

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

**Interviewee:** Daniel G. Schultz

**Interviewer:** Suzanne W. Junod, Ph.D.

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Interview with Dr. Daniel G. Schultz

October 30, 2009

TAPE 1, SIDE A

RT: This is another in the series of FDA oral history interviews. Today, October 30, 2009, the interview is with Dr. Daniel G. Schultz, who joined FDA in April 1994 and served as Director of the Center for Devices, CDRH, from 2004 to the present time. The interview is taking place in the Parklawn Building, Rockville, Maryland. Participating in the interview with Dr. Schultz is Dr. Suzanne Junod and Robert Tucker of the FDA History Office.

Doctor, as we begin the interview, we would appreciate a brief overview of your personal and educational background, where you were born and educated, and then we perhaps could move into any positions that you may have had prior to FDA that led to your interest in the agency. We'd then like to explore in more depth the FDA activities you have managed.

Okay, Doctor?

DGS: Sure. First of all, thank you for giving me this opportunity.

I grew up in New York City, went to Stuyvesant High School, City College of New York, CCNY, and graduated from CCNY in 1970. Then I went to the University of Pittsburgh School of Medicine, graduated there in 1974, following which I did an

internship at the University of New Mexico; and then entered the U.S. Public Health Service; and my first duty station was Tuba City, Arizona, which is a hospital on the western side of the Navajo Reservation. I served there as a general medical officer and Clinical Director of the hospital for three years. At that point, I transferred to the U.S. Public Health Hospital in San Francisco to do a residency in general surgery.

SJ: When was that?

DGS: That was in 1978.

SJ: Were you there pre-AIDS, then? Were you there during the AIDS epidemic?

DGS: I think it was just sort of starting at that point.

One of the interesting things at that facility was we actually, on surgical service as well as the medical service, took care of a number of patients with Hansen's disease. We were the largest service for Hansen's disease even though there's a big hospital in Louisiana that's known for that. But, actually, a lot of patients came up from Mexico through Southern California, and then to San Francisco to be treated.

So anyway, I did a residency there, most of it at the USPHS Hospital in San Francisco and a portion of it at the University of California-San Francisco in San Francisco as well.

In 1981, the U.S. Public Health Service Marine Hospital System was closed down, you may remember, and I was actually just beginning my year as chief resident in

surgery, so I was forced to look elsewhere to complete my surgical training and ended up in Denver, first at Children's Hospital, where I did a year of pediatric surgery, and subsequently at St. Joseph's Hospital, where I completed my general surgical residency.

I then went back into the Public Health Service, accepting a position as chief of surgery at the Indian Hospital in Santa Fe, New Mexico. Chief of surgery at the Indian Hospital in Santa Fe, New Mexico, meant being the only surgeon at the Indian Hospital in Santa Fe, New Mexico. It's a small hospital, 45 beds, and, as I said, one general surgeon, I think we had an ob-gyn, and several internists and family practitioners, but it was a relatively small place. And I served there as the surgeon for 11 years. And that's where my children, my daughter was actually born in Denver, and we dragged her down to Santa Fe when she was about two weeks old, so she essentially grew up in Santa Fe. And my son was born at the Indian Hospital in Santa Fe, which was a wonderful day from a lot of different perspectives, not the least of which was when he came out and he was this light-blond kid in an Indian hospital, and all the nurses were hysterical because all the Indian kids came out with this big black, bushy head of hair, and there was this little light baby who had no hair essentially.

Anyway, so that's where my kids started out, and I had a great 11 years there both professionally and personally.

SJ: How did you find the Indian Health Service? They continually struggle. I've got a friend who works in Chinle, Arizona, and . . . Tell us a little about your experience there in terms of challenges and opportunities.

DGS: Yes, yes.

SJ: It's different than practicing medicine here, certainly.

DGS: Absolutely, yes. I was given a great opportunity, when I was in Pittsburgh as a medical student, to spend a few months on the Navajo Reservation. There was a professor at the University of Pittsburgh who had a program that he had set up to send medical students out to the Reservation to give them a taste of what rural Indian Health Service medicine was all about. And I was just fascinated from the time I got there, both with the medical practice, which I thought was incredibly meaningful and fulfilling, and also just the Southwest, which I, having come from the heart of New York City, was probably like the opposite end of the Earth. But I just fell in love with the Southwest and at that point decided that, when I was finished with medical school, that was what I wanted to do.

I decided to go to Albuquerque and do my internship, and then went out to Tuba City. And the three years in Tuba City were as good as any years of my life. It was just a magical place to be, to be young and free and be able to practice medicine in that kind of setting. A lot of our patients either didn't or wouldn't speak English, so I actually had to learn a little Navajo in order to get started. And you're right, I mean, we did struggle with resources, but I think we made up for it in terms of the commitment of the staff.

And in particular, I met a surgeon who was also the head of the hospital out there. His name is John Porvaznin and he became my mentor and inspiration to become an

Indian Health Service surgeon, and that's why I went back and did my surgical training and then came back to Santa Fe to do surgery in the Indian Health Service.

It was fantastic. I mean, I wouldn't give up a day. It was hard because, as the only surgeon, I was basically on call every minute I was in town. The only way I was not on call was when I left town for a few days out of the year. So it was a lot of work, a lot of nights, a lot of weekends, a lot of time away from the family, obviously, which was hard. But in terms of the practice, it was fantastic. It was all about the medicine. It was all about the patients. It wasn't about filling out insurance forms and worrying about payment and all that stuff, although I did do a little bit of private practice while I was there, so I got a taste of what that was all about as well.

And the people; the main thing was the people. It took a while to sort of have them trust you as an Anglo surgeon coming in, taking care of Native Americans. There was some degree of mistrust of the government, of what the motivation was of the people that were there. But once you got their trust, you never lost it.

Today, I still have a house in Santa Fe, and I go back there and people stop me on the street and say, "You took out my gallbladder," or "You fixed my hernia," or "You took care of my cancer," or "You operated on my mother," or my daughter or, you know, and it's amazing. It's a really, really, really good feeling.

So, again, I have nothing but positive things to say both about the Public Health Service and, in particular, the Indian Health Service.

The only reason I left, after 11 years of being on call, basically that's sort of what got me to FDA. I decided to explore other opportunities within the Public Health Service, and it turned out that an old friend of mine, Dr. Marlene Haffner, who you may



know, was my first boss when I was on the Navajo. She was actually in charge of the Navajo Reservation Indian Health Service at that time, and I went to a commissioned officers' meeting and saw her again, and I just basically said I was thinking about trying to do something else, at least for a while, and she was the one that said, "Well, why don't you think about FDA and devices?" and at that point I really knew absolutely nothing about what that meant. I didn't even know that FDA regulated devices.

SJ: Much less television sets.

DGS: Much less television sets. That's exactly right.

But it sounded interesting and it sounded like something different and it sounded like it would be a different experience both for me and for the kids, and I thought it would be a nice opportunity for them to come back East and see something different.

So I came out for an interview. At that time we were on Piccard in Rockville and stayed at the Woodfin Inn. I remember all this very well. I had my interview, and a couple of weeks later they said, "Yes, we'd like you to come." And I basically got orders, and there I was.

SJ: You came as Commissioned Corps.

DGS: I came as Commissioned Corps. At that point I had been with the Corps for 17 years. My original plan was that I would stay here for three years and finish out my 20 years in the Corps and then go back to New Mexico. That was the plan. Obviously, that

changed.

RT: Well, you must have found interesting challenges here or you wouldn't have stayed.

DGS: Absolutely, absolutely.

RT: The Device Amendments had been passed, and the program was underway when you joined. Is that correct?

DGS: That's correct. The Device Amendments were passed in 1976, so the program had at that point been around for about 18 years.

What was happening in the early '90s, you may remember, the Temple Report had come out several, a couple of years earlier, talking about the need for more clinical input into device regulation. At that point the Center was really more of an engineering-run organization, and to this day remains heavily influenced by engineering, which, obviously, makes a lot of sense when you're talking about medical devices. But there was a big push. Dr. Bruce Burlington had come over from CDER and Dr. Meredith Alpert had come over from CDER, both of whom were M.D.'s. He became the Center Director and she was the Director of the Office of Device Evaluation. And I think at that time there was a push for more clinical input, and I think that's probably why I was hired as quickly as I was, because I had, while I certainly didn't have any regulatory experience

or any research experience, I did have a fair amount of hands-on experience with medical devices during my 15 or 16 years as a general surgeon.

SJ: Let me ask a question. You can edit out anything that becomes extraneous or tends to go all over the map just to see where we go.

But you were a general surgeon.

DGS: Yes.

SJ: But you were the only general surgeon.

DGS: Yes.

SJ: So, did you do a little more elaborate surgeries, things like heart valves, things like pacemakers, things like that that normally a specialty might take over, which might expose you to a little more in the way of devices?

DGS: I didn't do cardiac, I didn't do heart surgery, I didn't do pacemakers. I did do a little bit of orthopedic surgery that probably most general surgeons did. I had some, a fair amount of training in hand surgery, so I did some of the hand surgery. I didn't do the big bones, but some of the smaller fractures and stuff like that. And I did chest, which is a little bit different.

And I did a lot of vascular access surgery. One of the big medical problems in Native Americans, especially in the Southwest, is diabetes. One of the results of long-term diabetes is renal failure, and so we had a large population of renal-failure patients, and one of the things that, as a surgeon, I was responsible for was making sure that they had access for dialysis, which was almost a full-time job in and of itself, keeping those accesses open.

SJ: Now, I think I know this but I haven't had anybody to confirm it with, actually. Isn't dialysis or access to dialysis one of the few nationalized, in other words, everyone who needs dialysis, they get it?

DGS: That's exactly right.

SJ: Say a little more about it so we can get it on the record.

DGS: Yes, yes.

SJ: Because I don't think most people know that.

DGS: There was a law passed -- and I don't know the date . . .

SJ: I think it was in the '40s. Is that too early?

DGS: I think it was a little later than that, yes.

But I think it became part of Medicare, became a particular clause in Medicare that basically mandated dialysis care for every patient with renal failure who required it. So, yeah.

RT: During those years in your practice, Doctor, did you have any personal experience with device problems or failures of devices to do what they were purported to do?

DGS: Sure. I mean, devices are not perfect. They weren't perfect then, they're not perfect now.

But I'll tell you what to me was a lot more evident. The impression that I had and I guess one of the things that brought me here and that I think they found somewhat appealing was the fact that I had sort of bridged the transition from open surgery to minimally invasive, so-called laparoscopic surgery, and actually had set up the first laparoscopic surgical unit in the Indian Health Service at our hospital in Santa Fe.

The other big surgical problems in the Native American population is gallbladder disease, so we did lots and lots of patients with gallstones, and that was one of the first operations that general surgeons started doing laparoscopically. So I was very, very fortunate to see that transition from open to laparoscopic surgery, and one of the main things that impressed me was how much more important devices were when you went from open to laparoscopic surgery.

Up until that point, I mean, if you think about it, general surgeons, we didn't have very many fancy devices. Basically, it was a scalpel, forceps, retractors, very basic stainless steel, mechanical types of devices. When you went from open surgery to minimally invasive endoscopic surgery, now you became really dependent upon laparoscopes, so optical technology, electronic technology, all sorts of very precise instruments that could be placed through trocars that could be inserted into the belly rather than having to make a big incision. So a lot more highly technical devices in general surgery as time wore on. And I think that holds true across the board, in cardiology, in radiology, etc.

I think what we've seen over the last 20, 30 years is basically an explosion in technologies that have really changed in many ways the way that medicine is practiced.

When I was in training and when I was a surgeon, we had an operation that we called an exploratory laparotomy. You don't hear that term anymore. I mean, that's basically a historical term, because nowadays, with CT and MRI and all the tests that we have available to us, it's very rare that you operate on a patient without having a specific diagnosis and a specific plan in mind. That's not to say that sometimes you don't find other things, but usually you go in knowing what you're going in for, and that's a really big change.

SJ: That's right. They used to talk about an exploratory operation.

DGS: Yes, yes.

SJ: I never made that connection.

DGS: And the reason for that, again, is improved imaging, improved diagnostic technologies that have really changed that, and so changed the way diagnoses are made, changed the way operations are performed, changed the way medicine is practiced. In cardiology, going from the open coronary artery bypass surgery to stents, first bare-metal stents, then stents plus brachytherapy, and now drug-eluting stents. All that really has happened.

SJ: What was the second stent you mentioned?

DGS: Well, one of the problems with stents was, when they first started being used, was people noticed that over time, there was ingrowth of tissue and the stent became occluded. So people started thinking about, well, what can we do to prevent that from happening. So the first thing they did was they used localized radiation, or brachytherapy, to radiate the tissue to try to prevent it from growing back. And that became the precursor to drug-eluting stents, where the drug was part of the stent, and the drug did the same thing, so you didn't have to add another procedure to the stent.

SJ: There's been a lot of controversy over the drug-eluting stents, though.

DGS: Yes.

SJ: Whether they're really worth . . .

DGS: Right, right. You know, I'm not sure there's controversy over the stents themselves. I think -- and this happens a lot in devices, and drugs; I think it's probably true across the board. But when there's a new breakthrough technology, there's this incredible amount of hype and excitement about this new technology. And, as I said before, devices, drugs, none of it's perfect and none of it is the be-all and end-all for every single patient.

So what happens is something new gets developed and gets approved, and people start using it, and then they notice that there are problems and that there are things that they weren't aware of when the product went to market, which in my mind is something that we should anticipate. We shouldn't be surprised by that. I think it's a natural sort of part of the evolution of technology, is that you have a breakthrough product, and as it gets used more and more, you learn more about it and you learn what its proper role is in the armamentarium of products that you can use to treat that particular disease. I think that's what happened with the drug-eluting stent. It went through this sort of a honeymoon phase where everybody said, "Oh, yes, this is the answer," you know, *the* answer. Well, it's not *the* answer, it's *an* answer and it's an important answer.

And then people started saying, "Well, it may not be the answer for everybody. Maybe we should only use it in these patients and not in these patients. Maybe we have to do some more studies to try to better identify who the right patients are and how long they should be followed, and what drugs . . .



Right now there's a study going on looking at the use of anticoagulants with the stents, because people still aren't sure exactly how long patients should be on anticoagulants after they've had a stent. So there's a lot of questions that need to be addressed, and sometimes those questions get answered over time.

But I don't think we should lose sight of the benefits that all those patients who have had their chests opened up who could be treated with a stent that could be put in through an artery and they could basically go home the next day, which is pretty impressive.

SJ: You came into the Division of Reproductive, Abdominal, ENT and Reproductive Devices?

DGS: Actually, I started as a reviewer.

SJ: Ah, how general.

DGS: I was hired as a reviewer for the Division of General Surgery, and that's where I was, that's where I did my first, I guess probably about a year and a half, reviewing, again, primarily laparoscopic devices in general surgery.

SJ: Did it have anything to do with Dr. Haffner that you moved over to Reproductive?

DGS: No, not really. Marlene basically gave me the idea, and from that point I started working with the folks in CDRH, and they sort of put me where it made sense. Since I was a general surgeon, they put me in the Division of General Surgery.

I moved over to DRAERD, which was the Division of Reproductive, Abdominal, and Radiological Devices. That was my first management or semi-management position. I became the Chief Medical Officer for that division, so sort of moved out of my comfort zone in general surgery into other types of devices.

SJ: What were some of the important devices that you were working on at the time? And I know enough to be dangerous about some of this. As I understand it, some of the reproductive devices, well, had been -- there were a lot, there was a backlog from the '76, a long backlog, and in some of the divisions it was worse than others.

DGS: Right.

SJ: How was it in your division, and what were you working on at the time?

DGS: By the time I got there, the backlog, I think, was really more in '91, '92. When I came, there was still a backlog, certainly in DGRD, there was a large backlog in Orthopedics. But by the time I moved over to DRARD, a lot of that had been resolved.

One of the big issues at that time was in radiology. People were moving from standard analog type radiology to digital radiology, and there was a fairly heavy

controversy about how we would treat digital mammography as opposed to other types of digital x-ray. We ended up asking for substantially more data for mammography because of the importance of mammography as a diagnostic tool for breast cancer, and that created a fair amount of controversy, and it took us a few years to resolve that, to get the studies we needed in order to be able to approve that technology.

There was a lot going on in renal, in dialysis. People were starting to think about alternate ways of delivering dialysis, not just three times a week in clinics, but starting to do home dialysis, and how we would regulate those changes. That brings up a whole other issue about devices moving into the home and moving out of the standard places where they'd normally be used. Whether it's going from an ICU to a regular hospital room, or going from a hospital to a clinic, or going from a clinic to a home, all those are different challenges in terms of how devices are used, and primarily in terms of how to label and how people are instructed in their use as well as how they're designed for use by people who may not have all the training of people who normally use those devices would have. So that was and, I think, still is a big issue for devices.

SJ: It sounds to me like what you're talking about is that you've got digital mammography coming in at the same time you've got the Mammography Quality Safety Initiative.

DGS: Right, right.

SJ: Because it started a little before this, didn't it?

DGS: Right.

SJ: But, tell me a little about how in one sense you're regulating an outmoded technology or becoming an outmoded -- I may be stating it too strongly. But were you aware that this might be an issue, or did you think there was just a continuum along the same spectrum?

DGS: Yes. I think that, I mean, the MQSA (Mammography Quality Standard Act) program -- and I don't know the exact dates -- but that, as you said, was already identified. Mammography had already been identified by Congress as a particular area of concern, which is why they put in the MQSA law and assigned CDRH to manage the program.

#### TAPE 1, SIDE B

DGS: We were talking about MQSA and then we were talking about the issue of the transition from analog to digital mammography, which really is, actually has not yet been completed. There still is currently both analog as well as digital, and the truth of the matter is that, for most patients, they work about the same. So, just to be clear, if you go and have a mammogram, the most important thing, I think, in terms of public health is that women actually go and get mammograms. Whether it's a digital or an analog is

really sort of a matter of certain technical things and what that facility happens to do, but that's really a secondary issue.

We were certainly aware that there was particular attention paid to mammography, and while the transition in other areas from analog to digital went primarily through the 510(k) process, basically looking at the technology, we insisted that there be clinical trials for mammography to demonstrate, at the very least, that there wasn't a loss of clinical information in going from analog to digital. Everybody talked about the fact that the technology was better and the pictures were clearer and everything, but we still wanted to answer the bottom-line question: how accurate would this new technology be in diagnosing cancer? Would it miss cancers? Would it detect more things that weren't cancers? And we needed to have that information, and we insisted that companies do those studies before we allowed that technology to go to market, to the chagrin of many people, including companies as well as many radiologists, who thought we were being overly -- what's the word -- rigorous, I guess, and saw this as an obvious . . .

SJ: No-brainer.

DGS: A no-brainer, right, exactly.

SJ: And what did you find?

DGS: Well, actually, what . . . It's interesting. When we did . . .

SJ: Because you talk about new technology.

DGS: When we actually got the studies and looked at the data, the truth of the matter was that the two were just about equivalent. I mean, there really, despite the fact that people thought this was going to be this wonderful new technology . . .

In this case, the technology clearly has some advantages. I mean, one of the simple advantages, if you think about it, is, if you have a digital technology, rather than having to store all these pictures, you can store huge amounts of data digitally without having these . . . If you've ever been to an x-ray department and you try to find the right folder with the patient's x-rays, I mean, it's really a challenge to keep all these things straight and keep all the follow-up films and keep all that together, whereas when you do it digitally, it becomes much easier.

The other thing that is a clear advantage is, suppose you want to open up a mammography facility in a rural area that doesn't have access to a radiologist. You can now do the film in one place, send the signal digitally to another place, and have it read a thousand miles away and be able to take advantage of the expertise in a facility that has a lot of experience reading mammograms. Or if, let's say, if you have a mammogram in Washington, D.C., and you move to Los Angeles, rather than carrying your big folder with you, they can just give you a disk or they can ship the information directly to your new facility.

So there's really a lot of advantages to digital mammography.

But, again, at the end of the day, the question was, how well does it or doesn't it diagnose cancer? And this is one of those situations where we had a certain amount of information. We were able to show that they were about equivalent in the early studies, in the first studies that led to the approval. And that was then followed up by a large NIH study that was done after approval that looked at about 50,000 women and 50,000 studies and showed that after age 50, there really was essentially no difference, but between 40 and 50, because women's breasts tend to be somewhat denser in that age group, there was a difference, and there was somewhat of an advantage for the digital mammography.

SJ: So you didn't find a lot of false positives that I think people were more nervous about.

DGS: Right, right, exactly, exactly.

SJ: Now, you moved from Chief Medical Officer to Division Director. Did that change your perspective somewhat?

DGS: Well, it certainly changed my perspective in terms of the amount of time spent doing purely science and regulatory versus doing personnel type issues. And in some ways, looking back, that position as Chief Medical Officer was one of the happiest times of my FDA career. I had a wonderful division director. Her name was Lillian Yin. I don't know if you have heard of Dr. Yin. But to my way of thinking, she is one of the true heroes or heroine, I guess, of FDA. And she is, she was in some ways my FDA

mentor in terms of how to do it right and how to conduct yourself in a way that was appropriate and in the best interests of the public health. And, unfortunately, she died during that time period, and that's where, at that point, I became Acting and then subsequently became Division Director.

SJ: What kinds of things did she teach you, or set an example?

DGS: I think the number-one thing . . .

SJ: Or teach by example.

DGS: Honesty, being straight, being tough but being fair, both with people in the organization as well as with companies. I think when companies did the right thing and when people in the organization did the right thing, she would be your greatest advocate and your greatest supporter, and when people didn't do the right thing, she let you know it in no uncertain terms. And she was just very smart, despite the fact that her English -- even though she came here as a young child from China and really never managed to lose a very, very thick accent, but didn't let that get in her way. She was just, I mean, if you talk to anybody who had ever come in contact with her, she was a truly beloved individual and respected individual within the FDA.

And she always said, "When in doubt, go back to the science." There's a lot of distractions. There could be a lot of distraction, which I learned more and more about as I sort of moved up through the management positions. There can be a lot of distraction,



and at the end of the day, her advice was always, “Go back to the science and the science will take you to the right decision despite all the other stuff that may be going on.”

SJ: Well, obviously, you were well thought of as well. Tell us about how you came to be in the Office of Clinical and Review Policy. You said that your medical background you thought was one of the things that brought you to FDA and had something to do with your promotion as well.

DGS: Yes. I think at that time there was an opening as an Office Director, there was an opening for this clinical Deputy Office Director, and there was an opening for the Division, and, frankly, the position at that time I didn't want was the one I ended up with. I actually applied for all three positions. I think I was still Acting Division Director at that point, and all three positions opened up, and people said, “You should apply,” and all that stuff. So I applied for all of them. I would have been very happy staying as Division Director because I liked the people I was working with and the products, and it was a great group and a great situation. But the idea of being Office Director was somewhat intriguing as well, but I really didn't want to be the deputy.

So they decided to give the Office Director position to a physician from the outside who came into the agency, and I said, “Well, that's fine. I'm happy staying as the Division Director.”

I can't remember all the details, but then basically he and some other people came to me and said, “We really, really need you since you have experience within the agency as well as a clinical background. It would be really helpful if you took this clinical

deputy position.” I thought about it for a while and decided, if that’s what they want, then that’s what I’ll do. So I took the position.

Then I guess -- I can’t remember; you have the dates there -- but I did that job for a couple of years. When the Office Director left, I sort of moved up.

SJ: Who was the Office Director at that point?

DGS: His name was Bernie Statland. He was actually a pathologist. He was more of an expert in laboratory, the clinical laboratory area, which at the time, the clinical laboratory was part of the Office of Device Evaluation. Subsequently, it got broken off and became its own office, the Office of In Vitro Diagnostics. At that point it was called DCLD, the Division of Clinical Laboratory Devices, and it was part of ODE. So he had a strong background in that, and I had more of a background in, on the therapeutic side and the surgical side. It actually made a lot of sense, and it resulted in a pretty good team.

SJ: Okay. There may not be anything in this, but we have been asking people about 9/11. You were in this position when 9/11 happened. People occasionally have, you know, experiences that are of special interest. Did you have any relating to 9/11?

DGS: I’ll tell you what was more of an issue for us, probably more than 9/11, was Y2K and the transition, and that was actually very, very interesting. And I’m not a computer person, and I really am not, in many ways, not a techie person either. I really look at things more from the clinical perspective. That’s what my background is. But there was

a lot of concern around Y2K about all the computers going down. And by that time, many, many devices were dependent on computer software, and the concern was, were all these devices going to crash? So we spent a lot of time sort of working with companies, making sure that they were aware of this as a potential problem -- obviously they were, at least most of them -- and making sure that they had a plan for ensuring that there would be a smooth transition. For the most part, that happened, and there really were not any significant issues related to Y2K.

9/11 actually, it's interesting that I was actually at the Naval Hospital, at my Breast Care Clinic, which is where I'm going to be this afternoon, after I leave here. But I was there that morning, in the Breast Care Center, seeing patients when they announced that the first plane had hit, and then . . . And I remember my comment was, "Just keep bringing my patients in so I can see my patients." And finally, when the second plane hit, they just decided that they would close things down and send everybody home because nobody really knew what was going on.

SJ: Concentrate on anything either.

DGS: As far as FDA was concerned, I'm not sure there was really a significant impact on the agency, although one thing that it did do and that we've continued, we've tried very hard to work with the military both in Iraq and Afghanistan, first Iraq, second Iraq, Afghanistan, to make sure that the military had access to the latest technologies. And if they came to us and said, "We've heard about this, this, or this, and we really think this can help our troops," we have put those on our priority track for, not to lower the

standard -- we still do the review and we want to make sure that it's safe -- but we've tried to expedite those reviews to try to get those devices to our troops as quickly as possible, and I think that's been pretty successful.

SJ: What are some things you think were expedited and that were advances for them?

DGS: Well, one device that I clearly remember was when a colonel who had just come back from Iraq came to us and talked about a vascular graft which could be deployed fairly simply in a relatively primitive field hospital, not on the battlefield, but in one of the forward stations, to treat people who had some kind of a blast injury where their blood supply to their arm or leg was disrupted. As you might imagine, time is of the essence in terms of restoring blood flow to whatever the affected extremity. In the past, many of those patients have had to undergo amputations in those situations.

This particular device could be put in as a temporary measure to restore blood supply while the patient was then transported to a larger facility for a more formal repair. He had heard about this. I guess some of the other forces in the area from other countries were using this device, and . . .

SJ: How did it work?

DGS: It was basically a tube. It was basically some type of plastic that you put the one end in one part of the artery and the other end in the other part of the artery.

SJ: And it just bypasses.

DGS: And it just bypasses and allows the blood to continue to flow.

SJ: Good.

RT: Would there be a similar arrangement for the vein?

DGS: Well, it depends. A vein is usually not quite as critical. Usually the veins, there tends to be a lot of collateral circulation, so, for venous drainage, so it usually is not quite as dependent on one vessel.

But, anyway, they brought this to us, and I remember we told them to come in with an application. We basically held their hand and told them how to do it, what kind of application, here's what you need to do, here's how you need to file it, you know. We got the application in on, I think on a Friday, and sent it up to our reviewers who review those kinds of devices. They came in on the weekend and spent the weekend reviewing the device, and I think within four or five days we were able to give the approval or clearance and allow that device to be shipped off to Iraq. So, yes, that's one example. There are obviously others.

SJ: Investigationally, or full approval?

DGS: No. We cleared it; we cleared it as a full approval.

SJ: Using some foreign data?

DGS: Yes. They had some data. Yes, obviously they had some data. We had seen similar types of products. Obviously, the concept was fairly straightforward.

SJ: But it wasn't mechanically sophisticated.

DGS: Right, exactly. So we did the engineering. You know, we were able to look at the material to make sure the material was safe, and that they had done the appropriate engineering to make sure it was strong enough and could do what it was supposed to do. We really didn't need a lot of clinical information in that kind of situation.

RT: When you -- now, that was a position you held before you became the Director of the Center. Is that correct?

DGS: Which position?

RT: As Director of CDRH. We're moving up to more current . . .

DGS: Right, but which position is the one you said was before that?

SJ: I think he means the Director of the Office of Device Evaluation.

DGS: I was Director of the Office of Device Evaluation, correct.

RT: From there, you assumed the Directorship of the Center. Is that correct?

DGS: I did. I remember the day when Dr. David Feigel, the previous Center Director, walked into my office and said, "Dan, I've got something to tell you."

And I said, "Really?"

And he goes, "Yes." He said, "I'm going to be leaving in two weeks, and I want you to take over."

SJ: How had you known Feigel? What had been your relationship with Feigel?

DGS: Well, he became Center Director while I was Office Director.

SJ: What kinds of things did you work with him on?

DGS: Oh, you know, I mean, the Office of Device Evaluation is the largest Office in CDRH, and we basically were responsible for all the pre-market reviews. We were in contact fairly constantly and had, I think, a very good relationship and continue to have a very good relationship.

SJ: I just answered a question from a couple of weeks ago.

DGS: Is that right?

SJ: Yes.

DGS: Yes, I think David did a lot of really good things.

I think one of the things he really contributed was this concept of total product lifecycle. That was his big sort of mantra, that we needed to not look at regulation as pre-market and post-market and compliance, but we really needed to think about it in terms of a life cycle of a device and think about being able to integrate data and information that we gather from the pre-market phase, from the post-market phase, from the compliance phase, and put all that together to get a better view of how that device was actually working and how it needed to be regulated. I think that was a very important concept, and it was one of the things I felt was my responsibility to try to operationalize, which is one of the things that I tried to do as a Center Director.

SJ: I was at one of his presentations on that. It was very impressive. I remember, one of the things that struck me, too, though, was -- and you may or may not agree with this; I certainly was just an outsider looking in -- but I do remember thinking that for the first time someone had looked and captured the key differences between devices and drugs.



DGS: Right.

SJ: I felt that was real . . . I've been doing a long-term research thing on heart valves, so . . . And the engineering part was what was missing from the concept of drug approval, I mean device approval, in my mind, because devices are never like drugs because they're constantly being invented and reinvented and tweaked and that kind of thing. So I thought for the first time, he had captured that essential difference and articulated it so it wasn't constantly taking after the drug approval process.

DGS: Right, right, right.

No, I think we've all heard that. I think all of us in Devices for years and years have heard, why aren't you like drugs, and I think you're exactly right. There are good reasons why devices are not regulated like drugs, and, in my mind at least, they shouldn't be regulated like drugs. I think there are certainly similarities and there are some commonalities where we can learn from each other in terms of how to do things, but I think that there are essential differences, one of which I think you articulated very well, which is the fact that once a drug goes to market, it never changes. It's that same drug that will be there for the next 20 years or 30 years, till the next new chemical comes along; whereas with devices, the minute a new device goes to market, they're already back in the engineering lab tweaking it and trying to make it better. So you're seeing these incremental changes occur constantly and you can't apply the same type of regulatory model to that kind of incremental change, basically, unless you want to shut

the whole system down. I mean, if you do that, you will not have any approvals and you will not have the kind of development of new technologies that I think . . .

SJ: Now, am I correct -- and this is just my question -- am I correct in thinking that a lot of these innovations are done on a very small scale, whereas if there's a change having to do with drugs, it's done all at the same time, you know, kind of across the board; it's a wholesale change. But am I right in thinking that a lot of the engineering aspects of devices and things are done by certain companies? I mean, there's more competition, in one sense, in the device field than there is in the drug field because one company gets the application for a particular drug and it's, what, 17 years later before a generic can enter the market. But if Medtronic is making a heart valve and Edwards Scientific comes along with a new one, they're actually head-to-head competing.

DGS: Right.

SJ: So you've got a smaller test sample. Would that be fair to say?

DGS: I think in general.

SJ: How does that make a difference in how you look at devices, to have this sort of competition with the industry? Does it make for more comparative studies which include efficacy studies? There's always been so much controversy over whether that is a good

thing or not, but I would think for devices, it would be even more inherent in the process than for drugs.

DGS: Usually the populations using the devices tend to be smaller than the population using drugs. So that means that many times the studies are smaller. We don't typically have the large comparative pharmaceutical studies. Sometimes we have longer-term studies because we have different types of devices that are going to be, you know, once you implant a device, it's in there for a long period of time. So we require studies that go out for longer periods in general for some of our devices.

In terms of effectiveness, we really don't require those same comparative studies, which we do require for a 510(k) device. As you know, it's sort of a legacy system where you come out with a new device and you have to show that it's substantially equivalent or at least as good as the device that you're comparing it to. So that tends to be a comparison between one device and another device.

For heart valves and some of the higher-risk products, which are so-called PMA devices, each device has to stand on its own. So if Starr-Edwards comes out with a heart valve, Medtronic comes out with a heart valve, each of those has to show independently that it's safe and effective. Now, they can do that a lot of different ways. They can do it comparing it to a control; they can compare it to another device that's on the market; so there's a lot of different ways they can make it work. But by the end of the day, each device has to demonstrate safety and effectiveness.

They don't have to demonstrate that they're the best, so if Medtronic has a heart valve and Starr-Edwards comes out with a new one, Starr-Edwards doesn't have to show that they're better than the other one, just that they are in fact safe and effective.

SJ: And those decisions are made by the surgeons as a rule. The decisions on superiority or preference or that kind of thing are made by the surgeons.

DGS: That's right. Basically, what I see, at least, is that we set a threshold, a floor, if you will, and the device that ends up winning out in terms of market share is really a matter of the decision for doctors and patients to make.

Our role, as I see it, is to make sure that the devices do what they say they're going to do, that there are no safety issues which are prohibitory in terms of allowing the product to go to market, and that we have enough data to be able to write a label which accurately describes the device and the performance and how to use it, and at this point it becomes the responsibility of physicians and other practitioners to look at the information and decide, for their individual patient, if this is what they want to use or this is better than that. This is their choice.

RT: In the case of devices, you have an adverse reaction program similar to drugs.

DGS: Correct. It's called the MDR program, Medical Device Reporting program.

RT: That would certainly be a source of essential information in the future.

DGS: Right.

RT: As far as devices, have you had any recalls?

DGS: Oh, yes. We have lots of recalls. As a matter of fact, we probably have more recalls than I think any other Center -- again, for the reasons we were talking about, because devices are constantly being tweaked and changed, and sometimes those changes can lead to unintended consequences. In general, I don't think people go about making those changes not to have a better device. But the truth of the matter is sometimes you make changes which seem fairly minor or fairly innocuous or, like you said, a no-brainer in terms of making the device better, and it can lead to unintended consequences. Sometimes changes in suppliers, a component that you got from one supplier, you change to another supplier for a variety of different reasons, and this can cause a device to have problems. Sometimes devices are used . . .

TAPE 2, SIDE A

DGS: You wanted to ask a question?

SJ: Yes. I know there have been a lot of issues having to do with cost and the implications of increasing costs with medical devices. But one of the ones I think has

been most controversial had to do with the reuse of single-use devices, tubing and things like that. I think you were involved with that issue.

DGS: Yes. This issue has actually been around for a while and actually spanned my time in various different positions with the Division and then at the Office level and then as Center Director. But let me try to sort of summarize it and give you my views.

First of all, you mentioned cost. Our mission at FDA very clearly is to look at safety and effectiveness and not to look at cost-effectiveness. We are, in fact, prohibited from using cost as a determinant in terms of whether we approve or don't approve devices. While we don't look at cost directly, that is not to say costs don't affect us in various different ways, and I think the reuse issue is a perfect example.

So, basically, how did this develop? Well, as more and more devices were being developed, for convenience sake many companies started developing what used to be reusable devices mostly made out of stainless steel, and started developing similar devices made out of some type of plastic material, which, like a lot of things in our society, the idea was, you use it once and throw it away, and then go get a new one rather than having to go through the process of cleaning and sterilizing and storing and all that stuff. So for many hospitals and clinics and other situations, this resulted in a big timesaver and something they wanted. So, again, what drives a lot of this is demand, and there was a demand for these types of devices, so more and more of them.

Well, then, as people started using these products, they realized they were spending a lot of money on these disposable devices. The truth of the matter is that, while the devices were called disposable, a lot of them were pretty well engineered, and

people started to realize that, wow, why am I throwing this perfectly good product away when it looks like it could be used at least several times before disposing of it? Well, you can imagine the issues that were associated with that. So people started, on their own, hospitals started reprocessing these devices, which were not labeled to be reprocessed. There were no instructions in terms of how to clean them or how to sterilize them, or how to make sure they continued to function the way they were supposed to function, because that's not what they were intended to do.

So the device manufacturers said, "We're not responsible for that. We labeled our device, and FDA, you approved our device for use once. The fact that hospitals are using it five times or 10 times, it's not our problem." But they were mad because . . .

SJ: They assume the liability.

DGS: They assume the liability, and, obviously, if we allowed this to go on, or somebody allowed it to go on, they couldn't sell this many devices. Right? So there was a little bit of . . .

SJ: Self-interest.

DGS: Self-interest, right, exactly. But they did have a point. I mean, again, as is usual in these things, there's logic to different points of view.

On the other hand, the hospital said, "We're getting killed by all the costs of medical care, and here we have these products that we think are perfectly good that can

be used five times.” And, obviously, if you use something five times as opposed to using it once, you can get a fairly substantial savings, so they were saving millions and millions of dollars by doing this reprocessing.

Well, this is the U.S. of A., and as this practice became more prevalent, companies actually started popping up that were specialized in doing the reprocessing, so the hospitals didn’t have to do it themselves. They could take all of their used devices, send them off to -- actually, they didn’t even have to send them. In many cases, these companies would come around and actually pick them up, they would take them to their facility, they would clean them, reprocess them, sterilize them if they needed to be resterilized, repackage them with their own packaging, and send them back, and the hospital . . . And so, let’s say a device that cost \$100 new, they would send back for \$20, and they would have another device.

Well, obviously, people started worrying about this. Was the device really as good? Was it fair to charge the same as a new device? And the government started looking because the government was getting charged the same amount. So was it fair to charge a patient or an insurance company the same amount of money for a reprocessed as for a new device?

We were asked to look at this issue and to basically figure out a way to regulate it. And, again, we had initially reviewed these as single-use devices, so we didn’t require them to have cleaning and sterilization directions.

The bottom line was, we essentially made a determination that if you take a single-use device and you reprocess that device, it essentially becomes a new device, and you have to demonstrate -- you, whoever you are . . .



SJ: In this case, it would be the reprocessor, not the original manufacturer.

DGS: Correct. So essentially, at that point, it becomes the reprocessor's device, which takes the responsibility away from the OEM, the original equipment manufacturer, and places it . . .

Now, that means that the reproducers, who up until this time had just sort of been doing this without really any regulatory oversight, they now needed to come in with 510(k)'s or PMAs -- usually 510(k)'s -- to show that their reprocessed device was substantially equivalent to a new device, and that, obviously, that whole effort to figure out how to do this. And, basically, if the hospitals wanted to reprocess, the hospital would have to come in with a 510(k).

Well, the hospitals realized very quickly, they didn't want to mess with this, so they basically got out of the business, and this entire process then shifted over to the reprocessing companies, who we worked with very extensively to try to get them into compliance and get them to do what they needed to do.

And I'd say overall, while there are a lot of people who don't agree with the whole concept of reprocessing and there are still questions about this cost issue about who deserves to make the profit on these reprocessed devices -- is it the hospital, should the insurance company get a profit, reap some of the benefits of this; should the patient be informed that they're not getting a new device, that they're, you know. There are still a lot of questions, but from our point of view, from a safety point of view, I think we've got a pretty good handle on the fact that if they do what they're supposed to do, that we

can be sure the devices are safe, that they're clean, that they're sterile if they need to be sterile, and that they function in a way that will be satisfactory.

SJ: And what kind of devices are we talking about? Then tubings were an issue that .

..

DGS: Oh, across the board, lots of different things.

SJ: Like, are we talking explants or things like that?

DGS: No.

SJ: Nothing that would be Class I . . .

DGS: Not really implants, mostly things that are used in surgery or in patient-care types of activities. But there's a variety of different devices in a lot of different areas that can be reprocessed.

The number has shrunk because, basically, every time a company wants to reprocess a particular device, now they have to come in and they actually have to show us that they can in fact reprocess them. So whereas they used to reprocess many different types of products, that number has been somewhat condensed.

SJ: Now they're doing the ones that they can profit from.

DGS: Well, that they can profit . . .

SJ: Or that they have a margin.

DGS: And that they can prove to us that they can actually do it safely.

SJ: Well, good. I'm glad we went back and picked that up.

DGS: Sure.

SJ: So now we're talking about transitioning into your tenure as head of the entire Center for Devices and Radiologic Health. Tell us a little about the transition and things that were different.

DGS: Well, I guess the first thing to say is it was not something that I had actively sought. And by this time, as I mentioned previously, when I first came to the agency as a medical officer, I had no real aspirations in terms of management or in terms of anything else really.

SJ: You were going to stay three years.

DGS: I was going to stay three years and go back to do surgery. So I had already sort of

gone way beyond my original plan both in terms of time and in terms of responsibility. But it seemed like that was kind of what was in store.

But, again, the transition was rather sudden, as I mentioned, with David coming in and saying that he was leaving and asking me to take over in Acting capacity. And it was certainly a little scary because my focus had really been pretty much exclusively on the pre-market aspect. I learned very quickly that there is a lot of activity that goes on outside of pre-market. You know, once a device goes to market, there's a whole other world out there in terms of adverse-event reporting, which you had mentioned in terms of compliance activities, making sure of the manufacturing and all that, in terms of international activities, in terms of a whole slew of things that I really didn't have a lot of experience with. So I would say while the good news was that I had been with the agency for 10 years, which I knew, probably more than some people, sort of from the ground up about the review process and how devices get to market, which people from the outside really don't have that kind of knowledge or experience, so I think that was the good news. The bad news was that there was still a lot more to learn, and I figured that out pretty quickly. While it was challenging and in some ways nice to be thought of as someone who could do that, there was obviously a lot of learning, a lot of growth.

SJ: What area do you think that the learning curve was the steepest?

DGS: I'd say probably in the compliance area, because that's really a very technical, specialized area.

SJ: And recalls and things like that.

DGS: Yes, and not something that I had spent a lot of time on.

SJ: Isn't a lot of that work sort of cross-Center work as well?

DGS: Well, a lot of it is. Not so much with other Centers, but certainly with ORA (Office of Regional Operations) and OGC (Office of General Counsel).

SJ: Well, with the lawyers and that kind of thing, too.

DGS: Right. So a lot of it, obviously, the biggest group that we worked with in terms of the compliance activities is ORA. The compliance groups in the Centers work with the Office of Regulatory Affairs, who are the people that are actually out in the field doing the inspections. And then, if there are problems and issues, then many times the Office of General Counsel will get involved as well in terms of taking these actions, and so it's a process and, again, I think a challenge because all the authorities don't necessarily rest within the Center. So a Center Director, while you're supposed to be "in charge" and have responsibility for all this, really, a fair amount of it is out of your control because it depends on coordination between people in the Center as well as ORA and OTC and even others outside the Center, so you're sort of dependent on everything working right in all those areas.

SJ: Were there any big legal cases during the time you were Center Director, that you had any involvement in, or any China importation problems?

DGS: Well, we did have issues related to heparin. While heparin is obviously a drug, heparin is also used as a component of many medical devices to prevent clotting.

Tubing, you mentioned tubing. There are a lot of tubing, different types of tubing devices that have a heparin coating. And a lot of heart bypass equipment is coated with heparin. So while it initially was thought of . . .

Actually, initially -- I don't know if you know this, but the heparin problem was actually discovered in a dialysis unit, and initially we were the ones who were called because these patients who were getting dialysis were having these issues, these allergic, what looked like allergic issues, and people thought it was a device that was causing it. Well, subsequently, they figured out that it was not the devices, it was actually the heparin that was causing it. So then people said, "Ah-hah, it's a drug!" and so then it sort of became a drug issue. And then, eventually, people said, "Ah-hah, but heparin is actually used in devices," so it actually came full circle. It was sort of interesting the way it all developed, but, obviously, a lot of it was a drug issue, but we were heavily involved as well on the device side.

SJ: Do you have any comment about Janet Woodcock's, the company that's now revealed that they thought her writing an article with one of the lead manufacturers or something . . . You read about this?

DGS: I read a little bit, but I don't know the details.

SJ: Okay, skip over that, then, because I'm not as up on it as I should be either, because I was told that it was just a matter of the company revealing something, their choice, not required.

Okay. Do you remember any legal cases or anything that, where you got involved?

DGS: Well, there were certainly some well publicized recalls.

The one that sticks in my mind, and the one that actually prompted a lot of subsequent activity, was the Guidant pacemaker recall, which you may remember. This was actually brought on by, there was a young man who had one of these pacemakers which failed, and then it turned out that the company had made some changes to the device that hadn't been reported to us in certain ways that didn't necessarily allow us to connect the dots between the changes and some of the effects of those changes. And that was, obviously, well publicized by the press and questions were raised about how could that happen.

As Center Director, this led me to really think more about how this total product lifecycle concept could be operationalized in a way that would hopefully allow us to get more information more quickly and be able to hopefully prevent some of these things from happening in the future. That led to the two reports we put out on the status of our post-market surveillance program, followed by a second report which talked about things

we as a Center could do differently in the future to try to improve the way we handled post-market information. Those reports are on the web. I don't know exactly what the titles are, but they're there to see.

This led to the development of what we call the CDRH matrix, which is a way of trying to integrate pre-market information and post-market information to allow us to really try and predict and prevent some of these types of problems before they occur. That's actually still ongoing. But the process is in place, and it's obviously now a matter of execution.

RT: During your tenure as Director, there was a lot of congressional interest, of course, in the program and the enactment of the legislation and so on. But now that it's been in effect and operational a while, was there any particular congressional committee oversight during this period, or interest in the Center's operations during your time of being Director?

DGS: Yes. We always experienced such interest in that. There's always interest.

Actually, the one hearing I remember going down to testify at, there was a piece of legislation that then-Congressman, now Senator Coburn had introduced back about, during the Clinton administration, on condoms, which a lot of people don't necessarily think of condoms as medical devices. But, as you know, they are, and they are probably one of our most commonly used medical devices. It is interesting that sometimes the biggest problems or the biggest headaches can occur with, not the high-tech products, but some of the lower-tech products.



Well, Congressman Coburn was concerned that condoms were not appropriately labeled to reflect the fact that they worked differently for different types of sexually transmitted diseases. In other words, for HIV and gonorrhea, they're very effective, but for other types of sexually transmitted diseases, particularly HPV, which, as you know, is one of the causes of cervical cancer, the evidence is less compelling. This sort of reflects what we see not infrequently, which is sort of the interface between social and political policy and the work of the agency. Obviously, there are people who believe in promoting the use of condoms as a way to prevent sexually transmitted diseases, and there are people who are more fond of the policies like abstinence and basically say, you know, the only thing that really works is not having sex.

So, again, without commenting on the social issues, basically this got dumped into our lap, as well as NIH and CDC, to try to figure out what the appropriate condom label should look like. And, as you might imagine, it's a challenge to try to take all of the scientific data, and NIH was responsible for sort of collecting all the data, and then CDC was responsible for helping to review all the data in terms of public health, and then we were responsible for rewriting the label.

SJ: Does it make it more complicated to have different kinds of condoms? For example, I know when I came to FDA, they announced that condoms would help prevent the spread of AIDS, but they weren't sure about sheepskin, and so they actually had to scramble to do the study of sheepskin.

DGS: Right.

SJ: Are there even that many sheepskin?

DGS: I don't think there are that many. I think most of the condoms now are latex.

RT: Senator Coburn, what was his committee? Do you recall?

DGS: Oh, God, no.

RT: That's all right; it's not that essential.

DGS: The committee, it was, by the time it got to the committee and they had the hearing was like 10 years later, and despite all the work, we still had not rewritten the label, and they were not happy with the Center because we had not "done our job." So we got called down there along with NIH and CDC.

And I remember it was one of those hearings that, if I hadn't actually been there to testify, I would have really enjoyed just being there and watching the theater, because it was actually great theater. You know, you had the pro-abstinence congresspeople arguing against the anti or pro-condom people, and we were sort of there as little pawns, you know, in the middle of all this. But that was one that I remember.

I've had more interactions, not necessarily at formal hearings, but a lot of, certainly a lot of times being summoned or asked to appear before various staffers, you

know, various committees, to talk about decisions that I made, and obviously there were some controversial decisions.

RT: Having worked in the legislative office and been responsible for testimony preparation, I certainly understand. It would be more pleasant to be at some of these hearings as an observer.

DGS: Spectator, yes.

SJ: Even David Kessler got nervous testifying.

DGS: Yes.

SJ: I didn't think there was much that could intimidate him.

One of the notes that I have on developments -- I'm in history of medicine, so I try to keep track of a lot of stuff on this -- but you were talking about Parkinson's. But, anyway, the deep-brain stimulator, was that one of the key things? Because that's been applied in other areas as well.

DGS: Yes. I think the whole area -- that's why I was interested in your historical devices, all the electrical stimulation in some of these historical devices. I think things have sort of come full circle now, because now I think we're entering an era where neural stimulation is going to be where cardiac stimulation was 20 years ago, you know, the

pacemakers, the monitors, and then the ability to stimulate certain parts of the heart in order to prevent arrhythmias and treat various conditions. I think those same technologies are now being applied to the brain, which is obviously a lot more complicated organ. So I think it's going to be challenging to try to figure out where do you put the leads and how much energy to apply.

SJ: All the brain-mapping technology, too.

DGS: Exactly, exactly. But that's an area of intensive investigation at this point. And I think what we're going to see over the next few years is, again, I think people want sort of the big breakthrough and we're going to cure Parkinson's. I don't think we're going to cure Parkinson's or we're going to cure these movement disorders or we're going to cure depression by stimulating different parts of the brain, but I do think that as time goes on, just as with cardiac pacing, we're going to learn more, we're going to understand what kind of pacing, what frequency, what intensity, what duration, what parts of the brain can be stimulated in order to help improve various different diseases.

Some of the results for some of the movement disorders are actually very, very impressive.

SJ: Tourette's?

DGS: I'm not sure about Tourette's. I'd have to go back and actually look at the specific diagnoses. At this point a lot of this is anecdotal and sort of patient-by-patient,

and there's a lot more work and studies that need to be done. But I think the results, the early results show that this is certainly something that we'll be seeing more of in the future.

SJ: Do you think any of this is going to either benefit or research is going to be stimulated by some of these traumatic brain injuries that we're seeing?

DGS: Well, that's a good question.

SJ: From the Gulf War, the Iraq War?

DGS: That's a good question. I honestly don't know enough about traumatic brain injury. I'm not sure anybody does, really, at this point in terms of understanding the etiology and what kinds of treatments may really be effective, but it certainly would not surprise me if it was a device, and probably would be some drug components to it. That wouldn't surprise me at all.

SJ: Talk a little bit about artificial limbs, because that has some stimulation elements involved as well.

DGS: Yes. I think, again, that's another area which, unfortunately, has been, I think, developed out of necessity . . .

TAPE 2, SIDE B

DGS: We're going to go another 15 minutes or something like that?

SJ: Yes, exactly.

RT: That would be fine.

We were speaking about traumatic injuries.

DGS: Yes. And I think, obviously, one of the things that we're seeing, especially out of Iraq, is that there are a lot of patients who are surviving who, in previous conflicts, would never have survived. We talked about the graft and some of the other things that are allowing patients to survive, but, unfortunately, what we're also seeing are patients with major injuries and major disabilities. We are actually, I think, on the verge of looking at replacement parts, if you will, that are much, much more sophisticated.

As you know, in the past, when somebody lost, say, their upper extremity, they were given a hook or a couple of hooks. Well, now they're developing computer-controlled hands and arms where the person can actually . . . We actually had a demonstration by someone from DHARPA, which is the agency that does research for the military, and they're working on some incredible technologies. And basically what the person who was heading the project said, "Our goal is for somebody to be able to pick up an M&M and put it in their mouth," which would have been impossible using previous technologies. So figuring out how to create, do the engineering to create the

motion and all the different things that the hand does. The hand is just such an incredibly complex organ. It really separates us from the animals in many ways. The ability to oppose the thumb with the different fingers allows us to do things that most other species can't do. But trying to get that prosthetic coordinated with the brain is a very interesting area.

But I think, again, necessity is the mother of invention, and the fact that we have all these people coming back with these injuries I think is, both in terms of traumatic brain injuries and in terms of loss of limbs, will stimulate a whole new round of technological development. And then I think, again, it's going to be up to FDA to make sure that there is appropriate evaluation, which is done efficiently and so we can get these technologies out to patients in a way that is going to improve their lives. I think that's the challenge.

You know, one of the things I think I've seen during my years at the agency is, depending on which party and which administration is in power, the pendulum tends to swing back and forth.

I go back to what I mentioned to you from my mentor, Dr. Yin, is to try to keep your eye on the science; usually you'll get to the right decision, and try to not let the other stuff get in your way in terms of how you make those decisions.

RT: In terms of drugs and devices, you're familiar, of course, with the drug-lag accusation regarding drugs in particular. Can one just generically compare the two in terms of time involved for clearances? Would you say that devices require as much oversight and time for clearance as drugs?

DGS: In general, the timelines for device review are shorter than the timelines for drug review.

RT: I would think so.

SJ: There was a provision in, I don't remember which law, for external review from a pilot project, as I recall. Do you have anything to do with looking at the results or analyzing them or evaluating them.

DGS: I'm not sure what you mean by external review. I mean, we've had . . .

SJ: Third-party review.

DGS: Oh, yes, yes. Well, we actually have a third-party review process that is no longer really a pilot, it's actually in place, for certain types of 510(k) products. Not for the highest-risk products, but for certain types of 510(k) products, companies can either opt to submit to us or they can submit to a third party who then submits their evaluation to us. In any case, we have the final say no matter what. We always have the final authority, in terms of whether or not it goes to market, but they can have the review done by an external third party.

SJ: What are the advantages or disadvantages?



DGS: To?

SJ: Either.

DGS: Well, the advantage to the companies theoretically is they can get the review done somewhat faster. They're basically paying a third party to do the review, and theoretically they can get it done a little faster. The disadvantage is that they have to pay for it.

The advantage for us is, obviously, if the process works the way it's supposed to, it relieves us of some of the work in reviewing some of these lower-risk products, which allows us more time to devote to some of the higher-risk products.

There are theoretical advantages both ways, but there are also some disadvantages. Sometimes the third parties are not as -- how should I say this -- competent in terms of reviewing some of these high-tech products as they should be, and actually there are some issues related to access to historical information, specifically in 510(k), which is very important in doing these reviews that the third parties don't have access to. So in some ways we're asking them to do a review with one hand tied behind their back, and that's been a problem with this program all along.

In some cases it doesn't matter so much, especially where their products are sort of well understood, and especially where we've issued guidance, and if third-party reviewers can look at our guidance document and sort of follow our guidance document,

they tend to do a pretty good job. When there's no guidance from the agency, it doesn't work as well.

SJ: Does that have any impact on . . . You guys have a unique situation with user fees. They realized one of the problems with drug user fees, of course, was that companies they felt were going to pay more and more, and the government was going to be tempted to give the Center less and less. As a result, I guess the medical device clearance process basically had a trigger point where if you weren't going to be solely responsible, industry was not going to pony up unless the government made a commitment to put a certain amount of resources to work, being in the position of having to pay for most of it.

DGS: Right. Well, I think the whole issue of user fees is obviously something that we spent a long time on. I mean, in terms of my tenure both as Office Director and a Center Director, implementing user fees first, the original user-fee bill was in 2002, and then a follow-up reauthorization was in 2007, and I think implementing the original legislation and then analyzing it and trying to improve it in the second round is something that obviously I was very involved in. I think for the most part, we've managed to get the benefits of the user fees without some of the down sides that we're concerned about.

But, again, it's still something I think we need to pay a lot of attention to. We need to make sure that since a lot of the user-fee goals are time goals, one of the things I was concerned about from the beginning was making sure that, as we try to shorten the timelines, we don't sacrifice quality. So we put in some programs to make sure that, as

we're tracking time, we're also tracking quality and doing things to ensure that the review program remains strong.

SJ: In order to meet your timeframe, I have a couple of other notes, but we can add those later.

DGS: Okay.

SJ: They're simple things. So if you want to just go ahead and talk to what degree you're comfortable talking about the circumstances of your leaving, it's been in the news all over the place for us, but obviously you have a different perspective than the rest of us, having been the center of it.

DGS: Yes.

Well, let me say, first of all, I think that the opportunities I've had in FDA in the last 15 years are really beyond, as I mentioned, anything that I really even thought about when I first started at the agency. So my overall comment, I guess, on the career I've had at FDA is really one of profound gratitude and respect for the agency and mostly for the people. And, obviously, I know the people at CDRH better than I know people in other parts of the agency, and the talent and the dedication has really, I think, been really pretty impressive. So I think I've been very, very fortunate to be given those opportunities at different levels. I've enjoyed all the different levels.

The last five years as Center Director, there have obviously been some challenges. I went into this job believing that, as Center Director, I was responsible for making the hard decisions, and I've always felt that. And that sort of dates back to my time in surgery where the buck stops somewhere, and when you're a surgeon deciding whether or not to operate on somebody, you have to make those decisions. I mean, they need to be made. If you don't make the decisions, in many cases the patient is not going to do very well, so you have to make decisions. There are going to be times when your decision turns out to be the right decision, there are going to be times when your decision turns out not to be the right decision. But I've always believed that as you move up the management chain and take on these different jobs, you have to be prepared to make the hard decisions, and I think I did. Were some of them controversial? Yes. Did some of them sort of put me out there on a limb? Yes. And were there people that have expressed concerns and preferences, perhaps, for another person running the Center? Obviously.

In leaving after five years, I feel like there have been some really good things that we've been able to accomplish. As I mentioned, the matrix, the implementation of the total product lifecycle, the implementation of user fees and being able to use those resources in a way that I think has improved the way the Center operates both from a scientific standpoint as well as from an efficiency standpoint. So there are a lot of things that I'm proud of.

I think I've been around Washington long enough to understand that when a new administration comes in, a new Commissioner, new people, the Office of the Commissioner, a new point of view, you know, I think that they're entitled to have

people reporting to them who are of their choosing. And I think in many ways this was the right time for me to leave.

In looking at it, I look back at my experience as 99.9 percent positive. You know, there's always a few things that you wish had gone differently, but most of it has been very positive.

SJ: Regarding the future, what are you looking at? You're not on a flight on a plane back to the Southwest yet, but . . .

DGS: Yes. I still have my house out in Santa Fe, and I'm looking forward to spending more time out there. I've had the opportunity recently to spend more time with my family. I have a 93-year-old father who I just moved from Florida up here so I could keep an eye on him a little bit closer. I've been spending more time with that.

Obviously, my kids are grown, but I get to spend some time with my son. My daughter is actually over in England for a year, taking a graduate course.

But, you know, professionally, I really haven't made any specific plans. I suspect that there'll be some opportunities in the area of devices and that I'll hopefully, be able to use some of my experiences, some of the things that I've learned.

I think that people talk about FDA and industry as, in some cases, sort of adversaries. I've tried to look at it in terms of the fact that the system we have is that companies make devices, and we regulate those companies, so I think there are opportunities to work on both sides of that system and do things that hopefully will

ensure both the safety and the effectiveness and the benefits to patients of these new technologies, and see where that takes us.

RT: Doctor, we certainly appreciate the interview that you've accorded us.

DGS: Certainly.

RT: Of course, we haven't had an opportunity to take note of the many achievements in your curriculum vitae, which are impressive. I see you've been an author of a lot of articles and books, so you've made your mark, and we appreciate this interview.

DGS: Pleasure. Thank you very much. Thanks for the opportunity.

END OF INTERVIEW