History

of the

U.S. Food and Drug Administration

Interviewee: Gary Dykstra

Interviewer: Suzanne W. Junod, Ph.D.

Date: June 27, 2008

Place: Atlanta, GA

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

CASSETTE NUMBERS: 1 - 2

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

DATE: June 27, 2008 PLACE| Atlanta, GA

INTERVIEWEE: INTERVIEWER(S):

NAME: Gary Dykstra NAME: Suzanne W. Junod, Ph.D.

FDA SERVICE DATES: FROM: 1967 TO: 2007

LAST FDA POSITION HELD: Regional Food and Drug Director, Southeast Region

INDEX

Tape	Page	Subject
2 – A	34	"9/11" impact on agency – new hires; training; tomato episode
	35	Commentary on politicization impacts on agency – need for managerial growth from within the agency
	36	Maggie Glavin, Associate Commissioner for Regulatory Affairs – relocated USDA manager – command-and-control type
	39	Agency reticence to recognize & develop effective global scope import controls, e.g., China, et. al.
	41	Import strategic plan – Office of International Programs
	43	Jurisdictional issue between Federal Departments, i.e., FDA, Department of Commerce, State Department, includes role of Ambassadors
	44	Consideration of Honolulu, as FDA operations hub for the Far East countries – operations/coordination problems
	46	Press Office & Commissioner Office constraints on certain field office prerogatives & activities
	47	Field laboratory upgrades
	48	New hire employee & training strategies

Interview with Gary Dykstra

June 27, 2008

TAPE 1, SIDE A

SJ: Today we're in the Southeast Regional Office, located in Atlanta Georgia, speaking with the former Regional Director, Gary Dykstra. Today is Friday, June 27, 2008.

We just want to get started talking a little bit about your upbringing, your education, and how you came to eventually work for the Food and Drug Administration, so why don't you start off with that.

GD: Okay. Starting, I guess, at the beginning, I grew up in Detroit, Michigan, actually north of Detroit, Michigan, and ended up going to Michigan State University, where I studied microbiology and public health and received a bachelor's degree in microbiology and public health way back in 1967, the wonderful '60s; and actually was kind of a spectator to a lot of the campus unrest that occurred during that time, and Students for a Democratic Society started on the campus of Michigan State University. But I was a bystander; I just spectated those events.

In any event, when I graduated from Michigan State, I had a girlfriend at the time -- and I enjoy telling the story. She was just about ready to graduate but didn't graduate at the same time that I did. So I needed to find a job, obviously, and decided that I would try to get as close as I could to the campus of Michigan State University.

The Food and Drug Administration was hiring at the time, and they were recruiting on campus, and at the time I knew nothing about the FDA, what it was, what it did, anything like that. So I went and was interviewed for the jobs. Actually, it was a chemist from FDA that was doing the interviews for microbiologists, which I found kind of interesting. What happened was I interviewed and [for the job] I was offered the job, and I took the job with FDA. So in June 1967, I started my career with FDA, never thinking that I would ever be with FDA for the next 40 years. As I tell people, the girlfriend is long gone, but here I still am associated with the Food and Drug Administration.

That's where it all started, so to speak, back in 1967.

When I started at FDA, of course, I knew very little about the agency and what it did, but I was very fortunate

at the time to have a very caring supervisor. His name was Eric Batchelor. He spent his whole career with FDA, ended up in Cincinnati District at the end of his career.

He taught me so much about what it meant to work for FDA; what it meant to work for the federal government, and public service generally; and how important our job was; the kinds of things that we would be involved in; and the kinds of products that we would be analyzing in the laboratory; the types of analyses that we would be doing; and how I would be trained to do these analyses, because I had no idea at that time what I was getting into. I knew a lot of the basics from my training at the university, but it was far different from what we were actually doing in FDA.

I joined in 1967, along with, I think, four other new microbiologists, and it was a point in time in FDA's history when they were recognizing the importance of microbiologists and the importance of issues surrounding food safety and the need to do a lot more of food type analyses, and drug analyses, too, for things like sterility. They were ramping up their laboratories; they were hiring more people and training more microbiologists.

Quite honestly, I was excited and enthused about that opportunity, and it turned out to be very fortuitous to me.

Eric Batchelor taught me what it meant to be both a government employee as well as a FDA employee. He taught me how to deal in the government system. He taught me personnel matters and taught me how to interact with people. He got me involved in investigations, where I was not just working in the laboratory, I was actually going out in the field with our investigators, learning about what FDA did day in and day out and how we accomplished that job. He taught me about imports and what we were doing in the import area at that time. And I started early on analyzing imported gelatin capsules for salmonella, and actually finding salmonella in those gelatin capsules.

It was at this time that we encountered the Bon Vivant episode with botulism, and we were inundated with cans of soup. And, again, keeping in mind that I'm a relatively new employee, but I was the one that had to set up my workbench so that the local news media could come in and see how we analyzed cans of soup for botulism, and just how that analysis was done in the laboratory; and I actually got my picture in the newspaper, the *Detroit News*, for one thing, and also was allowed to actually talk to the news media about what I was doing and answer some questions about it, which was quite interesting for a rather neophyte in terms of the Food and Drug Administration.

From that experience, I had an opportunity to do a detail with our Public Affairs Specialist, and she was the one that told me that I needed to develop my public-speaking skills and get over my fear of talking to audiences, sometimes large audiences. It was at that time, again in the late ‘60s, that I got opportunities to talk to large groups of people. We went to schools, we went to local clubs, women’s clubs and things like that, and talked about the Food and Drug Administration, what we did and how we did it.

I often reflect back on that experience as a very good experience. She pushed me out there and told me, “Sink or swim, go do it, go do it,” and I went and did it. I learned a lot from that experience. It forced me to think strongly about what the FDA was and what it meant to me and why I was doing the things I was doing.

It also taught me another interesting lesson about public service and the fact that -- and I reflect back on when I was sworn in -- I was sworn in to uphold the Constitution of the United States, and at that time I was given a small paperback version of the Constitution, and I carried that well-worn version of the Constitution with me for the total 40 years that I was in the Food and Drug Administration just to remind me why I was there. You

know, on those days when you question what you're doing and why you're doing it, you pull out the Constitution and you see that you have a very serious obligation. The people that are paying you to be there every day expect you to do the things that protect them from the things that they can't protect themselves from. I often reflected on that during my career, and I had other mentors along the way that reinforced that message to me.

Another mentor that I had when I moved to the headquarters operation of FDA, in Rockville, Maryland -- another interesting story about that.

When I was in Detroit District, I would often get mail from Parklawn in Rockville, and I couldn't figure out whether Parklawn or Rockville was the city where our headquarters was located, until finally I went to a meeting or a training course or something at the Parklawn Building, and it was then that I recognized that Parklawn was a building and not a city, although it housed about 5,000 people. It could be a small city.

In 1972, I moved to Rockville, and to the Parklawn Building, where I spent the next 27 years in that building and had a lot of good experiences, some not so good, but overall it was a good bit of management training,

leadership training, that I was able to accomplish while I was in Rockville.

SJ: Give us a little detail.

GD: I moved to Rockville in a management development program, the Management Intern Program that was sponsored by FDA. I felt that was probably one of the best management development programs that FDA ever had. It was a two-year program, so you had lots of time in your various developmental periods to really learn something about that particular area before you had to move on to another area. It was not a quick-and-dirty program. It was well run. I felt very fortunate to get selected for it. There were only six of us that were selected at the time, and all of those people did very well in their careers with FDA and went on to leadership programs.

I left that program and I moved into the enforcement area, the compliance and enforcement area of FDA, as opposed to the pre-market approval area. I worked in what was at that time called the Associate Commissioner for Compliance office. We had a fairly small staff, but we were responsible for all of the compliance and enforcement policy in the whole agency, which meant we had to work with each one of the product areas, product centers. I worked in

the coordination part of that, and our job was to make sure that everybody was doing it the same way.

We had a particular relationship with the field organization. At that time, the field organization and the compliance organization were separate. The field organization was run by the Executive Director for Field, let's see, it was called EDRO, Executive Director for Regional Operations, and it was run by Don Healton. We had to work very closely with them on compliance policy issues, and we had to, we were sort of the go-between between that organization and the Centers at that time. They were called Bureaus at that time and subsequently changed to Centers, but they basically were all product oriented. It was a challenge to get those different Centers all doing it the same way, making decisions about enforcement actions, recalls, and whatever we were dealing with enforcement-wise in a relatively consistent way.

SJ: You dealt with the lawyers?

GD: We dealt with the Office of Chief Counsel also. They were obviously a big player, particularly with regard . . .

At that time, they were not having a big influence on policy. This was in the '70s. Our office was principally in charge of enforcement and compliance policy. We were

making that policy and setting the standard for each one of the Centers to follow. In the particular office that I worked in, I had to come behind that policy and make sure that it was being followed appropriately.

In the mid-‘70s, when Peter Hutt joined the agency, that was the era of regulations. He brought the whole notion of regulations to the Food and Drug Administration and said that, “You have all these laws on the books, but you’ve got to have implementing regulations and you have to have explanations of those regulations, and you have to follow the notice-and-comment rulemaking policies of the federal government to put those regulations out. And as a result of that, the office within the Office of Compliance was developed to do nothing but help write regulations. And Peter orchestrated a lot of that and made sure that a lot of the stuff that we were doing were set down in regulations.

A particular regulation that I helped write and implement was the regulation on recalls. A lot of it was written by John Wessel at the time, but John and I worked very closely together on lots of things. John loved to write. I remember this so clearly. He would come in typically seven-thirty or eight o’clock in the morning, and he would sit down at his desk -- this was before computers

-- to start writing. He was a prolific writer and wrote a lot of policy documents, and he wrote a lot of the regulation on recalls which are still on the books today, have not been changed, and that's what the agency follows to this day.

I actually wrote the regulation for what was then regulatory letters; it's now called warning letters. But that regulation went out for publication and comment, but we never finalized it, and I think that that had to do a lot with the fact that Peter Hutt left and things changed. I'll come back to why things change in FDA as I noticed it over time.

One of those things that helped change things, obviously, were people like Peter Hutt, you know, very outspoken proponents of the way the agency, their view of the agency and how it should operate. If they got into positions where they could change that, they changed it. Obviously, Commissioners could do that, but people like Peter Hutt could do it too.

At this point in time, I'm in the Office of Compliance, and I moved from a staff position -- very fortunate again to have good mentors and coaches who helped me along in my career. Paul Hile was the Associate

Commissioner for Compliance. He succeeded Sam Fine, who was a very powerful personality at that time in FDA.

SJ: As was Don Healton.

GD: Don Healton was a strong personality.

Paul Hile brought me up from the staff work that I was doing and brought me into his office as his special assistant. I had the opportunity to observe him and observe his management style and his leadership style. It was at that time, in the early ‘80s, that I started to notice how people managed and how people led the agency -- or in some cases didn’t lead the agency -- and noticed how important it was, for my own development, to take note of what worked and what didn’t work. When I got into situations where I had to make decisions or had to do something, I could call upon that experience and say, “This is the right way to do it, this is the wrong way to do it,” and that served me well. From sort of that point on, I made it a habit to watch managers in meetings and when they were giving speeches and when they were interacting with people, to notice how they did it and how they accomplished their particular objective, whatever it was, or what went wrong. Why weren’t they able to accomplish their objective?

I always marveled at Ron Chesemore. He was the next; he took over after, actually after John Taylor. There was Paul Hile, John Taylor, and then Ron Chesemore.

Just as an aside, with Ron Chesemore, I was always taken by his ability to give people bad news and have them accept it and go out of the room smiling. I mean, he could always put a good face on a bad moment, and I never quite mastered that myself, but I was always fascinated by it. I think that was certainly one way that Ron Chesemore, as the Associate Commissioner, was so effective.

But getting back to Paul Hile, while I was his special assistant, Paul made the decision to -- and he was, I think, frustrated by the fact that he could not always implement things, particularly with regard to the field, but he had the same problem with the Center, you know, implementing his compliance policy, things that he wanted to get out there. He finally decided that he needed to combine the EDRO organization and the Compliance and Enforcement organization together.

I had an opportunity to watch him maneuver and cajole and discuss things with the Commissioner at the time -- and I can’t recall who the Commissioner was at that time; Sherwin Gardner was there, and he may have been Acting at the time. In any event, Paul sold his idea, obviously, to

the Commissioner, who had to bless it, and he was effective in getting those two very important organizations merged together.

That also required him to find something to do with Don Healton, and here you had two very strong personalities. Don was arguing the other side of the coin to the Commissioner, saying that the field should stay separate and that he should remain in his job, and Paul arguing his, and ultimately Paul won out. It was very fascinating to watch this dynamic, and I had an opportunity to see some of it, but not all of it. The piece that I didn't see is when the two of them went and talked to the Commissioner together and made their pitch.

SJ: Was it Ley?

GD: No, it wasn't Herb Ley at the time. Let's see. There was Herb Ley, and then there was Mac Schmidt and . .

SJ: Kennedy, Don Kennedy.

GD: Don Kennedy was in there, and Charlie Edwards. So I'm not quite sure which ones of those played a role in that.

Anyway, the ultimate happening was that the two organizations were merged, and they became the Office of Regulatory Affairs. That was the -- Paul Hile came up with that terminology, and that has stuck ever since.

I've often wondered about that terminology because that terminology is out there in the regulated industry, and it doesn't mean the same thing. Also, many times within FDA, we get confused and the industry gets confused by the role and function of the Office of Regulatory Affairs (ORA) and the fact that, aside from bioresearch monitoring, we don't have a lot to do with the pre-market-approval side of the agency, whereas in regulatory affairs out in the industry, they have a lot to do with that. So that's something that maybe we could think about for the future.

In any event, I moved on from that position in the Office of Regulatory Affairs to a position in one of the Centers, and that was the Center for Veterinary Medicine. I can say that that is the Center where I really honed my management skills, because it wasn't until this opportunity in the Center that I really had an opportunity to manage and lead people. In the past I was always in various staff positions. I did have a brief time when I was supervising a small staff, but they were all fairly high-level people and self-starters and had their own projects, and I didn't have to do much except sign timecards.

But in the Center for Veterinary Medicine, I was invited to come down to that job, and I started to learn a

lot about the positions and how you get positions in the agency, and who rises to the top in the agency and how that happens. I started to notice, with regard to my own career, that I wasn't really applying for positions, I was being noticed by other managers through my work and my participation in projects and task forces, and they were finding me and asking me if I would be interested in doing such-and-such a thing or project, or would you be interested in a certain position. That's when it started to dawn on me that it was important for me to have that influence on people. It was also important for me not to do things that would irritate people, because you never knew, know, or knew at the time, when those people would come back into your work life and be your boss or be someone that could affect your career.

In this particular case, the Center for Veterinary Medicine and the Director of their compliance and enforcement office was put into that job himself, did not have a lot of experience for the job, had worked with me on a task force, and thought that I could bring a lot of experience in there to complement his veterinary medical experience. As it turned out, that was a good fit; it worked very well.

I had a lot of people in the Office of Regulatory Affairs who said, “You don’t want to leave ORA,” you know. “Why do you want to go out and work in a Center?”

I talked to Paul Hile about it, and, surprisingly enough, he was a very good coach and mentor and told me that this might be a good career move for me. I knew a lot about ORA, but I didn’t know a lot about the Centers and how they operated. Because the Center for Veterinary Medicine was fairly small, I’d have good access to the Center Director, who at the time just happened to be Lester Crawford. That’s where our paths crossed more than 20 years ago.

I decided ultimately to take that job in 1984, and went down there and, as I said earlier, that’s where I really honed my management skills, and that was when I learned how to manage people, learned how to involve people in decision-making, learned how to get people to buy into what we were doing, and learned how to work with teams, how to form teams, how to get lots of people involved in projects. You really had to do that in Veterinary Medicine because we didn’t have large staffs. We had fewer people, and you really had to get them all involved.

I learned a lot at that time, about personality types, you know, that . . .

TAPE 1, SIDE B

GD: . . . every person brings something different to the table, and you had to recognize that and you had to use the strengths each person brought to a particular project, to a particular issue, to a particular crisis. In particular, when you had crises, you had to recognize your people's strengths and bring those to bear on the crises. That was not the time to figure out what people's strengths were. But I learned a lot about that in the '80s, and I spent from 1984 until 1991 in the Center for Veterinary Medicine.

I worked on a lot of very tough issues in the Center for Veterinary Medicine. I can't say that I solved a lot of the veterinary medicine issues at the time. I worked on low-level antibiotics; I worked on salmonella in animal feed, worked on salmonella in animal feed with Gary Yingling, and we had a lot of tussles back and forth because there were two sides to that issue. There was a side that wanted to have the animal-feed industry make sure that there was no salmonella in animal-feed, and there was the other side of the argument that said that you can't completely remove salmonella from animal feed, and

therefore if FDA required that, it was a no-win situation. You would have lots of violative product out there, and you would impact the animal-feed supply in the country, you would drive prices up, and you had to balance those kinds of things against what you were trying to accomplish.

I learned a lot about the mission of FDA and the public health mission of FDA, and how we accomplished that mission, and how you balanced what the law was saying versus what was really doable and practical.

SJ: And what the public expectation was.

GD: Yes what public expectation was, which sometimes you had to spend a whole lot of time, again, working with the lawyers and with others, trying to explain to the public and explain to the regulated industry what it was FDA was trying to do, and you had to work out compromises with people; and I learned again that FDA had many, many constituencies that we answer to and that we had to work with. Every time we had an issue, we had to make sure that we brought all of those constituencies in to be part of the problem solving.

I learned, in some cases the hard way, that you couldn't just go out there and try to do something by fiat and simply say, "Well, the law says this, and you have that, and that doesn't conform with the law. Therefore,

that’s illegal, and we have to take tough regulatory action against you.” Well, that didn’t always work. Sometimes you had to negotiate a middle ground, and I learned a lot about negotiating, I learned a lot about seeking that middle ground, but also, as I often told people in FDA, you still have to keep your eye on the ball. The ball is public health. Sometimes you had to dig in your heels because it was a matter of public health.

I learned that the regulated industry, even though they talked a good game, they answer, not to the public, they answer to their shareholders, and their motivation was profit. They had to protect their company, they had to protect their shareholders, they wanted to sell their product, and that was their motivation.

Our target was the consumer and public health, and we had to do the right thing in the right way to protect the public health.

I learned that in the ‘80s, in my time in CVM, and those lessons served me well as I progressed through the rest of my career.

SJ: How was it working with Lester Crawford?

GD: That was an interesting experience.

Again, as I said earlier, I made it a habit to watch people and watch how they accomplished things, and Lester

Crawford was a master at getting things done. He was, in a lot of respects, a visionary. He could look at things and look at issues and figure out ways to get to his ultimate objective. He was a master at schmoozing people, and he was a very good and articulate speaker, and he was very good at putting things together in a way that people could understand them and that they would come around to his side of a particular issue, and very good at steering an issue so that it would ultimately come out the way he wanted it to come out.

Generally, I liked working with Dr. Crawford. He felt -- and he made no bones about it -- at the time I was too young and I had a lot to learn, just keep my head down and don't push issues too hard. He said -- and some of the advice was well advised -- watch him and watch other managers to see how they got it done and learn from that, and that's exactly what I did, and I did learn. So that experience was very good.

Then, in 1991, Ron Chesemore had been the Associate Commissioner for about a year, and he decided that he needed a deputy, so he advertised for it. Again, the good thing about this is Ron and I were both in the management intern program, remember, that program that brought me into headquarters. Ron was in the class ahead of mine. I got

to know him very well and got to show him my strengths and weaknesses and had a lot of talks about what I felt ORA could be and the things that ORA needed to do and how it should be organized, and things like that the Associate Commissioner needed to pay attention to. And I think I impressed him, and I got the phone call saying, “Do you want to be my deputy?”

The interesting thing about that was, that caught lots of people by surprise. You know, I wasn’t in ORA at the time.

SJ: And I’m sure there were a lot of people vying for the position.

GD: There were a lot of very good people that were vying for the position, and everybody was wondering why Ron picked me, and even I wondered that to a certain extent. But then I reflected on all of our conversations and the fact that I felt, and I think he felt, that we would complement each other, you know, that I was not going to be a yes-man, that I would be willing to do the things that Ron didn’t like to do, and that he had strengths that I didn’t have, and likes and dislikes, and that our likes and dislikes complemented one another. I give Ron a lot of credit for recognizing that and asking me to come be his deputy.

We worked together for nine years, and I can't say that we ever had a time when we really disagreed with each other. Certainly there were times when we discussed things, but no violent disagreements. We deferred to one another when we recognized the other had more experience, that the other could handle it better, and that the other could probably make better judgments about the particular situation. For nine years it worked well.

I came in at the same time that Dr. Kessler came in as Commissioner, and that was a very interesting time in the history of FDA. We didn't, Ron and I, neither one of us knew much about Dr. Kessler, and he came in on a big white horse, had a lot of political backing, and was a lawyer and a doctor. I mean, you had to be impressed with that. I often remind people that people with a lot of initials after their name; you have to be a little bit cautious. But Dr. Kessler was a very smart, articulate person, and I gave him a lot of credit for going out and doing his homework about FDA. He came in with ideas about FDA that he could only have gotten from others who knew FDA, so I knew he did his homework.

He came in and immediately started forming focus groups around FDA to give him advice on what's wrong with

FDA, what's right with FDA, what should he do as Commissioner.

That served him in two ways. First of all, he got a lot of good advice. Second of all, he got to quickly learn who the rising stars were in FDA and who the people were that he could sort of trust in FDA. He couldn't bring in all the people that he wanted to bring in, although he created what we then called deputyville. He brought in a lot of people that he turned into deputies for policy and external affairs and different things, and that was the first time that we had multiple deputies in FDA.

He brought in people like Jane Henney, who, I don't think at the time they really knew each other real well, but he knew of her and convinced her to come into the agency as the Deputy for Operations. I thought that, once I got to know Dr. Henney, that was an excellent choice. He brought in some really good people.

SJ: Carol Sheman, Mike Taylor.

GD: Well, Carol Sheman and Mike Taylor. He talked Mike into coming in and taking -- and we often joked about it, you know, that he didn't even make enough money to pay his taxes working for FDA. But he talked Mike into coming in and he had a good staff that he brought in.

Then, on top of that -- and, again, I think he got good advice from somebody that said that you've got to go in and you have to make an immediate impact; you've got to show the people in FDA that you're going to be a serious Commissioner, that you're going to take on the tough issues, and he looked around and saw that one of the tough issues at that time that FDA couldn't seem to make a decision about was food labeling, and we had a lot of food-labeling things going on at the time.

He looked around and he saw this concern about labels on orange juice. So he picked up the phone and started talking to people and talked to some of the CEOs out there. They were unwilling to change their labeling on the orange juice, so he came back to FDA and he says, "Well, what do we do when they won't do the right thing?" Well, we have options, but one of them is seizure, and he made that decision rather quickly. Being a lawyer and a student of FDA law, he knew those options, but he wanted to hear it from his people and he wanted the people -- and he was very good at getting buy-in and having people tell him what they thought they should do, and if he agreed with it, he'd go with it and he'd have immediate buy-in.

So he went out there and seized all the orange juice, and that just ignited the field. The field thought,

finally, we've got a Commissioner that's interested in enforcement, and I think that endeared him to the field at that time.

SJ: Eliot Nessler.

GD: Yes, Eliot Nessler.

The field started getting much more interested again in enforcement matters and started pushing harder on the Centers to be more enforcement-minded. It was a good time for FDA in the early '90s.

Of course, then he got diverted to tobacco, which, you know, I really understood that. I understood what he was doing and that he really felt strongly about that.

SJ: And felt like the political stars were in alignment.

GD: Yes, and that he had other people who felt and were like-minded with him, and he got, the brainpower in FDA together, and talked about how FDA might make an impact on that. They ultimately decided, let's go after sales to kids and take that issue on and get the states involved in it. I thought, you know, for an issue, he handled it pretty well. He knew he was in for a fight. I think he took every step very carefully, and he had his ammunition ready when people were going to fire back at him.

The unfortunate part about that is that it totally consumed him. He couldn't get back to a lot of the traditional FDA issues, and we had a hard time in ORA (Office of Regulatory Affairs) getting his attention on anything. Unless it was a real crisis, he didn't want to be bothered because he was working on tobacco, and he had his tobacco team that he had to manage, and it was an all-consuming effort on his part. What started out as a real good relationship with him gradually waned over time.

At the beginning, one of the things that he did was that he recognized dietary supplements. Again, somebody told him this is something that's going to bite you; you'd better get on top of it. He took the initiative to form a task force and asked me to head up the task force. This happened in 1991. As it turned out, even though I didn't have anything to do with the selection of the task force, it turned out to be a very good task force. Phil Derfler was on it, Judy Riggins, Dr. Hathaway from Foods -- a lot of good people on the task force.

We produced a task force report in 1991. We briefed Dr. Kessler in 1991 and made our recommendations, and he thought they were good. We thought they were good. We developed an implementation plan for him. He ultimately turned all of that over to Mike Taylor.

Well, Mike was consumed with other issues, and the task force report, the implementation plan, all of that kind of sat on the shelf until 1993, when the industry knew that we had done all this, and they were worried about what FDA was doing with dietary supplements. So then the decision was made to release my task force report.

Well, a lot of the work with the industry, which I coordinated back in 1991, had gone by the wayside, and those people kind of lost confidence in what, certainly what I had told them, and other things, and so they had begun to work the political network and get the Congress agitated about dietary supplements. Scott Bass and others started writing the legislation that ultimately became the Dietary Supplement for Health and Education Act (DSHEA) in 1994, which was not the best legislation that FDA had ever seen.

I think, without denigrating Dr. Kessler, he was off doing what he felt he had to be doing, and Mike Taylor was doing the same, and they lost sight of dietary supplements a little bit and didn't see exactly what was happening until it was too late. They did a lot of damage control, but they couldn't stop the momentum, and so we got saddled with DSHEA.

SJ: A little earlier, they had NLEA (Nutrition Labeling and Education Act) which they had touted as a huge success.

GD: Yes, and they felt good about that. NLEA was a huge success, and a new food label and all that was good stuff. But this dietary supplement stuff . . .

Then, of course, the industry got the consumers all worked up about it, and the write-in campaign started, and even I got some death threats. Dr. Kessler got them, but I got them too. We put the so-called Dykstra Report out there, and it was completely mischaracterized, completely mischaracterized. But I was out of it then. I couldn't come up and start to explain it because it was all being handled out of the Commissioner's office. As they explained it, they were protecting me. Well, I didn't really want to be protected because my name was on that thing and I wanted to get back into it, but they didn't think that was a good idea.

In any event, what happened, happened, and we're still struggling with dietary supplements.

I was the Deputy Associate Commissioner until 1999. Ron Chesemore retired. I felt it was time for me to either retire or do something different. The opportunity to come down to Atlanta and be the Southeast Regional Director

presented itself, and I always felt like when I was out in the field, I wanted to get back to the field, and I felt like I had the skills, the knowledge, the ability to be the Regional Director here in Atlanta. I talked to Ron Chesemore about it. I talked to Dr. Henney at the time, and ultimately they decided that they would allow me this opportunity to come down here, and it turned out to be the best part of my career. I always said that working in the field was the best part of FDA. I finally got the opportunity to come down and have an impact on the field organization. Being part of the senior staff of ORA and also being responsible for a large part of the United States was just, to me, a dream come true.

Then I came down to Atlanta and discovered that I had a wonderful staff, very talented people that, again, using the skills that I had learned along the way, got them involved in the things that they felt needed to be done down here, and then basically turned them loose and let the District Directors handle the things that they were handling in their part of the country. They knew it well; they knew their industry; they knew what had to be done. We would coordinate all the directives from headquarters and from the Centers and get those things done, but we had

a good run for about eight years. Was it eight years, from ’99 to 2007?

SJ: Yes.

GD: It was eight years that we handled things down here and did it very well. I think we had probably, if not the best, one of the best regions in the country.

SJ: Had you thought about going back to the enforcement area in ORA or for some compliance or . . .

GD: You know, I didn’t really think about that. I’d already moved up to the Deputy Associate Commissioner level, and there wasn’t anything to move to. They clearly were not considering me for the Associate Commissioner job, and that told me either retire or maybe get back to the field. The opportunity presented itself, so I decided to go back to the field. It turned out, I think it was good for me and good for FDA.

The one thing that I did work on here in the Southeast that was something that I will never forget, and that’s the response and recovery from Hurricane Katrina. That was something that none of us had really dealt with. We had dealt with hurricanes in Florida, but nothing on the scale of what happened with the New Orleans District and the devastation down there. That had a big impact on me that taught me, some lessons about management and how to deal

with headquarters, how to deal with just people in general, people who have been wiped out; and looking them in the eye and telling them, even though you've lost your house, you know, you don't have anything to go back to in New Orleans, but I want you to work. You have a job to do at FDA, and we need you, and you need to help us get things back to normal in New Orleans.

One of the most emotional and difficult meetings that I ever participated in was the meeting when I called all the employees back. They had scattered to the four corners of the United States, and I had to tell them that you've got to leave your families and you've got to come to Nashville, Tennessee, because we're going to set the office up in Nashville, Tennessee. I had told headquarters that's what I was going to do, and nobody argued with me. But I said -- and that was done within a week of the hurricane, and tracked everybody down and made sure everybody was safe and sound. But then I said, "You've got a ticket to Nashville, and you've got to be here."

Then I went over to Nashville and we had a meeting, and the first thing I did in that meeting is I just went around and let people talk and tell me what's on their mind. There was more crying going on in that meeting than

I had ever experienced in my life, and it was just gut-wrenching.

At the end of the meeting, people started to recognize that they weren't the only ones that were suffering; and they had a family there in that room, and that we could all work together and we could get things back, slowly but surely, and we'd get through this thing, and that they had the whole FDA family to fall back on. And the FDA family came through. They sent gift cards out to every one of those people so that they could go buy the things that they needed. People sent everything! You wouldn't believe the -- I mean, we had a whole room in Nashville filled with clothing and different things for people so that they could literally go in there and search for things that they might need.

We did need them to help get back into the New Orleans area and set up resident offices, resident posts, and we did that rather quickly. Those people made it happen. I didn't have to bring in a lot of people from elsewhere. It was those people that did it. And that was a real experience.

Then I told Dr. Crawford at the time, I said, "You've got to come out here. You've got to see this, you've got to feel it, and you've got to see what the people are

doing," and he did that and we did the tour of New Orleans, and that was quite an experience.

I went down to New Orleans. You just couldn't imagine the devastation. I mean, the areas that were flooded were -- and I told people this -- were totally brown, trees were brown, everything was brown. It was like a bomb had gone off, and it was all the same color. The cars were all covered with brown, just, everything was the same color. It was just desolate there. That's what I remember about it, quiet, no birds, no animals, no nothing. It's hard to imagine. It's hard to even explain to people what it was like.

Then the people started going back and looking at their houses and it was just . . .

SJ: Not much to find.

GD: Yes, there wasn't much to find.

But we got through that. We got through a lot of other crises, you know, the foodborne illness situations, which started to mushroom at that time, six or seven years ago . . .

TAPE 2, SIDE A

GD: We had to contend with 9/11, which happened during this time period, and, after 9/11 we were authorized to hire many new people. We had to gear up to train those people and get them out there implementing the new regulations that were put in place to prevent any sort of terrorism associated with the food and drug supply. That was a challenge, and I thought that our people rose to the occasion and did an outstanding job of finding the new people, bringing them on board, and training them.

We had the various foodborne illnesses that we had to follow up on. We had our own tomato episode here in North Carolina and Florida, and that resulted in a lot of effort on the part of FDA, the various states involved, and the academic institutions, particularly the University of Florida, coming up with plans to try to prevent this from happening again. But lo and behold, we're right in the midst of it again, so something's not working right, and FDA's going to have to try to figure out what's happening and why it escaped some of the measures that we put in place previously.

Some of the things that have concerned me related to FDA as I've thought about my career have been, obviously,

the loss of people, the loss of institutional memory, concern about the management in ORA, which I'm most familiar with, and how you replace what I felt were real good managers that came up through the organization and continue to build ORA to last into the future and be able to cope with all of the things that are coming down the road.

SJ: Give me some examples.

GD: In terms of the management?

Well, I'm concerned that they're -- and this relates to my next point, which is the politicization of FDA in general, plucking people from areas that have nothing to do with the organization or management under ORA and putting them in to manage ORA, when they have no knowledge of the organization itself.

It's a diverse organization both people-wise as well as geographic diversity, and you need people, I think and continue to believe, you need to grow the management from within and have, and programs like the Management Intern Program to bring people up through the organization so that when these positions become available, you've got people, and, hopefully, numbers of candidates that can fill positions so you can get the best and the brightest into those positions; and not have the political types just

taking someone from outside the organization and putting them in there and saying, “Presto change-o, you are the new Associate Commissioner for Regulatory Affairs,”(ACRA) and then they have to learn how to do that.

SJ: Has Maggie Glavin learned that lesson?

GD: I think Maggie has tried very hard and has tried to seek advice on that, but I think she was given a job to do when she came in, and she -- I’ve known her from her days at USDA (United States Department of Agriculture), and she did the same thing at USDA. She was reasonably successful there in transforming or changing USDA and the Food Safety Inspection Service (FSIS). She tried to apply those things that she did there to the ORA organization, and it didn’t work.

I think the reason why it didn’t work was because she didn’t involve the people. She made efforts to involve the people, but in the final analysis, she didn’t involve all of the right people in that process.

SJ: People have said that USDA is much more of a top-down organization. Did you see that in her managerial style?

GD: Yes. Clearly, she was a command-and-control type of manager.

SJ: Well, people were concerned that when she came . . . Well, first of all, she came into the Bioterrorism Office.

GD: Yes.

SJ: But people were always thinking that they had something else in mind, because she's not an obvious choice for that.

GD: Right.

SJ: She is an obvious choice for the kinds of things that you were talking about. So the thinking was, she was there for a couple of years, that they had a plan in mind, and it took longer than that.

But there was also the thought that this was also at the time when they were talking very seriously about a single food agency. Basically, from my experience in FDA, they were preparing to lop off the Center for Food Safety and Applied Nutrition (CFSAN) in particular and divide the field and put it into USDA.

GD: Yes.

SJ: It amazed me how quickly we could organize to do that and how quickly we could organize to decide against it and reorganize. Am I observing something that you've experienced?

GD: Yes. There were obviously lots of dynamics going on, and I was not privy to exactly what was going on in terms of the selection of Maggie for the Associate Commissioner's job.

I was very sorry to see John Taylor leave. Even though he had not grown up in the organization, his heart was really with the organization. He understood it from a lot of his days in the Office of General Counsel, and he knew a lot of the people.

The disadvantage that Maggie had when she came in is she didn't know anybody, and she came in with a mandate. I really believe that Dr. Crawford and Janet Woodcock and others sent her into ORA with a mission, and she was bound and determined that she was going to carry out that mission. It just didn't work out the way that she had planned it. I think it's because she didn't take the time to learn the people and learn things that could have served her better in trying to make changes.

Now, I'm not saying that change isn't needed. I think that ORA has got to change with the times and has got to be mindful of things going on around them, things going on with the regulated industry, things going on elsewhere in FDA.

SJ: Well, why did we take so long to realize that imports should have fundamentally changed the way we were doing business?

GD: Right.

SJ: There's really, I mean, as a historian, we have to think very seriously about why that got overlooked for so long. And, of course, you get a Republican administration that's anti-regulatory, and you leave an organization like ORA in total chaos.

GD: Yes. Certainly some of that happened as a result of the Republican administration. You know, they were not keeping their eye on the ball either.

But way back in the '90s, we recognized how important imports were.

SJ: And how they were growing.

GD: How we had to reach out around the world and see what was going on. In fact, Ron Chesemore and I created an international staff in ORA to start to reach out, to look at the data, mine the data, see where the problems were, go, actually go to those countries and work with those countries to solve, get them to solve their problem, because we were seeing things like inspections of low-acid canned foods around the world, all of those places were failing their inspections, so we knew we had a problem.

Simply blocking those products from coming into this country was not the answer. Besides that, it created trade issues. So we had to start working with those countries. We came up with programs, working with the Center for Foods, to start to get these countries to take ownership of their problems and solve their problems, and we would provide them with technical advice.

We formed some of the trilateral organizations, particularly with Mexico, the U.S., and Canada, to work on issues, not just trade issues, but compliance issues, and make sure that we were communicating with one another when there were problems.

It was during that time that I said that places like China, we knew then that China was a problem. We had problems with China. We had mushroom problems with China. They were growing. It was clear to see back in those times, back in the ‘90s, that China wanted access to our market, and they were going to send everything and anything to us, and we needed to be working with them and not simply monitoring their products when they got to the U.S. But we weren’t, ORA wasn’t convincing, in our arguments with the rest of the agency that we had to be more proactive with places like China.

Our argument in ORA was that let's again look at the data, see where the problems are, and focus our limited resources on those countries. Forget about the rest of the world. Let's solve those problems first, and then we'll move on to the next problem country, but concentrate on one country.

Well, finally, here in 2008, we got the message, you know, we're going to get out there and work with the problem children in the world and try to get those problems solved. We have this big import strategic plan that was worked on for so long. Why it took so long to start to implement that, I really don't know. ORA was not in charge. We were just a player in that. A lot of that had to do with people leaving and it would get put on a shelf for a while, and then somebody would take it off the shelf, and then we'd have a crisis and everybody would say, "We've got a plan, we've got a plan."

SJ: Let's make sure we read it carefully.

GD: Right, exactly.

SJ: What was the relationship between ORA's international group and the development of the agency's international staff? It started with, I guess, Linda Horton and . . .

GD: Right. Well, in the ‘90s, we cultivated that relationship. We met on a regular basis with Linda and Walter Batts and Sharon Holsten and talked about what we wanted to do internationally, and talked about these various work groups that we were setting up, and I think we had a very collegial relationship.

It started to deteriorate a bit because of some personality conflicts that started to develop between their people and the ORA people, and I had to spend more time than I wanted to spend brokering those relationships and patching things up from time to time. Then when John Taylor came in, I left, Ron Chesemore left, the international office that ORA had went away, so it all got turned over to the Office of International Programs (OIP). Since that time, they’ve been doing it, but I still think that they’ve been fostering a shotgun approach to it and trying to do too much.

SJ: And they’ve been specializing in small programs, from my observation.

GD: Yes.

SJ: We’ve got Africa really well covered, but we had nobody on China, I don’t think, until Julia Ho, and then one person.

GD: Right.

SJ: I can’t imagine how she functioned the last couple years.

GD: Right.

SJ: You know, one person.

GD: Yes. Now, finally, it’s a big focus, and Mac Lumpkin is Mr. China. You’re going to find that you’re going to have a whole staff devoted to China.

I’m still not convinced that putting people over in those countries and establishing an “office” in those countries is the best way to go.

SJ: And will those offices be under ORA jurisdiction? Has that been decided?

GD: I don’t know. That was always the worry. Will it be under FDA jurisdiction?

SJ: Rather than the State Department or Commerce.

GD: The State Department or Commerce or some other agency, the Trade Rep’s office. Who knows?

SJ: Commerce.

GD: Yes. When there’s a problem, there’s a crisis involving Chinese products, is FDA going to be left to solve it, or is somebody else going to jump in there?

What I see happening is -- and we investigated this before with the Environmental Protection Agency (EPA), who established offices around the world. What they found is

when there was an environmental crisis someplace, it was the ambassador that was running their people and telling them where to go and where to be and what to say and all of that. I think FDA is going to run into some of that.

We had argued back in the ‘90s, again, that we could cover the Far East from Honolulu and do it just, more cost-effectively, just build up our Honolulu office and have at least most of the contingent there just be travelers. They would travel out to China and Taiwan and Southeast Asia and handle things from there, because of these other problems that I just mentioned, and we’d have much more control over it. But they haven’t chosen to do that.

I think they’re going to find out that it’s going to be a money pit. It’s going to cost enormous amounts of money. Hopefully, Congress will give them the money, and I don’t know what happens when Congress starts limiting that money. It’s going to be hard to do it, and we’re talking about five regions of the world that they want to have offices in. That’s going to be enormously expensive, and we’ll see if it actually gets funded.

SJ: And we know from our history in FDA and ORA throughout the country, it was hard for us with three regions across the country, much less before we went to 10 or 11, to coordinate policies, to coordinate procedures, to

even communicate for a while, so that'll, even though it is a smaller global world, you're still going to run into those same kinds of issues, I would imagine.

GD: Right. You're going to have a bigger bureaucracy to go through. They will do their inspections there, but it won't come directly back here; it'll go to the office in Beijing. Or they'll do their thing, and then it'll be communicated somewhere else, and whether that somewhere else is ORA or it's the Office of International Programs, who knows. But I think we'll probably have to work through some communication issues.

But it's a brave new world out there, and FDA has got to find mechanisms to deal with it. I've already talked about the political implications. You know, FDA still has funding issues that it has to work with, and that's another concern that I have.

I think just developing FDA programs is an issue, and the way we develop programs in the agency has from time in memorial been a problem. The Centers develop the field programs. There's coordination, but not good coordination. It's put together in a field work plan on a yearly basis, and we're lucky if we complete that work plan. When we have a crisis, it just all goes out the window. So program planning and program evaluation is always an issue.

Communications around FDA, outside of FDA, is always a problem. I think we have tended to try to control the districts and the regions a little too closely, haven't allowed them to interact with their local communities enough. You know, the Public Affairs Officers now are hamstrung to a certain extent. They can't get out to their local media and do the things that they did years ago.

SJ: Why?

GD: I don't know. I think it's the influence of the Press Office and the Commissioner's Office that don't want them doing that sort of stuff.

It used to be, when there was a crisis in Georgia, and the local media would come here to get an interview, we would do the interview and, of course, coordinate it with headquarters, but we would do it. Now it's pretty much policy, everything gets referred to headquarters, so the *Atlanta Journal-Constitution* (AJC) and local media have to go to headquarters to get their story, and that's . . .

SJ: Which certainly means less local coverage.

GD: Yes, less local coverage, or no coverage.

So communications are always going to be a problem.

Employee involvement in the decisions. I think FDA has to guard against being that top-down organization. They have to involve their employees at all levels. And

I've always advocated the idea that the employees know best what's going on and how to get the job done, and we need to involve them in that process rather than tell them what to do, and you'll get a much better work product out of them.

The agency has got to be involved in continuous improvement. We always have to be looking at ourselves. Otherwise, somebody else will look at us. We have to be ready to tell the Congress and tell the people that are looking at us critically what we're doing and how we're doing it and what we're doing to improve ourselves, and have that in our hip pocket all the time. And have our employees understand what we're doing.

The other thing is, this is a science-based agency. We've got to keep up with technology.

I'm very proud of the fact that I was involved in the upgrading of the laboratories in the field back in the '90s.

SJ: Was Richard Baldwin involved in that, or was he doing things earlier?

GD: He was involved in it. He was the Director of the Division of Field Science at the time.

But Ron and I really played a pivotal role in getting the money to do it and being very creative in the way that we did it, funding it over several years. And that was

because Ron understood the funding process, the budgeting process. We came up with the ideas that they couldn't say no to. I told people that once we build a new laboratory, that lab is going to be obsolete in 10 years, and you have to be thinking about it right now because it takes so long to fund a new laboratory and get it built. You almost have to start the process all over again when you open your new laboratory, because science marches on, and it's marching very quickly. If we want to have a good, solid science base in FDA, we have to be mindful of that. We have to keep up with the science, keep our people trained, keep our laboratories well equipped so we're ready to react to emergencies, and hire the right people.

SJ: We've been involved in several hiring initiatives, and I know you've been involved in them. Could you just reflect a little bit on the hiring process? We tend to hire people en masse, and I don't know, people have varying opinions on how effective that is. But it does seem to build an esprit de corps in some areas.

GD: Yes. To me, that's not the best way to do your hiring, because that results in what you're seeing now, is mass exodus. Mass entry means at some point you're going to have a mass exodus. So what I advocate is bringing people in, new people every year. That's the best thing

for an organization. That way you're not overextended in terms of training. Your training programs can be adjusted in an orderly way. You don't have to put on these huge training programs and new-hire programs and then have to put them on the shelf when you're not hiring, and then lose your speakers, lose your trainers. It's not the best way to do business. Unfortunately, FDA has been subject to that kind of hiring over the years. We've been fortunate to get a lot of good people, but when you have to do that mass training, it takes away from all the other things that you have to do, and you can't do as many inspections and you can't do a lot of the things that you need to do because you're off, your good people are off training people, because you take your good people to do it. So, not the best way to do business.

END OF INTERVIEW