

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

**Interviewee:** David Haggard

**Interviewer:** Robert A. Tucker  
Ronald T. Ottes

**Date:** May 30, 2001

**Place:** Rockville, MD



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David Haggard

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Last position held: Director Div. of Compliance Policy, DE, FDA

Date: \_\_\_\_\_

Interviewer: \_\_\_\_\_

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Director, National Library of Medicine

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

Date: May 30, 2001

Place: FDA History Office

INTERVIEWEE

NAME: David Haggard

INTERVIEWERS

NAME: Robert A. Tucker,  
Ronald Ottes  
ADDRESS: FDA History Office

FDA SERVICE DATES: FROM: June 1968 TO: June 2001 RETIRED? Yes

TITLE: Director of the Division of Compliance Policy in the Office of Enforcement/ORA

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RO: This is one of a series of FDA oral history recordings. Today we are interviewing Mr. David Haggard, Director of the Division of Compliance Policy in the Office of Enforcement. The date is May 30, 2001. The interview is being taken in the Parklawn Building. Interviewing Mr. Haggard is Robert A. Tucker and I'm Ronald Ottes. This interview and the tapes of the interview will be placed in the National Library of Medicine and become a part of the FDA Oral History Collection.

Dave, to start the interview, we'd like to have you give a brief biographical sketch of where you were born and raised, educated, and any relevant work experience prior to coming to FDA.

DH: I was born on October 24, 1942 in Lincoln, Nebraska. As a child, I moved around considerably. I lived in Nebraska, Colorado, Washington, Oregon, California, New Mexico, before I ended up in Maryland by the time I was in the eighth grade. I think I was in the eighth or ninth grade before I spent more than a single year in the school system.

RO: Were you the son of a military person?

DH: No, I was the son of a mother that had itchy feet and went through a series of husbands. (Laughter) But a very strong woman.

I went to the University of Maryland, graduated in 1968 with a degree in zoology and a minor in science. Going through junior high, high school and college, I worked ten years in an animal hospital in Riverdale, Maryland. My work experience there kind of prepared me for my subsequent career with FDA.

I used to work during the summers as many as ninety hours a week, and then sometimes work the nights where I got paid by the night. During my senior year in high school I actually averaged about forty hours during the week. I used to work before and after school. So when I actually started with FDA, it was like cutting back on my hours and taking a job that had much more career potential.

I remember how I first got interested in FDA. I was initially interested in becoming a veterinarian but did not get into veterinary school. I had gone to a job fair at the University of Maryland, where there was an individual, Tom Price, who was a supervisor in Baltimore at the time. He was under a

sign that said “HEW” (Health, Education and Welfare). “We’re looking for scientists.” I started talking to him and he said, “What’s your degree in?”

I said, “I’ll have a B.S. in zoology with fifty-some credits and a total of about ninety or a hundred science credits total.”

He said, “Well, perhaps you’d be interested in a research position at NIH (National Institutes of Health).”

I said, “Not really.” I said, “I would like something where I use my science background, but I would like something where I deal with more people.”

He said, “I have just the job for you.” And he told me about FDA investigators, and I went up to the library and I read up on it. June came. They asked me to kind of hold. At that time there was a freeze in FDA, and they said, “We think we’ll be able to hire one before the end of the month.”

I got called on a Thursday to come to Baltimore for an interview on Friday, they did a background check, and they swore me in the following Monday.

RO: Where did you report then?

DH: Baltimore, Maryland. I worked for a couple of months and then got drafted. I went into the Army right after Labor Day in 1968, stayed there until July 1970 where I worked as a medic. Also I spent a year overseas in Thailand, where I primarily did food inspection for the Veterinary Corps. They were looking for people that could step in and do food inspections and when they heard that I had worked for the FDA, they thought I was their person. They took me on with no training.

If you smelled something and you thought it was questionable, you thawed it out. If you still thought it was questionable, you’d take it to the mess hall and they cooked it. If you still didn’t know, you tasted it. That was my early training in organoleptic examinations. You can train yourself to detect food that’s bad. That was the most sophisticated test we had overseas.

RO: Were you also involved in inspections in terms of sanitation, as well as food quality?

DH: Not really. There we were serving food to the mess halls, but we did some work with the Thai government, because everything we imported was subject to their inspection. So they would come out and sample food items. It was more of a perfunctory-type examination. But primarily we were just checking the food to make sure it wasn't spoiled – but there were other people elsewhere that did sanitary inspections.

I returned to Baltimore in July 1970. About July 1972, I transferred to the Richmond, Virginia resident post. In January of 1975, I became the resident in charge of the Norfolk, Virginia resident post. In December 1978, I moved to Buffalo District, Buffalo, New York, as a supervisory investigator.

RO: Let's back up a minute. What type of inspections did you do primarily when you were in Richmond and again in Norfolk?

DH: Let me start a little bit with Baltimore, because there's an interesting story about it. In Baltimore I did a little bit of everything, but there was a particular inspection that, to me, was very important in my career development. That was the inspection of a Food Fair warehouse. I did an inspection of them probably about 1971. I had been back with the agency maybe fifteen, sixteen months.

The firm had been inspected several times during the previous year, and at each inspection we found some evidence of mice. I went in, I did a one-day inspection, I found evidence similar to what other people had found. I wrote the report that the firm destroyed one lot of goods. I sent it to my supervisor, who forwarded it on to Don Sherry, who was the DIB, as the chief inspectors were called then.

Don Sherry said he thought maybe there was more there that I had missed. So he sent it back to my supervisor. My supervisor, who was Bob Rice, told me that Don wanted me to send someone else out on the inspection because maybe I was inexperienced and I might have missed something. So I said, "Well, maybe I did. If I did, I should go back."

He said, "Well, Don thought that would be kind of a conflict, and put me in an awkward position."

So I went in to see Don Sherry and I said, "The issue really comes down to whether you trust me or not." I said, "You send me back and I'll redo that inspection and if there's anything more there to find,

I will find it.” I said, “You have no reason not to trust me.” He was reluctant, but he agreed. I went back and we developed a prosecution. (Laughter)

Years later he handed the report out to new people and said he thought it was an example of one of the finest inspections. As I said to him, “I learned, never, never get lackadaisical. Always give it your best.”

RO: Did you go back alone or did they send somebody with you?

DH: Yes, I went back alone. I said, “You send me back alone, I will...” And after three days, I found a lot of things. I started really digging and more people came in to help, and we ended up prosecuting the firm.

RO: What was the lapse of time between your initial and return inspections?

DH: Oh, probably a week or two. What I found the second time had to be there the first time. (Laughter) But what I appreciate about Don Sherry is that, when I went to personally talk to him, I said, “I will go back, if there is any more there to find, I will find it.” I said, “You don’t have reason not to trust me on this.”

He said, “Yes.”

And I think it’s an important principle that people want to be trusted and they do their best when they’re trusted. So it was kind of a turning point in my career.

When I went to Richmond, it had more drug work. They had A.H. Robbins and William Poythress. I started doing investigations of the clinical investigators. Back in those days we also did inspections of the methadone clinics.

When I went back to Norfolk, Virginia, I handled primarily food and imports but I did some unique things in Norfolk. We worked with the importers and I started working with the Import Association. At the time a lot of cocoa beans entered the U.S. at the Port of Philadelphia to be shipped to



Hershey and places like that but the entries were being delayed. The Norfolk Port Authority obtained a tremendous contract to get these cocoa beans, but they really didn't have the storage facilities needed. They approached me and they said these cocoa beans have to be entered and they have to move fast, because if another ship comes in we won't have room to store them.

I explained the process, that often when products arrived in import status, we didn't even know about it for a week or more. So we worked out an understanding where they would notify me when a ship was coming in, we would run by and the warehouseman there would tell us which cocoa bean shipments were being entered. We would take a look at it. If we saw insects, water damage, whatever, we would not collect samples but instead do it as a documentary sample (means no physical sample). We would tell the warehouseman that these lots had to be either fumigated or reconditioned. He would start the work and he would let us know when it was completed, so we could reinspect it.

We would fill out the paperwork and once they had been notified, the brokerage would come in. We would send it out. They would officially detain it. They would do all this other stuff. But that might follow weeks or sometimes afterwards. They understood all of this. So Baltimore said, "You're on your own." See, you have to realize when you get in 100,000 tons of cocoa beans and the next ship may be sitting at dock, I said the cost of all of this is minor compared to the demurrage costs. We did it for two years; we never had a single hitch.

RO: You said "we." How many people were assigned to the post?

DH: When I first go there, there was a person by the name of Don Meska. Don Meska had, at that time, seventeen years with the agency, and I had about five and a half. I started with the agency about the time he showed up at Norfolk as the second person in charge. He had been promised that when the resident in charge, Schylure Elsbree, would leave, he would be in line to get the resident in charge. So when I showed up, a lot of people thought there would be hard feelings, because initially I got the position which by all rights he expected to be his.

Don and I worked together very well. It was a good kind of management training, because what I would say to Don on imports, was, "Okay, we need to cover this," and I would make sure I covered my share and Don would always make sure that he would cover his share, so we worked well together. But it was never my actually telling him he had to do this or that, but us just working in a cooperative fashion.

It amazed some people in Baltimore, at that time, because they said, “You’re just a kid going down there over a person that has a lot more years.”

But even in Norfolk I use to do the BIMO (Biomedical Research Monitoring Program) inspections, non-clinical bioresearch laboratories, when we started those inspections. In Richmond, I had also done inspections of radiopharmaceuticals. I was the only one in the district who was trained in radiopharmaceutical inspections. So I did a significant amount of travel outside of the Norfolk area to Washington and western Virginia, and did a number of bioresearch-type inspections.

RO: When you were in Richmond, were there other drug firms besides A.H. Robbins?

DH: Yes, Poythress.

RO: Where was that? Was that located right in Richmond?

DH: Yes, that was right in Richmond. Poythress, I don’t even know if it’s still in business now. Poythress at one time had A. H. Robbins Sr. working for them. Then A. H. Robbins vastly exceeded what Poythress was. I mean, A. H. Robbins became at least ten times, twenty times bigger than Poythress. But there was an old gentleman at Poythress who was kind of like a Southern gentleman, and he would remind me that A. H. Robbins, Sr., once worked for him.

RO: When you were in Norfolk, was fishmeal still being imported for animal feeds and similar things?

DH: I don’t think so. I don’t really remember fishmeal coming at that time.

RO: At one time, there was a big problem with fishmeal corning for the animal feeds and salmonella, and so I was wondering.

DH: I don't think so. For a time they got a lot of cocoa beans.

RO: You were at Richmond before going to Norfolk, is that right?

DH: Yes, I spent three and a half years at Richmond.

RO: Were there any particular cases or other regulatory matters there that stand out in your mind?

DH: Yes. There was a gentleman by the name of Wheelright who operated out of, I think, Salt Lake City. He would fly around the country with a half dozen people and put on conferences, typically sponsored by health-food stores. He had this health food line of vitamins and what we would now call dietary supplements. He would give a series of three lectures. I attended these lectures unidentified.

He would talk about all these different diseases and how he could read the soles of your feet and the irises of your eyes, and he would prescribe these dietary supplements to save your life. His therapy typically ran about two hundred to five hundred dollars a month. It was rather expensive. Then after the three one-hour lectures, he would stand up there, and it was just incredible, the type of things he would talk about. He would say how he carved out an ice cave in Alaska and he lived for two weeks just taking these little E-pills, which were high-energy pills, and how you couldn't wear a watch on your left hand, because that would interfere with your heart. If someone had a heart attack, instead of calling a medic, you just massage a pressure point above the heart.

I would look around the room and I saw people there from college, people that could be my neighbors. And this guy was just utterly ridiculous and people were just buying it. Then when he was signing people up, people were fighting to get appointments. By the time I called the district to see if I could actually go to an appointment, he was already booked for two days. It kind of impressed me how vulnerable and how naïve people can be to the old-fashioned type con.

RO: In that instance, did you ever use a recorder and tape his presentations?

DH: No, that was in the days when we couldn't do that. You listened, and when you got out, you wrote as much as you could immediately recall. So I would go to this lecture at night, get out of the lecture, go to the car, drive to an obscure point and start writing notes down left and right, because obviously I couldn't really take notes. If you're pulling out paper and taking a lot of notes, they would get suspicious. He skipped in and out, but it was an interesting experience.

The other thing that I found interesting at the time was a drug called Imipramine. I forgot what the legitimate use is, but it was used by a lot of pediatricians to give to children for bedwetting.

RO: What was this drug?

DH: It's Imipramine. Because you can give it to them at bedtime, and it does something that retains the urine or something like that, so they don't wet the bed. If you get an overdose, it's extremely toxic. At the time we had three or four reports of death, all in children. I went out and investigated those to obtain adverse drug reporting information.

It really left an impression on me, because a couple of the doctors I talked to were totally unaware of the potential adverse effects of the drug if it was overdosed. In fact, one denied that it could kill a child. But in one case a babysitter had given a child a tablet and left the bottle on the table next to the child without the cap on. She left the room, and realized it a couple minutes later. She came back in and the child had taken the tablets. They called the doctor immediately, but the child was dead within twenty minutes.

In each of the instances, it was an accidental overdose or something like that in which the drug was so potent, it caused electrical disruption in your heart. If they took any number of them, the child was as good as dead. I remember at the time thinking that none of the parents were aware of the possible impact of an overdose, and, for the most part, the doctors were not aware either.

RO: So that was a failure of the company to have proper warnings?

DH: For the life of me, I don't remember now whether the literature had the warnings or not, but what I remember is that even if it did, doctors generally aren't aware of all the adverse effects, and most parents or patients are not aware of these things. I mean, if someone had given you a medication and said, "Give your child one of these every night to stop bedwetting - if there's any chance that your child takes a half dozen, that child is as good as dead," I think that most parents would have said, "I'll put up with the bedwetting."

RO: What was the endpoint of that investigation?

DH: I filled out the information and sent it in, and I really don't know if it changed the labeling or not. It just had an impact on me that drugs had a potential for very, very serious adverse effects that most people aren't even aware of.

RO: Now, going back for a moment to the previous spieler of health food or fraud claims, what was the end point of that situation?

DH: We didn't do anything, because he skipped on to another town. He would fly in and he would stay in town for three or four days. Frankly, at that time spielers weren't a high priority. So the report simply got forwarded to the home district, and I don't know whether they took more action.

RO: I just wondered if you happened to know.

DH: I made a visit to a health food store about a year later, and they looked at me like they weren't sure if I was at that meeting. It was interesting, I showed them my credentials and I think they semi-recognized me, but they never brought it up. I think it made them very nervous.

RO: Where was the point of origin of the food or dietary supplements? It was another district apparently, other than Baltimore.

DH: Yes, he operated out of Salt Lake City. It wasn't a national brand. I think it was something that he was essentially putting his own little labels on and sold to health food stores, but typically they sold it from under the counter. You had to go in and say, "I want some H-pills," or, "I want some E-pills," and they would pull this out. It was rather expensive. It was interesting because you see aspects of how people believe these things.

RO: That part of the country is the point of origin of a number of dietary supplements, and I believe that one of the prominent members of Congress was instrumental in trying to curb FDA's dietary supplement additives.

DH: One Senator promoted it on grounds that people have a right to pick and choose. I agree with that, but inherent in that is knowledge of the properties associated with it. I don't have to tell you, there are a lot of dietary supplements that no one knows very much about.

My concern is down the road somewhere someone's going to find a dietary supplement that no one thought was hazardous, but now we know, because a million people have taken it for ten years, that there's a high instance of some very serious condition that we would only have known of after people have been injured. With legitimate drugs you monitor the adverse drug reports, because you never know all the impacts that a drug may have until it's tested on a large number of people. And drugs go through a lot more testing than dietary supplements, which in many instances may go through no testing.

RO: In your career in the Food and Drug Administration, has your experience primarily been in the drugs area, or have you been in the broader range of activities as you moved along?

DH: I've been in the broader range. When I was in Norfolk, we started regulating medical devices. I did some of the early inspections of medical devices, intraocular lenses and artificial kidneys. So it's kind of been dictated by the area that I was in. But late in 1986 I was the director of the investigations branch in San Juan, Puerto Rico, and about 50 percent of our investigational force spent full time in the

pharmaceutical industry, and about 25 percent on medical devices. So it was more heavily weighted toward pharmaceuticals.

RO: Before you went to Puerto Rico, you served in Buffalo for a time, is that correct?

DH: Yes, I went to Buffalo in December 1978, and left Buffalo January 5, 1986. I was in Buffalo for seven years.

RO: At your Buffalo service point, were there any significant matters that you dealt with there that differed from those that you've talked about so far?

DH: Yes. I can look it up, but I don't remember the name. It was something like Buffalo Plasmapheresis Center. They had two plasmapheresis (takes blood, returns red blood cells to the body leaving plasma) centers in the Buffalo area, and they were engaged in some falsification of records and lot of poor processing deficiencies. Under my supervision, Mary Cardin, who is now a national biologics expert, completed one of the earliest inspections. Subsequently, we revoked their license, and I think it went to prosecution. I'd have to look that up, also. But we revoked the license for both establishments.

There was another inspection, and it was a clinical investigation that I did along with Mary Carden. (At that time, Mary Carden did have the special credentials to do clinical investigators and therefore we did a joint inspection.) This individual was a cancer specialist and he did a series of seventeen clinical studies for NIH, and he was keeping two sets of records, one which was accurate and showing half-doses of medication and one showing he followed the required protocol of using full dosages that he submitted to NIH.

[Begin Tape 1, Side B]

It came to light when the numbers that didn't add up comparing what the hospital pharmacy dispensed to what the doctors records showed were being used. Eventually it led to his prosecution. He was falsifying records that were being submitted to NIH showing patients were administered full doses when in fact they were only being half-dosed.. His initial response was that he thought that he was benefiting his patients because by giving half doses they didn't suffer nearly the adverse effects that they would have. From a medical prospective he may have been doing serious harm to them, because cancer drugs frequently at half dose may be very ineffective.

RO: Was there any findings in your investigation of that?

DH: We didn't pursue that aspect of it, because it then becomes a medical judgment. So we didn't prosecute him for that. We prosecuted him for the information he was submitting to NIH, showing that there was no adverse impact which resulted in people dying on half medication while NIH would have thought it was based on full medication. So from a scientific evaluation of the effectiveness of the drug, you're doing serious harm to someone who's trying to evaluate it. "Well maybe we could up that dosage, because there are no side effects here and it doesn't seem to be effective.

So they might either pass on it as not being effective or they might think about increasing the dose, thinking that they got the full dose. So from a scientific point, where you're trying to rely on the safety and effectiveness in doses, what he was doing was extremely detrimental to making safety decisions.

RO: Was this individual an oncologist? Was he a qualified practitioner in carcinoma?

DH: Yes. His medical practice was limited to cancer patients. He worked through several hospitals there that were quite well known and very reputable. When we asked him for his Institution Review Board (IRB) Committee approval, he provided forms to us, not thinking that we would go out and verify. He simply falsified the approval, the people existed, but they were unaware that the doctor was even conducting the studies for the NIH.



But it was interesting, because even after we had all this evidence on him, he sat there and contended that as a doctor he thought he was making the right decisions for his patients.

RO: Pitt Smith was director at that time?

DH: Yes.

RO: Burton Love was –

DH: Burton Love was the director of the investigations branch the entire time I was there, up to just a couple months before I left. Pitt Smith was there, I think from about five or six years before I left, to a number of years after I left. As you know, Pitt was very enforcement minded. I can remember one time we had gone three weeks without a regulatory case being submitted to headquarters.

Pitt called the district together and said, “It’s been three weeks and I don’t have a single seizure, injunction, prosecution or regulatory recommendation.” He said, “This has to end now. Everyone that’s on detail returns to their office. I don’t want any supervisor to hold a group meeting. I want their people out finding an action.” He said, “I don’t even want any supervisor taking a break until they can look me in the eye and tell me that they’ve done everything they can to get a legal action.” He said, “That’s the word,” and he left.

So the next day I said to this other supervisor, Dave Kiessling, “Let’s go down and get a Coke.”

He said, “You heard what Pitt said.”

I said, “You understand Pitt was just being emphatic. Don’t take everything he says literally.”

He said, “I’m not taking a break.”

So I went downstairs to get a Coke. Pitt was down there. He walked up to me and he said, “I thought I said I didn’t want to see any supervisor taking a break.”

I said, "Pitt, what you said is you didn't want any supervisor taking a break until they can look you in the eye and tell you they done everything they can to get you a legal action." I said, "Pitt, I've always done everything I could to get a legal action, and I knew you would want me to take breaks."

Pitt said, "Well, all right." (Laughter)

Pitt used to say, "Is it my fault that everyone takes me literally, when I'm just trying to make a point?"

RO: Who was the director of Compliance?

DH: When I first got there, it was Ray Sweeney. Then later it was Ed Thomas, but Ray Sweeney was the first one. I really enjoyed working for Pitt. You knew where he was coming from; you knew to hold your ground. I had a new investigator that started working for me and had only been there about two months when I had sent her on a road trip to Rochester. She called me one morning and she said, "Dave, I'm in this inspection. It's a bakery, they have various mixed cookies. They have this commingled lot. It's insect-infested. I have three questions to ask you."

She asked me the three questions and I answered them, and I said, "Do you need help?"

She said, "No. No I can handle it."

So I said, "Okay."

So I got off the phone, I went and told Burton that we had a possible seizure. Burton Love said, "Dave, she's only been with us two months. I think you should go immediately to Rochester and help her out."

I said, "I can't do that. I asked her if she needed help and she said, "no."

He said, "What do you think the chances are that she'll blow it?" I said, "About 50-50." I said, "After all, she's brand new." He said, "Well then don't you think you should go up?"

I said, "No. Worse than if she blows it, is that I asked her if she needed help, and if I go up now, I'm telling her I don't trust her."

I said, "That's the worst thing that I can do." I said, "I can't do it."

So he went in and he tells Pitt. Pitt comes to my desk, stands over my desk and he says, "I think you should get in the car immediately and drive up there. You can be there in an hour and fifteen minutes."

I said, "I understand that's what you're saying, Pitt."

He said, "So what are you going to do?"

I said, "I'm not going." I said, "If you leave it to my judgment, she said she didn't need help." I said, "If I go up now, I'm not trusting her." I said, "If you order me, I will do it, but I would also tell you that it's a mistake."

He said, "Well, if she blows it, who do I hold responsible?"

I said, "You can hold me responsible, because I'm the supervisor."

So he said, "Well, okay." And he walked away.

Fortunately, the firm destroyed the product. With Pitt, if you held your ground, he respected that. If you caved in, then he would say, "Why do we pay you as a supervisor?" So there would be people that could cave in, thinking he wanted this or that, and then they would get criticized and they didn't know where it was coming from. All Pitt wanted from you, if you were responsible, you would accept that responsibility, and then fine.

RT: When you went to Puerto Rico, who was in charge down there at the time you transferred? Was that Max Crandall or was that after him?

DH: No, Dr. Lynn Campbell was the district director during the first year I was there.

RO: As you've already indicated, there was a great workload in the pharmaceutical area. Was that pretty much exclusively your venue there?

DH: Drugs made up 50 percent of the workload, when I went there; San Juan was having a lot of problems. They had had something like four regulatory cases in the previous four years. The investigators were severely criticized for mistakes when they tried to make a regulatory case. The compliance branch didn't want to take cases. It was a very chaotic situation. It required really turning the district around and getting the investigators excited about doing their jobs. Because even if you don't do a terrific job in documenting inspection findings, finding violations was the primary part of doing the job, and that any criticism afterwards was always less than the points you got for finding the problems to begin with.

In the first year after Lynn Campbell was transferred out of the district and up to Rockville, MD, we had forty-some regulatory actions in Puerto Rico during that year. That was before warning letters. That included regulatory letters, seizures, injunctions and prosecutions. So the district did turn around and became very regulatory minded and, I think, became respected by the industry.

We have authority, and when firms deny it, you have to stand up for your authority. Well, we would have firms that would refuse to allow us to take photographs. We said, "Fine." You would find the first thing that you would normally take a photo of, come back, write it up, send it forward, and get a warrant.

We had one year that we delivered three warrants, inspection warrants to enforce taking photographs. You always got a U.S. Marshal to go with you. One was a large pharmaceutical firm, two U.S. marshals went in, and accompanied the investigator around while they took photos. Newspaper articles appeared in the newspaper about marshals showing up at this firm. They even interviewed some of the management. They said, "I'm just so sorry we ever refused." (Laughter)

RO: You were a supervisor at Buffalo, so you were a supervisor (director of investigations branch) then again in Puerto Rico?

DH: Following Lynn Campbell's transfer to Rockville, MD, we went through a period where we had acting district directors (DDs) on details for about nine or ten months. Then it was Ed Esparza. He was subsequently the regional food and drug director (RFDD) in Dallas before Gary Pierce. Ed became the district director in Puerto Rico around the fall of 1987. I left San Juan in August of '91, Ed had left San

Juan maybe in the spring of '91, and then for the last week I was in San Juan, Stephanie Gray was the DD.

We had some big cases in Puerto Rico. We had one of the original cases regarding generic drugs over in the Virgin Islands. I forget the name of the firm. Later on we had the injunction on Warner Lambert. The investigational work and all that was done during the time I was there, was used for injunction. It was also during the time that the generic drug crisis that we put increased emphasis on approving drugs. So it was a very significant time for Puerto Rico. In the medical device area there was a firm that was making surgical gloves that were recycling their processing records. They would take their records from a year ago, the record date would be in pencil and they would put a new date on it. But if you held the record up to a light, you would see the indentation of the previous year date. If you asked for the records for the previous year date, they were missing. The place was also rodent defiled and we ended up prosecuting this manufacturer of surgical gloves.

RO: Were there defects in the surgical gloves themselves, holes and so on?

DH: Not necessarily, but you have to remember that when you do surgical gloves, you're only taking a statistical sample, and the sample is based on the uniformity of the manufacturing process. So if your manufacturing process isn't controlled, then even a good sample doesn't give you an assurance. We had some reports that he would import gloves and he might have been mixing imported gloves in with the ones he was making. So at that point, sampling doesn't mean anything.

We had different actions down there, even sanitation. At one time in 50 percent of the warehouses that we inspected we found seizable size lots of food that was insect or rodent defiled. Because Puerto Rico is a very warm, humid climate, outside in the environment you have lots of rats and mice everywhere. You just can't control that, because you have food falling off the trees and all of this, so it's a haven. If you're going to be a rodent, you want to go to Puerto Rico. A cold winter night in San Juan could get down to the lower 70's in the wintertime.

RO: Were most of the pharmaceutical manufacturer's prescription drugs or were some of them over-the-counter?

DH: Most are prescription. Some did over-the-counter. Very large. Probably 50 percent of all the dosage form consumed in the United States is actually made in Puerto Rico. So you would have plants that have a batch size of a million tablets and might be making a number of batches every day.

RO: Did they do a lot of bulk drugs, and then were they shipped over to the States for packaging?

DH: No. There were some bulk drug plants there, but primarily it was finished pharmaceuticals. In fact, there were about 100 pharmaceutical firms in Puerto Rico. Of those, 90 are probably large. I think of the largest 30 pharmaceutical firms in the world, at the time I was there, only one did not have a plant in Puerto Rico. I think about twenty or twenty-one of those plants made parenteral drugs.

The reason for all this, there were tremendous tax advantages for manufacturing in Puerto Rico. You could manufacture in Puerto Rico and you didn't see much in the way of research. All the research labor intensive stuff is done in the States, because there's no tax breaks. The tax breaks were for the actual manufacturing. So they could move a plant to Puerto Rico, and within about a year and a half it would pay for itself from tax breaks. I had read that the typical pharmaceutical firm in the States, at that time, operated on about a 12 percent profit margin. They were looking at finished pharmaceuticals, which you can load on a plane and ship. What about shipping costs, you say? But per unit, when you say the cost per unit, and you're shipping, it's smaller. If you were making bottled water, you would say the water is cheap, but it weighs a lot. A bottle of drugs is very expensive, but it doesn't weigh very much.

RO: In addition to the taxation advantage, is a part of the attraction to the pharmaceutical industry to Puerto Rico based on lower wage, lower labor costs?

DH: In part. The other attraction of Puerto Rico is wherever you have a pharmaceutical industry; you want to have a very skilled labor force. Puerto Rico, probably still true today, had the highest number of college graduates per population than any state in the United States. The reason for that is you have a very high unemployment, so that drives it. If you wanted a job, you needed to go and get a bachelor's degree and many times go and get a master's degree. So you're talking about a skilled labor force. The island is only 120-by-30 miles wide, so wherever you build, you're going to be within commuting distance.

Outside of the education, you have a lower cost. I think at the time I was there, the typical pharmaceutical worker made about two-thirds of what they would make in New Jersey. So those are important factors, the tremendous tax advantage, the fact that you have a highly educated, skilled labor force, and the fact of lower salaries. But some of these very large plants only employed 100 people. So it wasn't the salaries driving that; it was the fact of the tax advantage. Of course, you want qualified people that you can hire, even if you're hiring only 100 people.

But I think at that time the total number of people working for the pharmaceutical industry, I think, was only maybe five, seven, eight thousand people. It wasn't that big of a population. The population, at that time, was about three and a half million.

RO: What was the complement of FDA personnel in the San Juan District?

DH: At that time we had about twenty, twenty-two investigators, and about four or five inspectors.

RO: Was there any greater frequency of the inspection cycle for the pharmaceutical industry in Puerto Rico as perhaps compared to the New Jersey and New York area?

DH: Yes and no. The biggest problem we had in Puerto Rico is when they did the work planning; they had this complicated formula to decide how many hours it took to do the inspection. If you come to the States and you look at a district's drug inventory here, there are probably as many medical gas firms as there are drug plants. So on the work plans, if you go to Texas, Texas has a major pharmaceutical industry because they have numerous medical gas plants all across Texas. Every little town has a couple of medical gas firms.

In Puerto Rico there are only maybe five or six medical gas firms. So the way they gave you the time, the problem that I constantly had in Puerto Rico was, you could have a very large prescription drug firm and you would get "X" number of hours for it, while some in the States that had a very small firm might actually get more time. An OTC (Over-the-Counter) drug manufacturer that was making a salve to

put on your skin, was, maybe, making a solution to treat athlete's food, and then had a cough syrup, would come up to get more time per year than the largest prescription drug plant in the world.

So we were out at these firms a lot, but these firms often times manufactured a variety of products. We were constantly driven by these government contracts that you have to inspect this product line or that product line. At one point, I would say that more than 50 percent of our firms had at least 50 percent or more of their product lines that we had not inspected within a couple of years. So it was a problem during the time I was there, that it did not fit the model of the drug distribution you had here in the States.

Here, some of these districts, Dallas probably had half to two-thirds of all their time was for medical gas inspections. If they ran out of time, they could postpone the medical gas inspections.

RO: I suppose the geography of Puerto Rico, as you described earlier, is a relatively small area, which would permit more coverage in the plant and less travel time, as compared, for example, to Texas, where you have great distances involved between facilities.

DH: Oh, you've never seen the traffic in San Juan. (Laughter) Some of that's true, but the travel time isn't a factor in your work plan. Your work planning time doesn't include travel time; that time is allocated separately.

RO: Is working with the local authorities any different than in the States?

DH: Yes. For instance, on the sanitation inspections, I think we paid for fifteen inspections a year – the Puerto Rican government is set up locally, so your inspectors inspected places in their town. In Puerto Rico he's probably inspecting places that are owned by cousins or relatives or the like, and their inspections generally don't find much. Many of them don't even carry a flashlight. So their inspections were a bargain, because we would pay fifty dollars an inspection and we would use it as a kind of a screening. If they saw anything, then we knew to go back.



But the part that they were extremely good on was the cooperation that they gave us. If we wanted something to be detained or held under embargo, at the time I was there, we could call up the head of the Health Department, who was the brother-in-law of the governor, and we could say, “We have some product out here and we want it embargoed.” It could be on Friday afternoon, in which most people would just kind of disappear from work. He would get someone out there to embargo it.

Another time we had an old manufacturer that had an illiterate worker filling his bottled water and rubbing alcohol. His labels were black and white, and the worker was illiterate, and occasionally he would put the wrong label onto the rubbing alcohol. So it was being labeled as distilled water, one of the uses being infant formulas.

Now, when we found out about it, we did an investigation, we found that actually it had happened on three separate occasions that this guy had made the same mistake. The owner even knew about it, and each time he found out about it, he would exchange the product when the complaint was made.

We looked at it and we said, “You have water; you have 70 percent alcohol, rubbing alcohol. That’s poisonous. You’ve got a label that says it can be used in infant formulas.” So someone puts it in infant formula and gives it to a child, and they say, “Well, but the child probably wouldn’t drink it.” You don’t know that.

So we had to use a little persuasion on him. I said, “We found this to be an imminent health hazard,” and we could either go out or make a radio announcement and a press announcement, or he could choose to do it himself. So he did it himself. They ran these, but we came up with 5,000 potential consignees between Puerto Rico and the Virgin Islands. We elicited the Puerto Rican government to help us, and they pulled out every person they had and we hit 5,000 places in just a couple of days.

So the cooperation that we got from the Puerto Rican government was unsurpassed by any means. The same was true in the Virgin Islands. When the hurricane hit, we had very good cooperation. They had tremendous respect for FDA.

There was a time where we wanted to do a seizure at this place, so we had them go and embargo all this food. The firm started selling some of it between the time that it was embargoed by the Puerto Rican authorities.

[Begin Tape 2, Side A]

RO: Since you spoke of the cooperation that was provided, did the FDA engage Puerto Rico in the State Control Program?

DH: Yes. We could have a contract for about fifty sanitation inspections a year.

RO: In the food area?

DH: Yes. Now, realize their inspections were not the quality of ours. We used them as a screening. If they saw any rodent droppings, we followed up. But at fifty dollars an inspection, these were bargains, and we could use them on places that were very remote but just the cooperation they gave us on everything else was excellent.

So they went to prosecute this firm, because they had not held their stuff. So we sent one of our investigators to testify in court, and the defense starts asking him questions, and he said, "I'd like to refer to my report."

He said, "Report? What do you mean, report?"

He said, "Well, during the inspection we take notes and we write up our findings, we take photographs, and then for each thing we sample we have a special report."

He said, "You have photographs? You have notes on all this?"

He said, "Yes, and I brought them with me."

He said, "Your Honor, we change our plea to guilty." (Laughter) Because the Puerto Ricans often don't document like we do, they don't use pictures.

On another case we had on a prosecution for sanitation, we started out the morning showing the photographs to the judge, and they showed all these rats and mice. We broke for lunch. The judge came back; the defense hadn't even started their case. The judge said to the defense, "I went to lunch, I ordered

food, and I couldn't eat. I remembered seeing those photographs of the filthy conditions in your plant, and I couldn't eat lunch. I'm going to excuse myself for a half an hour and I suggest you make a deal with the FDA now. I will come back in half an hour and if there is no deal, we'll hear this case and we'll decide this case today. But you take my word; you'll wish that you had settled this before I get back."

He walked out of the room. The defense had not presented anything and the defense quickly agreed to everything. The judge came back, the case was out.

So, FDA, because of the way we did things, had a very good reputation there and very good cooperation from the Puerto Rican government and the Virgin Islands on everything we did.

RO: After you served at Puerto Rico, where was your next tour?

DH: I came to headquarters, this was in August 1991. I became the director of the investigations branch under the Division of Field Investigations (DFI). Division of Field Investigations is now known as Division of Investigations and Emergency Operations (DIEO). That was the time that Bob Fish was the director of DFI.

Probably the most noteworthy thing I did there was the Investigations Operations Manual (IOM). Prior to my coming, the Investigations Operation Manual had been a loose-leaf manual, roughly about nine hundred pages. The font had, over the years, gotten smaller and smaller to where it could be equivalent to about a 6 font, which is quite small. Government standard is pretty much a Courier 12 or 13, so a 6 was pretty small.

It had essentially been run by one person, Bill Jance, who had managed it for almost twenty years. It was his pet project and he was very defensive of it. Nothing got into the IOM without crossing swords with Bill Jance.

I started to want to do something with it. I worked a lot with Tom Johnson. I don't know if you knew him. Tom Johnson was an engineer that worked in the branch, very computer-minded and somewhat of an efficiency expert authority. We started talking about the IOM, and I looked up and found what it cost to publish. We determined something like, I think, eighteen dollars a year in printing costs for loose-leaf updates for each user and we would mail out all these things that people would file. People would typically file the inserted pages every so many months as they would stack up. If you were going

to supply 1,800 manuals, you needed to print 2,500 updates inserts because some inserts got lost. There were people who could always call and say they were missing this or that.

We did a survey out of the FDA Baltimore office and we found that the only people that had an IOM that was complete were the new hires. The longer some had been around, the more likely there were pages that were outdated or missing.

So we came up with the idea to completely reprint it and put it into a bound format. The initial reaction we got from people is that the cost would be prohibitive. It wasn't. We had it electronically. We ran it through spellcheck. It had never been run through spellcheck. We did a sampling and figured that we had something like 5,000 misspelled words. Most people never noticed because the font was so small. We had an English student working for us during the summer and she would go through and point out all of the grammatical, capitalization and punctuation mistakes. We figured that in the IOM we had 50,000 grammatical or spelling mistakes in this 900 page document.

So I said, "Okay, let's completely revamp it. We'll run it all through spellcheck. We'll correct the grammar. We'll do all of this." By nature I'm what they call an intuitive thinker. I like to always change things.

My boss was Bob Fish. Bob Fish is very much a feeler, and he said, "How will people feel about it? The manual has always been loose-leaf. People like it loose-leaf. He said, "They may not like it bound."

So I went back and I thought about it because for me it is facts and figures, but that wasn't persuading Bob Fish. He wanted to know whether people would accept it. So I came back and said, "Let's do it bound, electronically." I checked on the cost, we could print 5,000 copies at three dollars a copy. Actually, the first edition came out as \$2.20 a copy. I said, "We save all this money. We give everyone an updated manual, and six months from now we survey them, and if they don't like it, then on the next edition that we update, we'll do it as loose-leaf, a complete reprinting."

So he said, "A survey to see how people like it." He said, "I like that." He says, "We can tell people to hold on to their binders." So we did, we went out, we told people. "Don't throw your binders away. We'll do a survey."

Six months later, I did a survey and we got back something like seven or eight hundred responses, which is incredible for a survey. Eighty-eight percent of the people said they loved it. I also had posed

another series of questions about reorganization, other changes, everyone approved by votes between 60 and 90 percent. Bob said, "You can do anything now." So I would change, we started reorganizing, changing all this. His limit was on the color. I finally said, "I want to change the color. This is a new edition. Let's make it maroon or something, a different color."

He said, "It's always been blue."

I said, "But a different color, it shows it's a new book."

He says, "It's always been blue."

I said, "They change the color of some publications every year."

He said, "Okay, you can change it to any color, as long as it's a shade of blue." (Laughter)

RO: A little like Henry Ford and black Model-T's.

DH: So even with the IOM, if you looked at the first bound copy, I went out and I did different font sizes. I showed people the font that ranged from 8, 9, and 10. The majority of the people picked 8, so we did 8. The next year I did the same survey, people picked 9. The next year we did the same survey, people picked 10. What it illustrates is that people take changes incrementally, that going from 6 to 10 was too big of a change. If you went 6 to 8, which was larger, so each year they could go to a larger font.

RO: What it was telling you, Dave, was that you're getting an older inspection workforce and they need larger fonts.

DH: This is true. We went to the library, we got things on publishing. We found that ideal reading speed is five to eight words a sentence. That's why when you look at newspapers, they have all these columns. So we put the IOM in double columns. We calculated how many people would be reading the IOM and the reading speed and what it meant for every word you had in there, how much productivity.

So I went through the administrative chapter, did a word count, and you go through and you start pulling out all this excess verbiage, and reduced it by 42 percent of the words. Yet when you gave it to someone, they didn't realize anything was missing. This is editing, and you're figuring the longer it takes someone to read the same information, the more you're taking away productivity. If you're giving this out to thousands of people, it all adds up.

So it became very much an exercise, I think, a customer-based exercise, of looking and saying, how do you give it to a customer to do that. When I left DFI and I went to my current position in 1994, we had a Compliance Policy Guide Manual (CPG). I can't even tell you how many chapters that it had – it was thirty-some, forty chapters. There was no index to it. So if you were looking up a CPG, a policy guide on something, you kind of had to look from chapter to chapter.

The guides were in numerical order, so you might go to this chapter, which might be Chapter 32, and there might be sixteen guides. Number one was the oldest; number two was the next, and so on. Except if number five was abolished, and all of a sudden a new one came along, they might give it the same number. That caused some problems, because then you would find an old reference that would refer to a number, but when you looked up the guide, you would see that it was newer, but it was on a completely different topic. We did not have it electronically, we just had information that had been scanned in. Some of it wasn't the current copy. Some had areas that were missed, so we had to go through every single one, proofread it, put it in electronic format and completely reorganize it into chapters by centers. It had no index. We built an index. I think the index alone is sixty or seventy pages, on every conceivable topic that you could look up. We made it more user-friendly. Where there were 900 copies nationwide, we printed 5,000, one for every investigator, compliance officer and others who would use it. Most investigators in the field were not even aware that there were Compliance Policy Guides.

From that we moved on to the Regulatory Procedures Manual (RPM), which we did the same thing. We updated it and reorganized it. There were sections in it that had never been updated. I would call Import Operations and I would talk to someone like Marvin Blumberg. I said, "Marvin, here's a policy guide on imports that's dated twenty years ago. Is it still current?"

He said, "No, we haven't followed that for fifteen years, but no one knows how to rescind it."

So we would just say, well, we're starting anew. So we took out all the old ones. We found the Regulatory Procedures Manual had a whole section on laboratory procedures. The only problem was that the Division of Field Science had their Laboratory Procedures Manual (LPM), which gave all their

procedures. So they would update that first and if they got around to it, they would update the Regulatory Procedures Manual. So you had things in the Regulatory Procedures Manual that were outdated, that conflicted with what was in the Laboratory Procedure Manual.

So we adopted a principle that guidance should only be in one place, because if you had two different guidances on the same topic that means for the regulated industry there's confusion. If one is more advantageous to them, they can argue, and if that fails they'll say the agency's undecided. So we eliminated the laboratory procedures sections in the Regulatory Procedures Manual. Instead we said, if it's elsewhere, then it shouldn't be here in the RPM. There should be one primary source.

We created the first International Cooperative Agreement Manual. The hardest part, some of the International Agreements, The Memorandum of Understanding (MOU) in it were in the old Compliance Policy Guide Manual, but no one had really done a survey of the agency of all the different types of international agreements. For months these things would come out of the woodwork. We would ask all the centers, and even International Affairs told us that we had found international agreements that they didn't even know existed. So we put them all together and we put them into a manual.

RO: Those kinds of agreements probably lacked a great deal of uniformity in their format, is that right?

DH: Yes. Because we couldn't change them, we made what you'd call independent columns. So you would have one that would be two inches wide to the left, and then we would do the original agreement to the right. Then we would put notes in, so where the original agreement had some previous commissioner to the left, we would add into the left column "currently so and so." Or someone had retired here, and we would say "currently so and so." Or we would add, "The phone number now is."

So here you had an international agreement that parties signed, and then over to the left column you would see updating information. In some instances we had to call embassies in Canada to find out what the new numbers were or how it had reorganized. So it showed the original agreement, and then off to the left side it gave the updated information. Now, the ideal is to go back and update the agreement, but that wasn't always within our prerogative. But no one objected to notes on the side.

RO: These agreements had indefinite terms of effectiveness, is that correct?

DH: No, they varied. Some did, some don't. So in each one we would have to find out the current agreement, was the date on it, when is it effective, and we would put in that information also. For every agreement, we put in a point of contact, which is the current FDA contact for that agreement. So if someone looked it up and they wanted to ask questions, they had a name there.

RO: Was there an effort to keep current the cooperating countries; contact person, too, or just our part?

DH: Yes and no. The difficulty is, I always had a problem with staffing. So sometimes you take on these projects because they need to be done. Once we did it and it was a great success, International Affairs came down and said, well, it really belonged with them, and they would like to take over ownership. And they were right. When we did it, we did it with their knowledge, and no one else was doing it. Once they saw how valuable it was and that they wanted it, we gave it to them, electronically and everything, because it was logical that they should be the owners of it.

My belief is that when you come into a job, there are always things that are associated with that job. Everyone looks at what goes with the job, but not enough people look at what it should be. So you have to look at the things that you're saying, not just what's in a job. A lot of what's in a job you can actually eliminate. Look at the things you should be doing that one has ever thought about doing, that no one else is doing.

An example of that is the Information Disclosure Manual. We have a Freedom of Information (FOI) office. When they put on training, they would put out this loose-leaf binder that would have all these xerox pages, the preamble to the regulations, like 1974, 1978, all of this information. It stacks up to a very thick manual. But the preambles, which are very important to understanding FOI, were never electronic, so what you got is xerox copies from 1974.

So we took them and we got some cooperation from some of the centers, we typed all the preambles. You're talking over a hundred pages. We typed them all in and we put together a manual that had the regulations, the FOI Act, the preambles, and the Privacy Act. We also put in things like sharing



non-public information with other federal agencies with foreign governments, everything on information disclosure, not just FOI.

Then we composed a section of frequently asked questions and answers, and each one of those were run through the FOI office chief counsel, because it had become policy. So we published this book, we put it on the intranet electronically, which means it's searchable. So if someone says, "I think there's something in the preamble that talks about this," you can go in and because it's all electronic, you can search for it by a word or a phrase or something and find it.

At the time we did that, it wasn't that anyone was coming forth and saying, "This is something you need to do." You have to look out and say, "Part of my office role was to give FOI guidance to the field, part of my role was approving testimony of FDA employees in third-party lawsuits, or turning it down, sharing non-public information with other federal agencies." You're doing all this and you say, "But somewhere we need a better system than all these loose pages in this book here that's only giving out for training. It's not very current." So you see a need and you say, "Okay, this is something that we should do and it's worthwhile," and you take it on. That's what makes me tick.

RO: The title of your job is Director of Compliance Policy.

DH: Right.

RO: Which suggests that maybe as far as the field organization is concerned, that you have a responsibility to make sure that the compliance policy is uniform throughout the entire agency.

DH: Yes, and it's available and understood. Right. That's part of why you want manuals that are up to date, that are electronic, that are searchable, and produced in great enough numbers that people readily have them.

RT: Now, in one area, one office I'm familiar with had a directory of officials, and they used to print it and now they've got it online, if you will. Has there been any consideration of instead of having printed manuals that they go into a computerized format?

DH: Yes. They are on the intranet. The next stage (I was working with an outside potential contractor) is when you present a publication in paper form, you use what they call information mapping, which is how you display the information so the person can readily find it. An example of that is the International Agreement Manual, where you have notes off to the side that will key things in. The Cooperative Agreement Manual kind of does it in outline form. So when someone uses a reference book, instead of going through pages and pages to look for something, they can readily find what they're looking for.

So when you do a bound copy, you want to do an information mapping. When you do it on the internet, that's a different type of information mapping. When you put it up on the internet you don't want it the full-screen width, you want it narrowed down. There again, it's the eye-reading speed. You want icons that you can click on.

We started a newsletter called the *Enforcement Notes* and we send that to people electronically. It gives you topics, and you can click on any one of these topics and it takes you to the article. The article will be short, but then the article can have links to other internet sites. So here's a court case, and we're going to give you a paragraph about it, but you'd like to see the court case itself, because it's particularly interesting. We might have that case, click on it and it takes you into that full document.

Where we're going eventually on all manuals is to set up where a person turns on the computer screen and all your manuals are available by topic, and it will pull up the different ones that you'll click on. Then when you go into something, if there's a form associated with it, you just click on something and it will come up on the screen. So you try to do as much as you can without people scrolling down the screen, but just clicking from screen to screen to get the information they want.

RT: Are there any kinds of information in this general area that security or security considerations would suggest that it shouldn't be automated on computer systems?

DH: Most of our manuals are already available in FOI.

RO: They're public?

DH: Yes. And that can be protected behind a firewall. That is where we're going and these were the type of things that I was trying to move toward. Some of it is difficult during times that you don't really have the staffing and people are very reluctant to put money toward, but the day will come when either from a laptop or a computer or even from one of these small hand-held devices, someone will be able to go in and navigate around to quickly find what they're looking for. It will be updated by individual pieces.

It's like our Compliance Policy Guide Manual, it's on the internet. Every one of the five hundred individual guides is a separate file. So we can go in and update any Compliance Policy Guide individually and replace only that one. So you're plugging it in. It's much like the concept of the old loose-leaf manual, where you take a page out, but now you're doing it on an electronic database, where you're putting new pages in, but the lengths are still established. That day is coming.

RO: There was a time, that's probably historical now, when we had some sort of unwritten plans, standards and so on, and even at that time, I'm sure the industry pretty much knew what was never written down. Is that passé now?

DH: I was a representative on the agency's Good Guidance Practice Working Group that first made the guidance and then the regulations. Good guidance practice says we will involve industry more often as we devise guidance that is a new interpretation. Something that's going to have a substantial impact with new expectations is putting the new guidance document out for comment period to give industry a chance to comment on it. All guidance should be readily available, that is listing it in the *Federal Register*, and we placing it on the internet. Certain things are not guidance documents. Warning letters are not guidance documents. They respond to individual instances. But the agency has a tendency to use some of these things that we've defined as "not guidance documents" and that could get us into problems. If you issue a warning letter and a month later you issue another one to another firm, and someone says,

“You know, we’ve issued now three or four warning letters. This is something that we need to address.” At that point if you make a guidance document and you put it on the internet so the whole industry is aware that this is now guidance, if we go down the wrong path and we start circulating these warning letters to people to give them guidance on what to do, and we only give that guidance to inside, the industry’s compliant is, it’s like the old complaint against the Internal Revenue Service (IRS). That is, yes, IRS regulates us, but most people want to comply by filing their taxes. When you call the IRS, you expect to be told what you have to do to comply and what you can and cannot do. The same thing is true with us. Industry’s perspective is, “Yes, we know we have to comply and we want to comply, but tell us what it is you want so we can do it.” That’s one reason that they hire people like me, because they want to comply, but they don’t always understand or know what to do. I mean, the cost to industry is not just the warning letter, not just an injunction, and those are expensive. These days the cost to industry, especially the large pharmaceuticals, is they come out and report that they’re having problems with the agency, their stock value goes down. Some of these companies are valued at over 100 billion dollars. You talk about their stock dropping in value by 5 or 10 percent that goes into the billions of dollars.

[Begin Tape 2, Side B]

I was saying in industry you’ll always have some bad actors, but you’ll also have many in industry that want and will comply, and the obligation on the agency is always to make information readily available to those firms that want to comply, that will help them to comply, and to maintain a strong regulatory posture to those firms that are not willing to comply, and that I don’t think will ever change.

So you need FDA, but you need to recognize both sides, and sometimes within FDA, depending on the factions, some factions only recognize the bad actors, and you don’t pay enough attention to sharing the information, or realize that we’ve put out some compliance policy guides and other things, and that we’ve got comments from industry that actually helped us. They’ve clarified some things that might be misinterpreted or suggested some things to tighten it up.

We’ve actually made some changes in some of the things that we initially proposed, because we thought the suggestions made it better for everyone.

RO: Do you find now that by publishing our compliance policy on a lot of areas, that it benefits regulated industry, or do you find, as far as the agency is concerned, that we have greater uniformity in compliance? Do you ever have to get in and negotiate with different districts or regions because they are not following our policy?

DH: Not so much for the districts or regions, because that's more on a case level. Where we do get involved is within my division, I have an attorney that heads up the agency's Application Integrity Policy (AIP) group. We hold regular meetings with all the centers on what the policy should be, what it is, and informative applications. So when a firm commits fraud, if it's a device firm, it's going to be treated by the agency in a fashion consistent with vet medicine or drugs – so more at that level.

Certainly from the information disclosure, the approval of testimony, we assure uniformity. We do a lot to assure the knowledge of the policy guides. Whenever we make a new policy guide, we mention it in our *Enforcement Notes*, which is our electronic newsletter, and we have a link right to the site, and that goes out to every single investigator in the Office of Regulatory Affairs (ORA). So when there's been a change or a new policy, we have the means of telling every investigator.

Those also go onto an intranet site that's searchable. I think we're up to issue number fifty-two. If someone says, "I saw that in the *Enforcement Notes*," they can go in and they can search by a word, and electronically search all fifty-two editions. So if some said, "I think they wrote something about that, you don't need a sample to support a warning letter." So they go in and they type "sample" or they type "warning letter," and it will help them.

So part of it is to make information relatively available and organized in a fashion that people can readily find it. I don't know if you have staff manual guides here, but if you look at staff manual guides, you'll know that most people don't look at them, because they're so vast and it's so hard to find something that people hate to go to them. The future is where you go to a computer and you say, "I don't want to look through all these documents. I want to search on a topic and it tells me where I might find that." Much like you do on internet searches.

RO: What you're going to do is force everybody to be computer-literate.

DH: Yes. (Laughter) Until then, we are doing stuff both ways. Because you're right, some people like to reach out and stroke a manual.

RO: That was a question I had. Actually, the office I referred to earlier that put a director on line was the Division of Federal and State Relations (DFSR) where they had a catalog of all state and many local Food and Drug control officials. My sense was that there may be persons out there who would like to refer to this document without having to survey or surf on the computer.

DH: The solution to that, for instance, FDA had a phone book that was bound, only updated every so many years. Now they put their phone book electronically. But the electronic phone book is only half of a phone book, because you could go into the bound one and you could say, "I don't know who I want to call. I know I want to call this office, but I don't know anyone in the office." So you look up in the bound one, because you can look up the office. With the electronic one, you can't look up the office; you can only look up a person's name.

RO: Individuals.

DH: That's right. It's the way they designed it. There's nothing that stops us from having an electronic one. We did unofficially have an electronic one that you could have put in any symbol, you could have put in "HFA-250" and it would give you a listing of everyone in that office. So you could say, "I'm looking for this person. I'd know their name if I saw it. They're in HFA-250." You'd type in "HFA-250" and it tells you everyone in that office. They need to take the electronic phone book and they need to do it in a fashion that's not just searchable by name, but you could type in the state, you could type in the county, you could type in the health department and it gives you the same type of thing.

Where they have the electronic and bound, we put the *Enforcement Notes* on the internet. We'll have links, and if someone wants it and the HTML, which is the computer that looks all nice and narrow columns and stuff like this, it will be there. But if people want it exactly as it appears in the book, it will be that way too. If people want it in WordPerfect they can download the file. So we'll give them

WordPerfect, PDF, HTML, we'll give it to them in at least three different formats. Because if you have it in all these formats, why not let them decide how they want it.

RO: Dave, you've decided you're going to leave the agency. Why?

DH: Well there are a couple of reasons. Money is obviously one reason, but there's another reason that's even more important. Frankly, my job has become too easy. I have a very good, highly qualified staff where I am, and it doesn't produce much of a challenge to me. I have lots of ideas of things I'd like to do, but I don't have the staff or the money to do those things. So there are times that I'm bored. I feel there's more I could do than what I can do where I am.

When I was interviewed by Merck, they were very interested in many of the things I've done. They're interested in organizing things like Standard Operating Procedures (SOP) and all this in a better fashion. I'll have a staff there. I have almost the same excitement as when I came to the agency with new challenges, and after you've been in the job for seven years; you're looking for something that's new and exciting.

Frankly, what I saw was a company that I said I could go and not have a conflict with what I did with FDA. I can bring my knowledge to them about the importance of audits, the importance of having SOP's that people can understand. It's not having more; sometimes it's organizing it. You can make your SOPs so long that no one will read them. You have to ask, "What is it the person needs and how do I provide the information to the person that needs it in the easiest fashion so they can use it?"

How do you set up a system that rewards people for being honest? It's like you train new investigators. That investigator goes out and finds violations, but then doesn't know how to document it, and you beat on him for lack of documentation. You're teaching him never to go out and find anything again as bad. But if they get a very good feeling for finding or doing the job and they have a learning experience from that in a very constructive fashion, they'll develop. The same things are true with industry.

My wife is very much like me, so she is looking for new challenges. She's been in the same job for about six years, and essentially she has done great things there, but her chance for advancement was not there.

RO: She is in the ---

DH: Center for Drug Evaluation and Research (CDER).

You can move on to a new challenge, it doesn't conflict with your values, because when you've been with FDA, in my case thirty-three years, and my wife seventeen and a half, there's a part of you that will always be in consumer protection. But if you accept it, that same role can be played at the firm. Then you throw on top of that very good pay, all of the other things that go with it, and then you say, "Okay, that's a winning combination."

RO: This job you'll be doing in the private sector, you won't really be representing them to FDA, per se, then?

DH: No. My job there, I'll be in quality assurance, is to bring my knowledge of FDA and what we're looking for and what we expect, to bring that inside to help them achieve the type of quality assurance so they won't at some future point be in deep trouble with the agency and say, "Well, we tried to do the right thing, but perhaps we didn't have all the right people." So I see my wife and me going in as we can contribute to the organization to make it better. We're not going into an organization to help them avoid complying with the agency. That's a losing proposition, because when a firm fights the agency, there is no such thing as winning. Nowadays large firms like Merck, if you fight the agency, whether you win or not, you're going to lose in the public opinion, so you've lost before you've even before you've even started.

RO: You'll be going to making quality-control inspections.

DH: I won't be doing the inspections, but my wife and I will both be going. I think my title is Director, Worldwide Good Manufacturing Practices (GMP) Compliance and Policy Programs. My wife's title is something like Associate Director of Quality Systems. She is very innovative. They want her to



look at how they can improve their systems. I'll be looking at how they can improve their systems and also their quality control.

What my wife and I both bring to them is an FDA perspective. Oftentimes, firms when they don't have FDA people, look at things different than we do, and it's natural. We do the same thing in-house. If I design a quality-assurance system for my division, then our tendency to look at it and say, "Okay, you're following it." Once I've established it and you're following it, then that's the way you're doing everything right. Industry does the same thing.

But what you have to constantly look at is this is regulation, and your system, your SOPs and all of this, are only as good as they satisfy the intent to the regulations. The intent of the regulations is to keep current to good manufacturing practices. So it's an ever evolving system as your technology advances.

So if you base too much of your quality control on seeing whether people are following your procedures, then you're missing an important point, but do we know that we have the right procedures? So you may be following the procedures, but maybe the procedures are poor. Maybe the procedures are badly written or verbose. As an operator, do you ever look at some of these instructions that tell you how to put something together or how to program a VCR and say, "You've got all these things here, but who understands it? Who has time to read all that?"

So you have to make sure that a part of quality assurance is that you're giving the information, and it's not much different than our getting the information to FDA investigators. How do you get the right information to investigators so they know to do their job? Are you emphasizing the right things? Are you laying it out the right way? Are you keeping it current?

The same things in industry focus on the user, not just on someone saying, "These are all the procedures," but it's looking at what the user needs in order to use that information in order to comply. The easier you make it, the clearer you make it, and all these things go together. So I see parallels.

RO: We wish you success in that new undertaking. We appreciate the interview you've given us here.

DH: Thank you. I've enjoyed it. Thanks a lot.

[End of interview]