got the stuff."

I said, "All right. How much do you want for it?"

He told me twenty-five dollars or whatever it was, because it was about two dollars a set and he had 12 sets. .

I said, "Okay," and I started to pull out the money.

He said, "No, no, no. We're not going to pass it in here." He says, "It's too obvious. Let's go get in the car."

So we left the pizza parlor, and I'm looking across the street to see if the two detectives are watching for me. Right?

So we leave the pizza parlor and go into a dark alley, I mean, pitch black and get in a car. Scott is driving. I'm on the passenger side, the right front seat, and he had a friend with him who was wearing combat boots and Army fatigues. A rough-looking guy, who got in the back seat.

We pulled out of the alley and started down along the docks on the harbor in Baltimore.

This guy in the back seat says, "Look, man, you've got to show me something that says you're not a fed, because the feds are after me and I'm not taking any chances." He had a Bowie knife about this long, and I thought, "Oh, my God! These guys are gonna slit my throat, drop me over the pier into the Baltimore harbor, and I'm dead! How am I going to prove I'm not a fed?"

This is where God, I swear, God took care of me. I had my one hand on the door handle and I was ready to jump out in the street, just bail out at twenty-five or thirty miles an hour. I was going to bail out and take my chances.

I decided to pull out my wallet. I pulled it open and when I did, the only card I had in my wallet with a name and no address on it was my Social Security card. It fell out in my hand, Willie R. Bryant, Jr. was the name on it, and I

had told him my name was Bill Bryant. So I handed the Social Security card over the front seat to the guy, and because I had given him the correct name, he assumed that everything else was okay. He handed it back to me, and saying, "You're okay." So I put it back in my wallet.

They handed me a bottle full of drugs and a towel and said, "Wipe off the fingerprints, because you know possession's nine-tenths of the law." So I wiped off their fingerprints and gave them twenty-five bucks. They pulled back in the alley and I got out and they drove off.

And my police protectors were standing on the street corner a block down the street from the pizza parlor looking for me. I said, "Where in the heck have you guys been?"

"Well, where have you been?"

I said, "I almost got killed."

"Well, we didn't see you leave."

They're sitting over in the bar talking and not paying attention, so I could have been killed on my first undercover assignment. That was probably the scariest one I ever did, too.

RT: So did you do much more of that work after this incident?

WB: We did a little bit after that. It was mostly drugstores and pharmacies for prescription refills.

But we did wind up in court with that first case. It

did go to court and I testified. The guy's attorney thought I was a city official.

He came over and he wanted to talk and try to see what he could get out of me, and I said, "Hey, look. The best thing you can do is plead your client guilty, because if you open up, and you start asking me questions, it's just going to make matters worse. I'm not a city policeman. I'm a federal investigator."

The attorney's response was, "Oh, we have to make a show of it, we have to do our thing."

So he made a show, he asked questions and all the questions he asked just brought out all the wrong answers. This just got him deeper in trouble. So the young man got eighteen months in prison for selling drugs. That was that.

But after that incident, there was nothing of really great consequence.

RT: Did you receive a promotion at Baltimore, or did you have to transfer for that?

WB: I got my GS-7 in six months. In those days, we went from GS-5 to GS-7 in six months. So in December or January of '64, I got my GS-7.

Then, between my GS-7 and GS-9, there was a freeze on. All promotions were frozen for six months. So I was in Rhode Island, in drug school, when my GS-9 came through, so it took eighteen months from my GS-7 to a GS-9.

Then, after I'd been a GS-9 about a year, and I was just eligible to get my GS-11, I had to go in the Army. I checked with my draft board at home and found out . . .

Originally, to sort of summarize it, when I graduated from college, I went to Navy OCS (Officer's Candidate School), and I was all ready to sign up with the Navy. I took their test and did everything I needed to do in order to be a Navy officer. They then said, "Well, everything's done except the background checks on you and your wife. background." so now we have to go check your wife's I und." I said, "No. We're secretly married. She's in nursing school. If the school finds out that we're married, they'll kick her out of nurse's training." So we agreed to put my application on hold for the time being.

Soon after that, President Kennedy issued a presidential order that married men would not be drafted, so that exempted me from the draft for that first several years in FDA. Then, in '66, Lyndon Johnson rescinded that order, and they started drafting married men. It was at that time that I checked with my draft board and found out that I was 13th on the Draft Board list and could be drafted the following week. So I had to get on the stick real quick and try to get something going with the military.

I went back to all the OCS groups and recruiters to try to get back into the OCS program, but they had so many

college kids getting into OCS at that time that they said it would be at least a six months' wait before I could get into OCS. So I was lucky enough to find a Reserve unit in Baltimore, at Curtis Bay, a boat company that had openings, so I joined the Army Reserves.

At that time, I had been a GS-9 for about twelve or fourteen months, and I was looking for my GS-11 promotion. Phil Paquin, my supervisor at the time, was told I was going on active duty in the Army. When I asked him about my promotion, he responded, "Well, we're not sure that you're really going to be a career employee at this point, so we're going to hold up your promotion till you get back from the Army."

Needless to say, I was really ticked. That must have been the stupidest answer I've ever heard in my life. I had already put in three years, and obviously I was a dedicated FDA employee. Anyone who worked with me knew that.

So I was on active duty in the Army for six months before I came back. That's when I talked to Tom Kingsley and told him I wanted to go to a resident post. Tom agreed and I moved as a GS-9 to the Charleston resident post to work with Joe Pendergast, who was the senior resident then.

RT: Was Phil Paquin a branch director or . . .

WB: He was a supervisory inspector.

After two or three months working time in Charleston, I got

my GS-11 as Charleston resident inspector.

RT: You were a resident there for how long?

WB: I was a resident inspector about fourteen months. We inspected chemical plants like DuPont and all sorts of other small manufacturing plants, a lot of bakeries and food warehouses. There was no drug industry or anything of real significance in West Virginia.

RT: What was the FDA interest in chemical plants? What kinds of chemicals there were of concern to the FDA?

WB: Well, we were concerned with basic bulk drug chemicals. At that time, FDA still had responsibility for the Hazardous Substances Labeling Act, so we had interest in paints, varnishes, lacquers, and fireworks. Products like that were included in our regulatory responsibility.

RO: Were any of these chemicals intended for use as food additives?

WB: I don't remember. They could have been, but I just don't remember

RT: In the West Virginia environment, did you get involved in illicit drug sales at truck-stop type establishments?

WB: I did very, very little of that in West Virginia. I just didn't get involved in that activity. But I did conduct some interesting investigations.

We were involved in Krebiozen investigations, which

were going on across the nation in those days. There were a lot of people around the country who had fallen for the idea that Krebiozen was going to cure cancer. So we did quite a bit of talking with doctors, surviving family members, and folks who had been prescribed or who had family members who were taking Krebiozen.

I remember going to a school to do an investigation on a birth defect. A school teacher had contacted FDA and reported that a particular consumer way out in the boonies in West Virginia, had given birth to a baby with multiple birth defects. I was assigned to go there and check it out.

I remember when I finally located this little one-room school building the school teacher met me and said, "Oh, I knew you were coming."

I asked, "Well, how did you know I was coming?"

She said, "There's a system out here. When there's a federal government car in the neighborhood, the phone rings, and everybody knows that there's a possible revenue around." So she said, "I knew you were coming." That was interesting to me.

I mean, we had to go to places where you had to ford streams to get there. Paved roads ended and just became a gravel or dirt road, across which you had to cross by fording them, that is, driving through them to reach the other side.

RT: Well, did you learn if the birth defect(s) were caused by a drug?

WB: Yes, from a drug, although I cannot now remember what the drug was at the time. I just remember the incident. Perhaps because of the fact that this teacher knew that I was coming.

RT: Was this individual cooperative in providing useful information?

WB: Yes, she was, very much so. She had felt a very strong obligation to tell FDA about the incident.

RT: Were there any other unusual experiences of note at that assignment location?

WB: The misuse of prescription drugs was then being handled by an "off-shoot" part of the FDA, known as BDAC (Bureau of Drug Abuse Control), which was later organizationally absorbed into the DEA (Drug Enforcement Agency). The BDAC people once approached me and offered a GS-12 job if I would accept the position of being the BDAC agent in Charleston, West Virginia. I said, "No, thank you. I'm not interested."

West Virginia was, Logan County in particular, known to be a place where people really stick together, and an outsider didn't have a very good chance of really getting in to do undercover work or anything else in enforcement work, and it was dangerous. There was a good chance you might

find yourself run off the side of a mountain or something else like that might happen to you. I had a new family, a new baby at that time. My first son had just been born. So I wasn't interested in that kind of work. I was more interested in sticking with FDA.

RT: When did you leave Charleston?

WB: Our son Patrick was born February 21st of '68, and we left Charleston about sixty days later. I transferred to FDA's Philadelphia District, although, we actually moved to southern New Jersey.

RT: Did you get a GS-12, a grade advance, in the transfer to Philadelphia?

WB: No, I didn't. I transferred to Philadelphia as a GS-11. It was after I'd been in Philadelphia for about three years, I guess from '68 until about '72, so it was almost four years before I got a GS-12.

In those days, a lot of people were being promoted to GS-12's as drug investigators. Remember, we had the IDIP program (Intensified Drug Inspection Program), where an investigator would actually be assigned to a plant and he or she would stay there for six-months up to a year or longer as a full-time in-plant investigator. That program went on for several years, and a lot of people got their GS-12's through the program.

Basically, in Philadelphia, I was a generalist. I did

both food and drug work, including small drug firm inspections, homeopathic product firms and so on.

Remember John Boreman & Sons, a homeopathic drug manufacturer? I remember doing a very detailed GMP inspection there that was very time-consuming. At it's conclusion, the president of the company sent a letter to the District Director complimenting me on the inspection that had been done and thanking him for the help that I had given the firm, basically saying that I had explained things to him in a way that they understood what needed to be done and why it needed to be done and this had given them ideas as to how things should be done. He added it was by far the best inspection they'd ever had and they really appreciated it. My then-supervisor accused me of asking for the letter to be written in my favor.

RO: How did you get to Philadelphia? Did you apply for a job there, or did they just transfer you there?

WB: Baltimore District was opening a new resident post in Fairmont, West Virginia and bringing Burton Love in as the resident. District management decided they didn't need two people any longer in Charleston, and to bring me back to Baltimore. As you may remember Ron, it was policy that you couldn't become a GS-13 supervisor unless you had multi-district experience, so I needed to go somewhere other than Baltimore for promotional opportunities. I learned the

Philadelphia District office had openings and I contacted the folks up there. They were glad to have me transfer, really. That's how it happened.

RT: Who was your chief inspector in Philadelphia at that time?

WB: James Nakada, and the district director then would have been Irwin Berch. Bill Conway was the deputy district director.

I can tell you a quick story. I don't know if it is appropriate for this interview, but it says a lot about our field management at the time. You can take it out if does not seem appropriate. After we were there for about a year, my wife became pregnant with our second son, and about four month into the pregnancy, she started losing amniotic fluid and had to go to bed full time, total bed rest. She could only get up to go to the bathroom and back. Otherwise, she was going to lose this baby.

So we had my relatives stay with my wife Linda - -

TAPE 1, SIDE B

WB: - - - for a week or two, but then we were out of people, and somebody had to be there because we had a 22-month-old baby that had to be taken care of as well as my wife. And this was long before there was such a thing as "family leave."

So I went to Bill Conway and explained my situation. I said, "Bill, I need to take sick leave to stay home and take care of my wife."

And he said, "Well, you know that's something not normally done."

I said, "I know, but I have no choice. I have to take sick leave." I asked him, "Can you contact headquarters and find out if it's possible or if something can be done?"

He said, "Okay, I'll do that."

I checked back with him about two days later, and asked, "Mr. Conway, have you had a chance to contact FDA headquarters about my sick leave request?"

"No, Willie," he says, "I'm not going to contact anybody. You just come in here once a week and bring your sick leave slip to me and I'll sign it."

I took six weeks of sick leave to care of my wife until my son was about seven and a half months. He was born premature then, at five pounds. Without Bill Conway being willing to support me and permit that sick leave, my son would never have been born. So Linda and I will always be grateful to Bill Conway for his action.

We had a system in Philadelphia for handling recalls. We had a recall coordinator who left for some reason; I don't remember who it was or why at the time. Jim Nakada then decided he would rotate his inspectors through the

position, and he set up a six-month rotation system. He'd put his GS-11's and some of his 12's in as recall coordinator.

When my rotation time came up and I got on the recall desk, I liked the recall coordinator job. Not only was I a recall coordinator, but I also had about six other projects for which I was responsible to monitor. Plus, there was no travel. That was the other good thing. I had two babies at home, and my wife was tired of me being on the road at least one week a month, sometimes two weeks a month, in and out, and she wanted me to stop traveling.

So when it came time for me to leave the recall desk, I went to Jim Nakada and said, "I like this job and I'd like to keep the job and stay in it."

So he said, "Okay." He said, "I'm going to put you in as a GS-12 due to accretion of duties as a recall coordinator."

That was at the time when a lot of the other investigators were getting GS-12's the same way, accretion of duties in their drug inspections, in the Intensified Drug Inspection Program. He attempted to put it through, but personnel wouldn't approve it. They said, "No, there's been too many people that have had that job, so you're going to have to advertise it and let people apply for it." So we had to go through the advertisement process, although I knew

it was my job. Nobody else wanted it. I was the only one.
So that's how I became recall coordinator and got my GS-12.

The job included responsibility for district emergency functions as well under the job title "recall and emergency coordinator."

I was in that job for about four years, until John Brown was selected as Remle Grove's assistant in the headquarters recall office, which was in ORO (Office of Regional Operations) at that time. When John left that staff, they advertised his job. Remle called me and asked if I was interested in it. I answered, "I'm coming," because I had trained with Remle in Baltimore. We were old friends from before. Linda and I were interested in moving from where we were anyway. We weren't very happy with the neighborhood and some local situations there, and wanted to make a move anyway.

RT: While you were in Philadelphia, were there any, shall we say, unusual or noteworthy recall events that occurred?

WB: We had a lot of Class I recalls in those days, a lot of Class I food recalls and potential bot [botulism] problems.

RO: Of the Class I definition?

WB: Yes, of the Class I definition because they basically presented a life-threatening hazard.

We had a lot of recalls with peppers, canned hot peppers, mushrooms and canned mushrooms. We had a number of companies that had potential bot problems because of under-processed mushrooms. We had a farm product, Nancy's Peppers, that also had a bot problem.

At one time, four large Class I recalls were ongoing at the same time. Obviously, I couldn't handle and coordinate four separate recalls at one time. So we had great help from Janice Oliver, who was then a GS-11 investigator, to coordinate one of them.. She's now the Deputy Director of the Center for Applied Nutrition & Food Safety (CFSAN).

Elaine Messa, who was then Elaine Cahill, also coordinated one. Elaine ultimately became District Director in Los Angeles.

I believe Mary Mason was coordinating a third one; and Joyce Calibers handled a fourth one.

So I was the manager and had four people, each one coordinating a separate Class 1 recall at the same time.

In those days we did thousands of audit checks. We sometimes had half the district inspection staff out just doing audit checks.

Botulism toxin was found in one product, I believe it was the Nancy's Peppers recall, and it was felt critical that we visit every single retail store to be certain those peppers were actually off the shelves. We set up a recall

headquarters in a hotel in Pittsburgh, and Ron you may remember some of this. You may have been in headquarters then. Anyway, we pulled people in from about ten or twelve other districts. We had about forty investigators who flew in from other districts and rented cars. We were hitting every service station, every little mom-and-pop grocery, anybody that possibly carried these peppers. We actually visited and did audit checks to be certain that none of these products were still on the market. That's something that we don't do today.

RO: Let's go back a little bit. Willie, what is FDA's legal authority for a recall?

WB: FDA has no legal authority for a recall. We cannot order a recall on a food product.

There is a requirement in the Infant Formula Act, which is now incorporated into the Federal Food, Drug & Cosmetic Act, which states that if a firm learns it has a problem with an infant formula, the product must be recalled. But, again, it's not FDA authority to order it. The Act requires, the manufacturers to initiate a recall if they have a problem. So FDA makes the decision of whether there is a serious problem, and the firm is expected to follow the requirements of the Act. So it's sort of a quasi kind of ability to order the recall.

RO: That's done on infant formula.

WB: Yes, but on regular food, we have no authority. It's strictly voluntary.

RO: What if a firm resists recalling?

WB: Can a firm resist a recall? Then you have massive publicity, which is usually enough to prompt a recall action, just through the threat of massive publicity. We can enjoin the firm, and we can seize the product both at the retail and wholesale level and any product remaining at the firm's facility.

If a firm refuses up front, following contacts from our District staff, to initiate a recall that the center (CFR) feels is necessary, one thing we can do is to seek what we call an FDA-requested recall. In an FDA-requested recall, the ACRA (Associate Commissioner for Regulatory Affairs) signs a letter to the company which explains the significance of the recall and the health hazard that's involved, tells the firm that FDA expects them to recall the product, and should they not recall the product, that the agency is prepared to take all regulatory actions available to be used, which would include seizure, injunction, whatever. That's only happened only about twenty times in the last twenty years. Very, very rarely does that ever have to happen, because normally, once FDA goes to a firm and tells them that they've got what the agency considers a life-threatening, Class I health hazard, and they should be

getting these products off the market, they usually do it. The letter from the ACRA may also tell them we will issue a press release. Just the fact that the world would know that their product is out there and the firm is not taking it off the market opens up tremendous legal liabilities for the firm, and nobody wants that kind of problem.

RO: So, then, the agency does have an option of publicizing the problem.

WB: Absolutely.

RO: And you would do that through the media.

WB: Absolutely.

RT: Has the agency ever seized products rather than invoking a recall?

WB: Not in a situation where we had a Class I health hazard. Companies have always given in and recalled ultimately. There are different situations where the violation is significant but doesn't present a Class 1 hazard and there is a product that we can go and actually seize. But today, we've gotten away from taking the seizure actions. As soon as FDA finds that there is a seriously violative product, we go to the company and say, "Here's the analysis on this product. You're marketing a hazardous to health product here," or whatever kind of situation it is. "What are you going to do about it?" Most often the firm says, "Well, we'll call it back." So recall has to a large

extent eliminated the need for the agency to go through the seizure process, because firms do voluntarily a initiate recall of their products once they learn they have a health hazardous product.

RT: Of course, a Class I recall has the highest priority and the greatest urgency. There are other categories of recall, like Class II recall and so on. Could you just touch on what those descriptors would be?

WB: Basically, the Class II recall is one that does present a potential health hazard, but the condition that it would present is treatable, reversible, okay. Then a Class III recall basically is a no-health-hazard situation. It could be a labeling violation, net-weight statement, or other things where the product doesn't meet regulatory requirements, but doesn't present a health hazard.

RO: Class I requires 100 percent effectiveness checks by the agency. Is that right?

WB: No, sir. At one time, we did try to do 100 percent audit effectiveness checks, but that became impossible from both the manpower (person power) and resources perspectives. It's just not possible to go out and visit or contact a 40,000 retail establishment inventory, to verify that all have been notified and there is no violative product(s) on the market. So we rely more on seeing that the firm has an extensive notification process and that a

press release is issued, that it's well covered, that notification is out to the public, and that the firm does effectiveness checks of its own. We'll do a percentage check of the direct accounts, normally no more than 10 percent audit checks.

What FDA does, we refer to as an audit check. What the recalling firm does is referred to as an effectiveness check. So we're auditing firms' activities. There's a difference.

The checks are basically the same thing. The firm is required to verify that the customer received the notification and that they're returning the product or doing whatever is required by the recall.

Now, an FDA audit check does basically the same thing. We're actually contacting the recipient and saying, "Did you receive the notification? Did you take the action that the recalling firm asked you to take? Did you return products? How much did you return? When did you return it?" Okay? Or if you had to notify your patient, "Did you notify the patients?" all these kinds of things.

RT: So the Class II recall still would generate audit checks and effectiveness confirmation.

WB: Yes, sir.

RT: Class III, where there's no health hazard, would that be more in the category of mislabeling and so on?

Where there's not a health hazard, what extent of follow-up is done?

WB: We would not spend the resources on Class III. The Regulatory Procedures Manual (RPM) actually states that we will not conduct effective audit checks on Class III recalls unless there is a specific reason that the center management or district management feels a certain number need to be done. Maybe it is felt the firm is not going to do the job at all, or they're just not going to get all the product off the market. FDA may decide to do a 2 percent audit check, like maybe twenty audit checks with phone calls to find out if in fact the firm has followed through. If the firm didn't follow through and didn't do the recall effectively, then FDA may decide to go the seizure route, and we'd then want a sample for a seizure action. So it does happen occasionally that we will do Class III audits, but most of the time there are no audit checks done on Class III recalls. It's pretty much voluntary.

RT: It depends on voluntary cooperation.

WB: Yes, sir.

RT: Thank you for this explanation of the recall process. When you left Philadelphia, you came to headquarters, as I recall you saying earlier.

WB: I left Philadelphia in June 1976 and came to headquarters. I left my family at that time in

Philadelphia, although we actually lived in Willingboro, South Jersey.

RO: Willingboro?

WB: Yes, Willingboro, which was thirteen miles north of Camden. It was about halfway between Camden and Trenton, up Route 30.

So, coming to Washington, actually to Rockville, was a great experience, and, fortunately, I was coming to work with Remle Grove, who was a great supervisor. I never worked for anybody better than Remle. It was basically he and I running the recall and emergency staff for about fifteen years. We did have a third person most of the time. We had Patty Jaynes, Pete Shandruch, Petro Shandruck, and Ed Warren who worked with us for a while. Lastly, we had Cecelia Wolyniak. After several years, Cecelia left us and became the Center for Foods recall coordinator, where she still is. She's been there for about twelve years as the CFSAN coordinator.

We had responsibility not only for recalls, but for emergency situations as well. Our division was the Division of Emergency and Epidemiological Operations, with Dick Swanson as the director. Initially, we were part of the old Field Compliance Branch. Merle Ryan (Pat Ryan) was the director of Field Compliance Branch. And in those days, it was just Remle and I and a technician. I remember Harriet

Schwartz was the technician in those days.

RT: What were the emergencies that you covered?

WB: We oversaw FDA field activities relating to floods, hurricanes, tornadoes, and anything else that could in any way damage food and drug stuffs. In floods, of course, you've got drugstores, grocery stores, warehouses being under water and products being damaged. Major fires would present the same kind of problem.

But the biggest and the hairiest event that took place was Three Mile Island. On the evening that Three Mile Island problem occurred I was in the office working late. My wife happened to have been down in the Rockville area for some reason. I believe she'd been to a doctor's appointment down in Georgetown. So I was working late waiting for her to pick me up. It was about 5:30, and I got a phone call from -- I always call him deputy. The guy who was a political appointee.

RT: John Norris - Jim Grant?

WB: No, this was a guy who'd never been in the field.

RO: Bill.

WB: Bill what?

RO: Randolph.

WB: Yes, Bill Randolph.

I had a call from Bill Randolph, Deputy ACRA, about 5:30. He said, "Willie, do you know the Three Mile Island

nuclear plant in Pennsylvania?"

I said, "No, sir."

He said, "Well, we've just been notified that it's about to blow, and we've got serious problems. We need an emergency plan into effect by tomorrow morning. They plan on evacuating, potentially evacuating hundreds of thousands of people. We need to have a plan in process to handle the radiation exposure damage that may occur, including one for the products that are being grown in that area. Whatever needs to be done," he said, "I need you to get started on it."

My wife was there when Bill called and she said my face just turned white, all the blood just drained out of my face. I said, "Oh, my God! What am I going to do?"

So I called Remle who had just gotten home. I said, "You've got to turn around and get back down here quick. We've got a big problem on our hands." So Remle came back and we went to work and contacted Philadelphia. I believe at that time Bill Conway, Jim Nakada and Irv Berch were still running things up there. Anyway, Bill Conway became the architect of the operations being done by the district, and he set up a resident post up near Harrisburg basically in a motel and he had six or eight investigators up there full time. They were sampling fish, grain and other things that were growing in the area. In addition, they were sampling milk, a lot of milk

samples, and trying to ascertain whether or not there had been any radiation leak that had contaminated any food products.

We set up a radiation headquarters control center in John Villforth's office, and John and his deputy . . .

RT: He was acting commissioner for a while? Do you mean Jim Benson?

WB: Yes, Jim Benson. Right, John Villforth and Jim Benson. They had an extensive radiation staff group, there, and for about a week or so, maintained a 24-hour watch. We had people actually sleeping in Rad Health headquarters monitoring and staying on top of everything that was happening with Three Mile Island. The whole operation was basically monitored and run by John Villforth as the primary person responsible for nuclear monitoring operations.

That was quite an interesting night when I got that first call from Bill Randolph.

RT: As you've said, that was a very extensive sampling program.

WB: We sampled for over six months, and we spent a tremendous amount of resources to be absolutely certain there were no grains, foods, fish, or milk or any other consumable product that was contaminated and might cause illness or harm. To the best of my memory, I don't believe we ever found any significant radiation problems in any samples that were collected. We did a fantastic job of

monitoring and ascertaining that there was no problem.

It was scary, I remember that. I remember calling my wife one day and saying, "I want you to pack our bags and suitcases, and get the car ready. At a moment's notice, I want you to be able to put the children in the car and take off and head to southern Virginia, where our family is closest. I reminded her that Three Mile Island could explode at any time and since we're only about 80 miles from Harrisburg, I didn't want any of them to be this close to it should that happen.

RT: You were just mentioning, as the tape ended, some of the steps for emergency preparedness in case of a nuclear episode. Please further elaborate on that now.

WB: Part of the responsibility of the Division of Emergency and Epidemiological Operations was emergency preparedness. We were responsible for maintaining the relocation facilities for the top congressional leaders, and agency leaders in the mountains in West Virginia. We had a communications room set up there with basically everything the commissioner or other top FDA management officials would need in order to actually run the agency from this underground facility. About every three months we would drive over there for the day to upgrade the documents and be sure that everything needed was there and in satisfactory order.

RO: Other federal agencies besides FDA were there too. Wasn't other HHS top staff there as well?

WB: The facility was like an underground city. It's a huge space. But the space FDA had was probably 20' x 30' max. You had all the other government agencies, not only DHHS, but others, like USDA, whatever, all with their little cubicles. They were all set up in their spaces so the top managers could operate from there in case of a nuclear attack on Washington.

RT: Were there any practice exercises to explore the soundness of that emergency facility?

WB: Not to my knowledge. I don't think so. It was supposed to be a secret facility that wasn't so secret, and I'm sure that the Russians were well aware of it, where it was located and everything about it.

RT: You had an emergency coordinator who was more or less responsible for . . .

WB: Yes, we had a CSO (Consumer Safety Officer) who was the emergency preparedness officer and he was part of our branch and division, which we called the Emergency Operations Branch. His name was Peter Cifala.

RT: Did the field districts at that time also have an emergency preparedness plan?

WB: Yes, they did. We had emergency programs at the district level, and I hope they still have, although I do

not actually know at this point. Then there was an emergency preparedness officer in each district. Each district had an emergency plan so that in case of, not only a nuclear attack, but for any major emergency where it could not function from the regular office location the district could activate an auxiliary plan set up with a university or other facility to actually move the management of FDA to that facility and operate from there. I know that every district was to have an emergency preparedness officer and an auxiliary site set up to work from. For example, Cathy Hoggs is the emergency preparedness officer in Chicago, and she got her GS-13 grade, not as a recall coordinator, but as the regional emergency preparedness officer.

RT: This would be going a little farther back, but I think in the '60s or thereabouts, there was a radiation or nuclear training officer, who I think was John McConnell. He was the gentleman who used to give training to FDA personnel about radiation protection procedures. That may predate the period we're talking about now.

WB: I just don't remember.

RT: Well, getting back to the recall coordinator, when you were in Philadelphia, you got to be the permanent recall coordinator there as *recall*.

WB: Yes, sir.

RT: Before that time, it had been on a rotating basis.

WB: Rotating basis for several years. I was the permanent coordinator for four years.

RT: Did each district then have a permanent recall coordinator, or were they still just operating on the local management's staff rotation plan?

WB: Most districts had a permanent recall coordinator. There were a few that would rotate. Usually you'd get a permanent one, and then maybe the permanent one would get a job as a supervisor or retire or something else. Then they might rotate coordinators again for a while.

It was not felt to be a good career-ladder position, and so a lot of people who might enjoy the job, and knew the job, wouldn't take it as a GS-11 because they figured they wouldn't be able to get their GS-12 or wouldn't be able to go on into a supervisory position or otherwise progress career-wise.

TAPE 2, SIDE A

RT: We're picking up again because of the change of tapes. Hopefully, we have not missed any of the text of the discussion. You were commenting on . . .

WB: The position of recall coordinators in the districts.

RT: You were saying that. . .

WB: To the best of my memory, every district had a full-

time recall coordinator back in the '70s. The only time you had rotating ones would be when the permanently assigned coordinator might retire or move on to a different position. A lot of times management would want to let a number of people have an opportunity to try the job before they advertised it so that staff members would know whether or not they would be interested in applying for the job.

It's been a critical job in the field, but it's an underrated job. It has been underrated and underappreciated down through the years. The people who haven't done the job have no clue what's really involved, how much stress is involved in the position, and how much responsibility the coordinators have in dealing with companies.

The job has changed somewhat over the years. It used to be that when a company notified FDA they were going to conduct a recall, an investigator would immediately be assigned to go to the plant and gather what we called our Attachment B information. In the RPM (Regulatory Procedures Manual), Attachment B provides a long list of data to be obtained for a recall.

WB: When an investigator is sent out to gather all the background information, that person is also to make an inspection and try to find out how the fault occurred, why it occurred, if there are other products involved that could have had the same problem, the extent of the problem, the

extent of the distribution, and what needed to be done to correct the problem.

Today, that doesn't happen anymore, or it happens rarely. Let's put it that way. Unfortunately, whether it's primarily a lack of resources or whatever, we tend to depend upon the companies to provide that background information based on phone calls and e-mails or faxes back and forth between the field recall coordinator and the firm.

Basically you've got the recall coordinator having full responsibility an investigator as well as a recall coordinator, and they also act as a compliance officer making compliance decisions on the significance of the problem or hazard and what needs to be done. They're making recommendations to the director of investigations about whether or not an inspection needs to be made, and what follow-up needs to be accomplished, so it's more extensive than it used to be. When you get a district with twenty-five to thirty recalls going on, which may include all five categories -- drugs, devices, foods, veterinary medicine, biologics -- it gets very complicated to try to stay on top of them. That is, to monitor the progress and status of each one to be sure you've got all the information needed to close out the recall properly, and additionally maintain the notes and communications back and forth constantly between the district office and the firm. Most of that is being

done by the recall coordinators.

RT: I assume that the recall officer, though, can obtain other staff assistance for some of this oversight. Is that usually done?

WB: They can. However, in most cases my experience for the last ten years has been that these coordinators try their best to get the job done without asking for additional help. I just know they are generally very stressed and overworked and have a tough job.

RO: Do each one of the centers have a recall coordinator?

WB: Each one of the centers has a recall office. They vary among the centers, and between the centers, as to the size of the recall staff and their operations. The Center for Foods has two people. The Center for Devices has a recall coordinator and two technicians, but they farm the classifications out to compliance officers in various divisions. So when a product is recalled, if it's a defibrillator, for example, that recall classification is farmed to the division that handles those kinds of devices so the people who are working with the classification have some familiarity with the device. The recall coordinator, who is an engineer, a civil engineer, and has a lot of experience at this special area is sort of a manager of the system and oversees what's happening more so than actually

doing the classifications herself.

CVM [Center for Veterinary Drugs] only has one person, who also has other duties besides recall coordinator. The CVM doesn't have that big a recall volume, say about sixty a year, one a week or so, and that person is not as busy as some of the others.

The Center for Drugs has three people on their recall staff.

RT: Now, do these recall coordinators or staff in the Centers deal mostly with the field, or do they deal with you in headquarters?

WB: They deal primarily with the field. When the field learns that there is a recall taking place, they notify headquarters through an electronic system which we began building back in 2002 and put into place November 15, 2002.

It is called the Recall Enterprise System, and is referred to as RES for short.

This electronic system allows the districts to communicate information to headquarters, to the Centers, to the Office of Enforcement, DCMO, and to the Press Office. So when they want to initiate a recall, they put together what we refer to as an alert, which is just basic, minimal information that we may get from an industry phone call. Then they can start an alert and hit the "send" button, and the alert information automatically goes to the Office of

Enforcement and to the appropriate Center.

RT: So the individual Centers, while they operate directly with the field, also have the Recall Office and the Office of Enforcement tying in information-wise.

WB: Yes. Everything goes through the Office of Enforcement. We see every alert recommendation, classification, termination, and press release. Everything funnels ultimately through the Office of Enforcement. We have our fingers in the pie, so to speak, on everything.

Anything that's important, anything that's hot, the Office of Enforcement (DCMO) is aware of and is sort of overseeing what's happening. If our involvement is not necessary, we stay out of it. If we need to be involved, such as, for example, getting additional work done by the firm or by the district office, and if we need to be involved in press activities such as drafting a press release, or working with the Centers regarding the press matters, we do that. We want to see that there's a consistency across the agency in the recall operations and that all the Centers are on basically the same page. We developed a Health Hazards evaluation form so that the same information is evaluated and considered when Centers make their health-hazard evaluations; and we try to see that policy and press across the field remains as consistent as we can make it.

RO: Who initiates the press?

WB: Well . . .

RO: You?

WB: No, not necessarily. The [Acting] Commissioner, Dr. [Lester] Crawford, basically has stated that FDA will issue a press release on all Class I recalls. For the rest, there's good justification for not doing so. Okay?

So, at the present time, whenever a situation comes in that the field believes is Class I, the Center immediately gets that information. They look at it and say, "This is a Class I situation. We need to have a press release issued." The district will go right back to the firm and say, "The Agency considers it Class I. You've got a life-threatening hazard. You need to draft a press release. If you feel that you can't do it, then the Agency will do it." So it's, you do it or we're going to do it, one way or the other. That's the bottom line.

Usually the firms will then say, "Okay. We want to put out our own press." And we say, "Okay. You draft it, we'll look at it, we'll give you our comments, then you go with it." That's generally the way it's done.

RO: So usually the firm issues the press release.

WB: The firm issues the press release in most cases. Okay? But if they resist and the press release they want to issue doesn't have the information we feel is necessary, or

it's written poorly or it's not clear or whatever, then our office is quick to jump on it and issue a second press release, working with the Center, some kind of talk paper, to make things clear to the public on what's happening. The district recall coordinators will work with the firm to draft the press release.

We have guidelines for press releases. There are guidelines which are published on the FDA web site. For example, there is press release for *clostridium botulinum*, one for *salmonella*, one for *listeria*, and there's one for *E. coli*. These basically give the hazard and tells the firms what it is we want them to say in these press releases.. Thus, there are drafts and guidelines already available for reference.

The press release quality guidelines are usually not much of a problem as the firms can coordinate and issue them. The field has the authority to agree that the press release is okay and let the firm go ahead and issue it. It doesn't have to come from headquarters so long as it meets the published guidelines.

RT: During your tenure as a Senior Recall Officer, there have been a number of emergencies that have presented risks, no doubt to consumers. For example, the cyanide in Chilean grapes; the vichyssoise soup, and so on. Are there others that come to mind that may be noteworthy to mention

here?

WB: The cyanide and Tylenol episodes were among the most serious.

The cyanide in the Chilean grapes incident was interesting in that the Baltimore District laboratory found traces of cyanide in a grape that came in through the Port of Baltimore. That was to a very difficult decision for FDA management to make, whether to basically put a hold on all future incoming shipments of Chilean grapes and recall all Chilean grapes that were currently on the market. At that time, John Taylor was the ACRA, if you remember. I know that John really agonized over that decision because he knew what the impact would be if FDA recalled all grapes from Chile and put a ban on imports for a period of time and started sampling everything that was coming in. I remember discussing the situation with John, and he was agonizing as to what he should do.

RT: In that incident, the agency did send some representatives to Chile, who unfortunately were killed in a plane crash.

WB: Yes, it was in a plane crash.

RT: After that tragedy occurred, was there further sending of agency representatives to visit food source countries to conduct such investigations?

WB: I don't remember exactly what we further may have done

in regard to Chile and the grape situation. I know we've had similar situations with other fruits and vegetables, particularly coming out of Mexico. There have been a number of situations where we had *salmonella* or some other organism on fruits and vegetables coming out of Mexico, and we sent investigational teams down to Mexico to visit farms, and work with the Mexican government to see what we could do to improve conditions there to eliminate those problems from reoccurring.

We had a serious problem with cantaloupe about four or five years ago. It developed in southern Arizona, where a distributor recalled all the cantaloupe they'd imported for the previous sixty days or something like that.

RT: What was involved with the cantaloupe?

WB: I think it was *salmonella*. I'd have to check. We also had the big strawberry recall, if you remember that one. That involved strawberries coming out of Mexico. This was a USDA/FDA joint thing, because a lot of strawberries went to some USDA programs and . . .

RT: Some foreign governments have objected to some products that we have exported. Have any of those foreign countries come over here to the United States to check on our producers that you're aware of? That is to do the reverse of what we've been talking about?

WB: Not on foodstuffs that I'm aware of. I'm trying

to remember. I think there have been some joint inspections by representatives of a few countries related to drugs that were manufactured in the United States and distributed in their countries, so they looked at some drug operations.

RT: How about regarding the mad cow disease problem, for example?

WB: Well, I don't remember any foreign investigators being involved in inspections or investigations on mad cow disease. They pretty much accepted what we provided to them, as far as I know.

RT: Are there any other areas that . . .

WB: Oh, Tylenol was the big one. That one also involved cyanide, which we were earlier talking about. The cyanide grapes problem was a serious situation, but we also had cyanide in Excedrin and Tylenol products. Basically, McNeil Labs took off the market every product they made because of the problems they were having with cyanide. I remember we sampled just about every product they made. We had tons of products going to FDA laboratories for analysis..

RT: That was a tampering incident.

WB: Yes, it was a tampering incident.

RT: Legislation was enacted by the Congress to deal regulatorily with that problem, the Tampering Act.

WB: Yes, the Anti-Tampering Act was passed.

RT: Some of the industry now has gone to tamperproof, or tamper-resistant packaging, particularly for pharmaceuticals and other products of that nature.

WB: Everything is sealed and double-sealed and glued, fixed in a manner to prevent any possible tampering, or counterfeiting. That's another area that we've gotten into in the past several years which has gotten to be quite a problem and the recall staff here has been directly involved directly in it.

We were actually working with a number of drug companies over the past several years in situations where we learned there were counterfeit products on the market.. Sometimes it's difficult to distinguish between a tampered product and what's a counterfeit product. We've had people who would go to nursing homes, institutions, and buy a patient's drugs, buy bottles, empty bottles from nursing homes, get diverted drugs, drugs returned. You name the possible sources that you can think of, and these people have a way of somehow accumulating these drugs, turning around and packaging them and reselling them. We found situations where we'd have three different strengths of the same drug in a bottle labeled as one strength, and usually it was a counterfeit label. Or maybe an original label, yet it's a reused bottle with an old lot number. Anything that can be done to make a dollar is done.

But OCI, FDA's Office of Criminal Investigation, has had extensive ongoing investigations into counterfeit drugs for several years now and has made extensive arrests. There's been a lot of publicity on the arrests. I believe a year or two ago, about forty different people were arrested for counterfeiting.

There is a secondary and tertiary wholesale market out there with firms that are licensed as drug wholesalers but are in fact just paper movers. They'll just have stuff drop-shipped from each other. Ron buys from Bob, and Bob buys from Jim, and Jim buys from Dave, and Dave buys from somebody else down in Florida who actually has the drug counterfeited in Mexico or Ecuador or somewhere else and then brought in through the border into this country. These guys often don't even warehouse it. If they're buying it at cheap prices, they add a few bucks to each bottle. Eventually, they're going to try to get to the point where they're going to sell it back to Amerisource or Bergen Brunswick or Cardinal Drug, one of the big wholesalers, to get it out to the market. Some of them actually have flyers and do advertising to the retail pharmacy market, by saying something like, "You're paying X number of dollars for this drug and we can get it to you for \$20 a bottle cheaper." A lot of this was going on.

It seems, at the current time, that the publicity, the

arrests, and other things that have happened through FDA's OCI, and some of the regular district offices, plus the agency's regular investigational efforts have curtailed a lot of the counterfeit operations. But we've had a lot of recalls in the past five years relating to counterfeits.

RT: As far as expiration dating on products, and, in particular, pharmaceuticals are concerned, does the agency have any program for monitoring that, or is that more of the pharmaceutical provider's responsibility. I'm referring to products that may be over the expiration date?

WB: I'm not aware of the agency doing any monitoring of that particular aspect of the industry. I think the agency expects the industry, the retail trade, whatever, to stay on top of that, and if products expire, not to sell them, but to return them. I don't think FDA has resources to be involved in doing what we used to call surveillance. Back in the good old days, we did surveillance.

That was one of the early things I was going to mention. Back in Baltimore District during the early sixties, when we had thirteen new investigators and not enough older investigators to train them, they would send us out to do surveillance. We would go to a drugstore and just walk around and look for products that appeared to be in violation of the Federal Food, Drug and Cosmetic Act.

One day I was in a Towson [Maryland] drugstore, and

there was a cardboard cutout, full size, actual adult-size cutout of Jayne Mansfield in a bikini, which was advertising the Jayne Mansfield Health Tan Sunlamp, guaranteed not to burn. Well, I was right out of college and didn't know much but I knew that if you put your arm under a sunlamp long enough, you're going to get burned. Right? So I did my surveillance work and got the basic information about it, where the pharmacy purchased it and everything.

I went back to the office and told my supervisor. He assigned Remle Grove to go with me -- I was a GS-5, Remle was a GS-11 -- to do this investigation. We went to the gentleman's house up in North Baltimore, and he had a basement full of these sunlamps and the Jayne Mansfield cutouts. We gathered all the background information and documented the shipments and sales materials. FDA then seized the whole kit and kaboodle. That was my first FDA seizure - the Jayne Mansfield Health Tan Sunlamps.

After we collected the sample and brought it back, one of our scientists -- I don't know whether it was someone in the lab or someone down in CDRH in headquarters -- but somebody took this lamp and put it on their table, put their arm under it while they were working for a few hours and got a serious burn. That is how we proved that this Health Tan Sunlamp was violative and wound up seizing it.

To get back to the Tylenol and the Excedrins and the

cyanides, that was a very scary time. People were very cautious about taking medications and not knowing what could be done. In each case, it seems -- remember the Excedrin, it was like an airline stewardess took some Excedrin and passed away with cyanide poisoning, whatever, and it turned out it was a family kind of thing, I believe. Someone in the family was trying to get back at somebody else and it got out of hand, and people who were not supposed to have gotten the drug got it and wound up dying. It was a serious situation. Very interesting times.

RT: We understand that your associate, Remle Grove, has compiled quite a stack of exhibits of recall data. What disposition is intended for that compilation?

WB: Well, what happened is that, over the years, we've had a number of FDA recall task forces which have wanted to revisit the recall operational system to see if it was working properly, and see what changes, if any, need to be made. One of those task forces wanted to develop an agency recall history. So we went back and developed that, however, it was brought up only through '81. But from 1937, when the first sulfanilamide recall took place due to toxic ingredients all the way up to May 15, 1984, and it includes the background of the significant changes and developments over the years in recall operations.

RT: So, let me ask. Is this compilation regarded as

the agency's formal historical record in recall operations?

WB: Yes. There is a stack there of about four inches of documents and these are part of the Office of Enforcement archives. They have agreed to provide them to the History Office for you to copy and put into FDA archives or the National Library of Medicine, or whatever it is that you see fit to do with them. I think they will go a long way towards providing a formal history of recall changes and developments over the years.

RT: For researchers who have an interest in recall operations in the agency, that will be a good source of information.

WB: Absolutely.

RT: Fine. Is there anything else in your experience that you'd like to mention in this interview? You've had an extended tenure, having been in the agency for forty years or so. For example, was there anything in particular that led to your decision to retire when you did? You're still a very youthful-looking man.

WB: No, there really wasn't. There was nothing. I had reached my plateau of getting full 80 percent retirement, and my wife was tired of me being away from home so much since I was putting in a tremendous number of hours. For the last ten years, we've had any number of people who have rotated through the office and have assisted in recall

operations.

TAPE 2, SIDE B

WB: I've been handling the Office of Enforcement side of recalls pretty much by myself in large part, and have put in just a lot of hours, commuting an hour and half or so each way every day. And often my wife would call at five o'clock and say, "Are you coming home on time tonight?" Well, it's already a half-hour late, but, "Yeah, I'll be there." And just as I hang up the phone from her, the phone rings and it's someone in Seattle or San Francisco who has a problem and they need to work something out, so I'll wind up staying to take care of the West Coast problems, and then it's eight-thirty, nine o'clock when I get home. There's just a lot of fifty to sixty-hour weeks, and it was just getting very, very old to my wife.

Despite the long hours and stress involved, enjoyed my job, I loved the people I worked with. It's always been a great, great team, a really great team. The field coordinators were very responsible, dedicated people, and I just enjoyed working with them so much, so it's really been a pleasure. I've never had a situation where I woke up in the morning and said, "Oh, God, I've got to go to work today." I'm always thinking about, "Well, hey, we've got this so-and-so situation to work on today. We've got to do

this, we've got to do that," and its fun. It's still fun, even now as I'm thinking about it, and now I'm getting involved in some consulting related to it. There are still things that I enjoy, and I'm still working with the same people.

Currently, I'm setting up with meetings with the management and recall staff of each region and FDA district, and with the company, NNC Group, that I'll be serving as a consultant to...

[RECORDER SHUT OFF]

WB: . . . that is, the management of some firms who are interested in consultant help with the handling of recalls.

RT: As you look back at the recall operation in the agency in which you've been so vitally involved, do you have any thoughts or recommendations for changes. For example, do you feel it would be critical for the agency's headquarters recall staff to have an extended hour work schedule, to provide coverage consistent with the West Coast three-hour time differential so the headquarters recall staff doesn't have to extend themselves for dealing with those things that arise after regular working hours here?

WB: Well, it might be helpful. But over the years, it seems that it's pretty well worked out. They know that if

there's something coming up out there, they need to let us know early on. And we all have Blackberries now. I say "we." See, I'm still in FDA. The recall staff has Blackberries that are also telephones so they can send an e-mail, get phone calls, and be contacted 24 hours a day. And now headquarters has got two dedicated people, in Mel Szymanski and Pete Cook, who are the recall officers in the Office of Enforcement. So you have two full-time people, which we haven't had for some time now. I think they're doing an excellent job so far, staying on top of things, and managing things well.

RT: Prior to the system that we've got now, how was it that we used to send recall information?

WB: Teletypes. You had to write, you handwrote everything you did. Then you gave it to a teletype operator, and she'd type it all out and send it. You never knew what quality you were going to get or how long it would take to go out. Now everything is sent instantaneously. With e-mail, you're just constantly sending things back and forth all day. There's a tremendous amount of e-mail. I used to get fifty to sixty e-mails a day easily, just a tremendous amount of e-mail. In fact, when I left, I had thousands of e-mails that I'd never read. I just scanned them. The ones that were critical, the ones that needed to be handled, were taken care of. Those that were just not

necessary to read, I just filed them. A lot of my files I've never read. It's just impossible to keep up. One man cannot do the job, and it's a big job for two people in OE.

There's one thing that I think is important. The new Recall Enterprise System that we just touched on gives the opportunity, and establishes a database for the first time, for an agency-wide database that can be accessed by the field or by the Centers or by any manager who wants to have access to it, to know exactly what's happening with any recall at any given time. It can do trending and analysis, do all kinds of historical information, gather tremendous numbers of reports and things that are available to the system, and to the Office of Enforcement which oversees that entire operation. Anything that happens in the recall system, whether it's field oriented or Center oriented, is all overseen, and the OE has the opportunity to handle all district and center operations. If there was a recall in a district office and the district coordinator was out sick this week and there was nobody there to put the information in the system, then OE can put the information in. OE can also classify the recall if the Center coordinator isn't there or the Center coordinator needs help for some reason, OE can -- we have total access to the system. It's an agency-wide system, and OE staff are the managers of that system.

RO: Is it a secure system?

WB: Yes, it is. You've got to have a password and program clearance to do various functions. So we've got that kin of security.

But the system also has a very critical point that was part of the reason for development of the system to begin with. There was concern FDA was not getting information on recalls out to the public in a timely manner. That concern is still out there.

When we had the recall just this past week, when Able Laboratories recalled all their products, and the new ACRA was asked about it and he was on television. There were still complaints about that, including some from congressmen that FDA didn't get the information out quick enough.

Well, the system was devised to help eliminate that problem to a large extent, and here's how it happens.

When an alert comes in from a district office, it is reviewed in the Center and the Office of Enforcement, but primarily the Center. The basic information is there which tells what the product is, the recalling firm and the reason for recall and the lot numbers involved. Just those four basic things.

The Center coordinator then hits a "send" button that says, "send to the Internet." The information then is automatically sent to an Internet database which is

continually maintained. It's all part of the RES system. It's a separate file but it's part of the RES system. Then, as of midnight every day, everything that's sent to the Internet during that day is automatically put into the system. So tomorrow morning at 12:15 a.m., a consumer could get on the Internet, go to the FDA website, bring up the system, and can read the alert.

As things change, and as the recommendation comes in, now we've got twenty line items filled in, a lot more detail, a lot more background and things, including firm contacts, what time the recall letters went out, who they went to, and all this kind of information. When that recommendation comes in, the Center again reviews it, updates the Internet, and at midnight it goes to the Internet, so the next morning that information is there. It just keeps updating. And when it's finally closed out, it gets updated. So the information is available on a 24-hour basis, almost -- and real time is the buzzword, real time -- in comparison to the FDA enforcement report, which reports recalls after they're classified, weeks following their classification. It may take six weeks from the time a recall starts before all of the paperwork is done and it's officially classified and gets put on the enforcement report.

If you're talking about a biologic recall, it may be a

recall that a blood bank did a year ago, because there are thousands of them. And the field people didn't get to do the follow-up on that and get the information into the system, until now. So if you look at the enforcement report and you look at when the recall took place, you'll see that probably the most recent recall listed may have taken place three weeks to a month ago. You'll find that maybe some are six months old or a year old from when they took place, so it's old information.

We have a system which will allow the public to know about a recall on a real-time basis. The problem is that management at the present time has not seen fit to release this Internet portion to the public. The information is being put into the database. It's available, but it's all behind the firewall. There's a firewall that has not been broached [sic] to release it to the public. This has been since November 15, 2002, and it's still not generally available to the public.

RO: So when you were saying that this is released to the Internet, it's really not released . . .

WB: Not to the public Internet. No. It's supposed to be. That was the design of the system. But FDA managers have not seen fit to release it to the public. The enforcement part is still being done and this information is being accumulated, it's in the RES database. The press

office goes in and updates it. When there are press releases, they go in and put in the press-release information. The OPA (Office of Public Affairs) technicians are doing this work. It's all been going in to the system, but it's not released to the public.

I'm hoping that David Elder, the new Office of Enforcement Director, and the new ACRA will decide to cut this loose and release it to the public. Then we'll have a real-time information system when that happens.

RT: Has a recommendation gone forward on that point to Dr. Crawford?

WB: Directly to the commissioner, not to my knowledge. It's still in-house within the office of the ACRA.

RT: Well, that seems to have pretty well covered it.

We certainly appreciate your comprehensive coverage of the agency's recall operations, and wish you well in your future activities. You will perhaps be able to promote an increased awareness and improved cooperation in recalls on the part of industry people with whom you consult in the future.

WB: That's exactly what I'm planning to do. In final summation, I can show you an e-mail that Atlanta regional district director Gary Dykstra sent me yesterday in which he said that the meetings we're having with the industry through his regional and district offices are

furthering the education and commitment that I've had over the years to improve recall operations, both within the agency and the industry. He's in favor of such initiatives within his districts.

RT: Thank you Willie for this oral history interview.

END OF INTERVIEW