

History
of the
U.S. Food and Drug Administration

Interviewee: Susan Gardner, Ph.D.

Interviewer: John P. Swann, Ph.D.
Robert Tucker

Date: June 22, 2011

Place: FDA White Oak Campus
Silver Spring, MD

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

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Campus

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INTERVIEWEE:

NAME: Susan Gardner, Ph.D.

INTERVIEWER(S):

NAME: John P. Swann, Ph.D. and
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Interview with Susan Gardner

June 22, 2011

TAPE 1, SIDE A

RT: This is another in the series of FDA oral history interviews. Today, the interview is being held with Dr. Susan Gardner, former Director, Office of Surveillance and Biometrics, in the Center for Devices and Radiological Health. The interview is taking place on June 22, 2011, at the White Oak Campus of FDA in Silver Spring, Maryland. From the History Office, participants are Dr. John P. Swann and Robert Tucker.

Doctor, in beginning the interview, we'd appreciate a brief overview of your personal information, personal background, where you were born, raised, and educated. So, with that, we'll let you proceed.

SG: Well, I was born and raised outside of Pittsburgh, Pennsylvania, and really grew up there. We moved from different places around the suburbs of Pittsburgh, but that's essentially where I spent my childhood and teenage years.

After graduating from high school, I went to Johns Hopkins Nursing School, and that was a three-year diploma program, and I completed that. I then, as soon as I graduated, actually, moved to Boston to begin working, to start my first job, which was at Massachusetts General Hospital, as a staff nurse. And I worked there and then also went on to work at a state institution for people who are mentally handicapped; I spent time doing evaluations of children who were coming in.

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But also, an interesting part of that job was to go back into the historic records in these institutions. They wanted to move some of the older clients out of the institutions and into nursing homes, and that was the beginning of the time when they were trying to shut down the state institutions and move people to other facilities such as nursing homes.

RT: Was that a decision on the part of the state administration to lighten the load?

SG: Yes. They wanted to start closing down the state institutions, essentially. They were going to move these people out of the institution. But a lot of these patients were institutionalized as very young children and probably, diagnosed now, it would be something entirely different. Among the interesting things was how reluctant many of the family members were to let the patient leave the institutions, which I understood. They'd always been there. But we had some success.

Anyway, then I went back to school and, with a nursing diploma, that doesn't give you a degree, so I originally had thought I'd go back and get my bachelor's of science in nursing. But I was a little disenchanted with the profession at that time, and so instead of going into nursing, I decided to get my degree in sociology. I went to Boston University and finished my bachelor's in sociology, and then became interested in medical sociology because that was such a nice combination of my sociology and my medical background.

There were not very many medical sociology programs around, but one of them happened to be at Catholic University. And, in addition, for personal reasons, I wanted to

move here. So I came and got my master's at Catholic University and then also finished my Ph.D. in medical sociology at Catholic University.

RT: What year, Doctor, was it that you got your doctorate?

SG: What year was it?

RT: Yes.

JS: I think it was, it looks like it was 1981. Does that sound right?

SG: That sounds about right.

JS: Well, just a couple questions -- not to break things up here, but it's always interesting to get a read from people we talk to, what gets them interested in their fields, particularly in nursing and in healthcare. Were either of your parents involved?

SG: It's a funny thing about nursing. My mother was a nurse, and my father died when I was two. She remarried, and I honestly felt my stepfather was my father. But I always had this message growing up, and the message was, if anything happens to your husband, you'll always be able to have a job if you're a nurse because they're always looking for nurses. But I never did candy-striping, I never did some of that prep work.

And it wasn't that I didn't like nursing. Actually, there were parts of nursing that I liked very much. I did not like the nursing administration part of it.

JS: Was that part of the disenchantment that you referred to?

SG: That was part of the disenchantment, and the other part that was a disenchantment was how little patient care we were actually able to do. It was frightening, actually.

When I was at Hopkins on the wards, I liked working on the wards because that's where all the action was and that's where people need you. But they were very understaffed at Mass. General and Johns Hopkins, and it sometimes was just sort of frightening. So what I liked doing was really, again, the direct patient care, and it was hard to do that and feel that you were doing an adequate job.

But then, the steps up from there, also, if you're doing bedside nursing, is either to go to the ICU, intensive care. At the time, there weren't many other options; it was to go towards nursing administration, which I wasn't interested in, or to move into the ICU, and that, to me, took me further away from what I wanted to do, which was really to be more involved in healthcare and patient care.

And it was the '70s and it was an interesting time. Sociology had a lot of appeal to me for other reasons. It was different, and it seemed like a good combination.

I did work as a nurse when I went back to school. I supported myself by working part-time, so I worked at Mass. General during the years that I was going to Boston University.

And then, when we moved here, I worked at another state institution, Great Oaks. I worked in their children's unit in the hospital. So I did continue to nurse for quite a few years.

And my parents were right, you can support yourself. You can do it part-time, you can do it in the evenings, and whatever. I will say, I mean, I think the options for nurses now are vastly improved from when I was doing it. If things like nurse practitioner had been available to me, I might have gone that route.

RT: In doing work in mental hospitals, mental care facilities, was the nature of nursing different there in any particular way? Or was it just mostly medical care?

SG: I was in the hospital unit, so it was medical care. I mean, when I was here, the unit was children, and it was sort of tough. A lot of those kids were very, very sick. And other kids were just funneled in as they would get too sick to be out in the units or whatever. But it was pretty much direct patient care.

Actually, I liked it quite a bit. I really did like that job.

RT: Then you apparently went to, was it a private research . . .

SG: Westat.

RT: Westat Research.

SG: Yes.

So, I started writing my doctoral dissertation and, while doing that, talked to a friend of mine who was also in graduate school with me. And Westat at the time was a company of probably 50, 60, 70 people in Rockville, and they're a social science research firm. And I started working there part-time for a couple of months, and then I started working full-time there.

And the company -- it's a huge company now, several thousand employees, and a very well-established, well-known consulting firm. But I came in at a time when the company was experiencing huge growth. Those of us that came in at that time got to ride those waves up through the ranks to senior people and management, and, in retrospect, probably far faster than they should have in some ways. But we were the old-timers pretty quickly, and I was there for 18 years.

RT: Was that in the mid-'70s?

SG: It was in the '80s, mid-'80s.

RT: And the firm had been operational not long before you joined it, was still small.

SG: It was still small. So I can't remember, actually, when they started, but it was not that old.

RT: Was that company's scope related to contracts for research?

SG: Yes. It was all contract work at that time, so, working with the National Cancer Institute, the National Institute of Health Statistics, because that was separate from CDC at the time. I can remember standing there in jeans with a friend of mine, and t-shirts, Xeroxing these proposals to go out the door at probably midnight or something, trying to get them there on time. And I remember when we won our first million-dollar contract and we were beside ourselves. It was a lot of fun, actually; it was a lot of fun. And we worked really, really hard, but we were very young.

JS: These were fascinating projects you were involved in.

SG: Oh, it was very interesting, yeah. And it was really fun. It was a straight-up learning curve the whole time, and a lot of us were around the same age. It was fun.

JS: The salad days for people with a background in sociology. I mean, social science research was really becoming a factor here and doing work for lots of government agencies.

Now, you're doing research, Westat is doing research also for other types of institutions, right?

SG: Oh, yes. They have an education department, they have all sorts of different

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projects going on. But I was in the health section, obviously, so what I was doing was primarily survey research. I didn't do so much evaluation research, primarily survey research. And a lot of it was with the National Cancer Institute.

I don't know if you're familiar with the HANES program. It's an annual survey, it's a national survey, an ongoing survey done by the National Center of Health Statistics, so I did a lot of that work.

RT: I think in the information you gave us, your background, you served as Project Director for a surveillance study to obtain incidence estimates of Guillain-Barre syndrome. What is Guillain-Barre syndrome?

SG: It's a neurological condition, and, symptomatically, people start losing feeling and the ability to move, especially with their limbs. And if it's very severe, it can impact your lungs also. But it's reversible.

And it was related to -- I don't know if you remember this -- a vaccine. And, interestingly enough, my father got it. He was living in Brussels at the time, and he went and got his vaccination, and he got Guillain-Barre syndrome. So then I went to Westat, and it was my first project, the surveillance of Guillain-Barre. And, of course, looking for the relationship between, I think it was the flu vaccine.

JS: Right. That was one of the side effects of the swine-flu vaccine.

I have to ask -- and here's a chance to tie in your dissertation work -- but did what you do as part of your doctoral work tie in with your research approach, because medical

sociology can be lots of different things, different approaches. But did it tie into what you were doing at Westat?

SG: I used the HANES databases, and certainly I could go and ask people and talk to people about statistical problems or whatever. But basically I did that on my off-hours, so it took me a while, actually, to get that done. It took me about four years because Westat was a time-and-a-half job to get it done.

So, eventually, I got tired of seeing my dissertation sitting on the dining room table, and I decided that I would go into work an hour early every morning, because if you do it on weekends, you lose your train of thought. I thought it would be much better if I could just do it every day, so that's what I did. I'd just go in at six a.m. and work from six to seven a.m. or whatever and eventually got it done.

RT: While you were still at Westat, I think you also were in charge of a nationwide survey, I guess you would say, regarding a possible relationship of using saccharin and bladder cancer. Now that, of course, was a concern of the FDA. Was that study at all related to the FDA?

SG: Not at the time, at least not that I recall. I think we were doing, I imagine we were doing it for the National Cancer Institute. I don't know if I said it in my resume.

RT: Perhaps that's right.

SG: Probably what I did.

RT: Because we got into that issue about saccharin and carcinogenity.

JS: Well, you were at Westat for about 17 years, if I read this right, 18 years. And, of course, the nature of the work you were doing there looked at really large population groups and the health impacts of all sorts of things, whether it's mammography or diet or so on, the health impacts of these things. It seems like it was the sort of approach that would make you just a perfect candidate for what you eventually became when you were at FDA. Did that kind of background enter into both your decision to leave Westat and come to FDA? You would have been a very attractive candidate to bring into a position like what you went into.

SG: They found me, in a sense. When I was working at Westat, I was doing a study for the National Cancer Institute, and a guy named Larry Kessler was the Project Director. He and I actually had a tussle over how that project was going, but we were doing fine. He came to talk to me because he was job hunting, and his first question was, "Is there anything at Westat for me?" I thought he was not a good candidate for their program, from what I knew about his background and what I knew about Westat, but we had lunch and he went on job hunting.

He interviewed for the job of the Director of the Office of Surveillance and Biometrics at CDRH, which was only forming at that time. When he got the Director's

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job, he came to me and asked me if I would be interested in applying for the Deputy Director's job. He knew my background from Westat, my research background, so in that sense, yes.

JS: Had you done work with the FDA Center for Devices at Westat?

SG: We did do a study, and at that point I had a number of studies going on under me, so I wasn't so close to it, involving the Bureau of Radiological Health before it -- and I don't know this history so much -- became part of CDRH. We were doing a study of women who were irradiated because they thought they were sterile. I mean, you can imagine trying to use radiation to promote ovulation? But at that time, they just thought radiation would do anything. They used it for tonsils and many other purposes. Some of the records were actually at the Bureau of Radiological Health. These women had been radiated for as many as 40 years before we were able to do the study. Going back and finding their records was a little tricky. We didn't have Google. But we did find them, and so that was a relationship with FDA that I wasn't that much aware of at the time.

JS: This wasn't around the same time as the the Human Radiation Committee studies, was it?

SG: I don't know.

RT: You mentioned biometrics a moment ago. I think you were in the Office of

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Surveillance and Biometrics. Surveillance, of course, is, I think it is too, but I don't know if everyone might know what biometrics encompasses. Can you generally . . .

SG: Well, I think you would just think about the measurement, in a very broad way, as it relates to healthcare. It really reflects the fact that the statisticians were in the Office.

RT: Statistically, that's an interest of that discipline. Okay.

JS: Well, we want to talk a little bit, of course, about how one gets a handle on what happens with devices afterward, and, obviously, you were involved in that in many ways and started a new way of looking at that here in the agency and collecting data. But the people who look at these interviews are not necessarily FDA people. They've got very general interests. And so I thought it might be helpful, if you wouldn't mind, before we start going into what happens when you look at sort of the post-marketing end of things, if you would just sort of give an overview of the sort of device approval process and the extent it can or can't really capture adverse events with medical devices in that process, because clearly it's the post-marketing end that really gets a glimpse into those sorts of problems with devices. But I know we strive to try and capture that with the devices, drugs, and the other things we do here at the FDA during the approval process.

SG: Well, first of all, a large number of medical devices are exempt from the approval process at FDA. That does not mean that they are exempt from reporting adverse events,

so just hold that thought for a minute. We don't see everything for approval; we couldn't see everything.

Most product approvals at CDRH come through what we call the 510(k) process, and 510(k) is the device that is substantially equivalent to another product that has been approved. Examples are devices like infusion pumps. Industry may submit a new pump for approval. It looks like the old pump, so they don't need clinical data for approval. Essentially, industry doesn't usually have to have clinical data for 510(k) approvals.

Now, the 510(k) process is under huge review and scrutiny in CDRH right now, so what I'm saying today actually may be different at some point. But some of the problems are, for example, that devices that were approved in 1970 or 1980 have seen substantial advancement. And so the "substantial equivalent" designation, in some cases, is pretty far from what was originally approved 10, 20, or whatever years ago.

And the flip side of that is, of course, that it's a quick way to get things through the system and get product to market, which is really important. That's sort of the constant balance that you're looking for, particularly with the 510(k) program, of getting the devices out to market, getting people to use them, getting the docs to use them, and then making sure that they really are "substantially equivalent" to a device that has already been shown to be safe and effective.

Part of the scrutiny, the current scrutiny has to do with the fact that there has been so much advancement in the medical device arena. Should some of these devices have clinical data for approval? And the Center, as I was leaving, had certainly begun asking for clinical data in some cases.

In medical devices, you worry a lot about human factors. It's how the people use it and the environment in which they use it, and is it usable and intuitive to the person that's using it. So, when some of these devices come in for approval, they have not been adequately tested for human-factors usability. For example, if a device is used in the emergency room or a place where there's a lot of noise or commotion going on, and if the use is counterintuitive, the medical staff may err in using the device. So, human factors are an example of an area that CDRH has started to look very closely at, and I think the Center will continue to look closely at that. And I believe there's about 4,000 devices that are cleared every year through the 510(k) process.

For the high-risk or new devices, it's the PMA process for clearance. These devices are either first of a kind or perceived as high risk. The Center thinks that they need to have clinical data behind them, so they generally come in with clinical trial data. But for medical devices, clinical trials are very small and they tend not to be particularly long. And a large number of medical devices, for example, are implanted in people's bodies. So if you are getting a new hip or a new knee or you're getting some cardiac implant or whatever, that clinical trial may have lasted only a few number of years, but often not the number of years that you're going to be living with this device. We don't get a 10-year clinical trial before approval. It's too expensive for the companies to do that, and you do want to get it on the market. So, again, the PMAs generally are approved with a post-approval study as a "condition of approval."

JS: That's a typical situation, then, not . . .

SG: That is a typical situation for the PMAs.

So, again, those are your high-risk, high-scrutiny devices.

JS: Right. And that's obviously a big difference between many of the other commodities that we regulate, where you have a longer period, a larger patient population that's exposed to this.

SG: Yes, oh yes. I mean, you can conduct a drug trial with thousands of people. It's very hard to do that with devices. And sometimes, for devices, you can't have a control group. Who are the patients who don't get treated, and how do you mask the treatment group if you're implanting a neurological device? So there's a lot of differences in devices from drugs, and the pre-market is a lot trickier in that sense.

JS: Right.

RT: Now, are there any particular types of devices that have been more pronounced involvement with adverse reactions? Is there a particular type of device that is particularly troublesome after marketing more than others?

SG: It changes over time.

One of the big initiatives that we recently did -- when Dr. Shuren came -- was with infusion pumps. We had seen growing problems with infusion pumps in the Center.

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We just couldn't get our hands around it, and we kept forming work groups, but no one knew what to do about it. The pumps are so pervasive in the clinical setting and in the homes, as a matter of fact. Yet, we were seeing lots of adverse events. The adverse events went from pumps not working or shutting off to what we were talking about earlier, human-factors issues. There was quite a big initiative in the Center to reexamine our approach to pre- and post-market for infusion pumps.

We had some very big recalls of infusion pumps, and that's really challenging. A recall doesn't necessarily mean the product is taken off the market, but it may mean it's going to be replaced, it may mean they're going to make a change to it. There may be a software change, for example. But in the hospital, if your entire hospital is using one kind of pump and there's a problem with that pump, it's very, very difficult in a clinical situation to figure out what to do. We would talk to the hospitals and they would say, for example, "Well, when we take this pump to surgery, I always make sure I have a backup pump there because, yes, you're right, it has been stopping," or it has been doing something wrong.

And the older infusion pumps get passed down from hospital to home; they make their way out of the system into homecare, and they come to homecare with no instructions. What we hear from the home healthcare nurses is, they get in the home and the nurses may not be familiar with this pump. And, again, there's no instructions, no label.

Another initiative that is being worked on is the home healthcare initiative in CDRH. Part of that initiative is to see if we can find the labeling to these pumps and get it online so that the home healthcare nurse will have access to it.

JS: We have to interject here that if we're talking about laying our hands on an older medical device that's being passed down, say, we hope the records are still around because these are product-approval records and they should be not subject to destruction.

SG: The concern here is for product labeling. Industry may change their labeling without FDA approval. FDA would not have those records.

JS: That's true.

It wasn't long after you came on board that we saw the passage of the 1997 FDAMA, the Food and Drug Modernization Act, and, of course, included in that act, it addressed issues on medical device reporting, adverse event reporting. And I wondered if you could say a little bit about how the Center responded to what those requirements were, in a nutshell, not in great detail, but what those requirements were under the law and how we responded to those, because that sort of preceded what came later. I know you started this as a Deputy, but particularly under your leadership in the Office, the Medical Device Safety Network came a little bit later.

SG: I came to FDA when the Safe Medical Devices Act (SMDA) was passed, which was 1995 and 1996.

First of all, manufacturers have to report adverse events if they think there's evidence that there is a device-related death or serious injury or a malfunction, so they had mandatory reporting for adverse events. And manufacturers -- when I was leaving,

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we were up to 300,000, 400,000 adverse-event reports a year from the manufacturing community. Most of those reports tend to be the malfunctions, but there are deaths and many serious injuries in that also. That number has grown; the number increased the whole time I was there. Somewhere in the late '90s, we thought it was leveling off, but then it began to increase again.

So, when I came to CDRH, the Safe Medical Devices Act was just passed. The Safe Medical Devices Act said that “user facilities,” which is defined as hospitals and nursing homes and dialysis centers, had to report adverse events, if it was a death, to FDA and to the manufacturer; and if it was a serious injury, only to the manufacturer. And it was my understanding that this was Congress’s intent to check on the manufacturers. For example, did we get a death report from a hospital and not get one from the manufacturer.

As it turned out, we got many more death reports from the manufacturers than the hospitals because the hospitals didn’t report. And when I got here with a survey-research background, they were telling me about this, and I said, “You mean every hospital in the United States has to report?” and they said, “Yes.” And I said, “This isn’t going to work.”

JS: And it’s not just the hospitals, right?

SG: It’s nursing homes and dialysis centers and . . .

TAPE 1, SIDE B

JS: How many establishments are we talking about?

SG: Many thousands.

JS: Yeah. And so when we're talking about involving every hospital in the country and all these other institutions, we're talking about a lot of reporting facilities.

SG: Yes. And we were getting a very, very few number of reports.

And I have to say also, when I came to FDA, I was puzzled by what I thought was the lack of relationship that the FDA had with the clinical world. There was a relationship with the manufacturers, but the clinical people are the device users, so I was always puzzled about that.

But coming from the sampling research background, we said, well, why would you want to get every hospital to report? Why wouldn't you just take a representative sample of hospitals and see what's going on there?

Dr. Bruce Burlington was the Center Director at the time, and we went and we talked to him. The first thing was to do a feasibility study and find out why hospitals weren't reporting to us. So we did some focus groups and we went and visited some hospitals, and they said, "Well, I have lots and lots of people to report to, and FDA's just not on my list. I have to report to the state or I'll lose my license; I have to report to the Joint Commission; I have to report to my own state, and I'm just too busy." And they said, "And," importantly, "reporting to the FDA does nothing for me." These were the

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risk managers. “It doesn’t help me get my job done at all. It’s a black hole. I submit a report; I never hear anything.”

JS: And, by the way, this is a perspective that you uniquely can appreciate, given your own background.

SG: Oh, absolutely!

In addition, the reporting form is not user-friendly, although it has improved. The agency has designed one form for drugs, devices, and biologics, and it’s a very crowded, not-user-friendly form. And it was not in the question-and-answer format. The risk managers told me, “The form is confusing, the coding is confusing, and third is the liability concerns. We don’t want to take on any liability that we don’t need to.”

For the next step, we did a lot of research about surveillance systems. We went to talk to the national transportation system, the FAA, and other surveillance systems.

We did that preliminary work for a couple years, and we did a pilot study with 25 facilities. We took the barriers that we recognized and we just reduced the barriers. First of all, we gave them very, very good information on the liability concerns and why that was not a problem, and how we would protect the data. And we built a very robust feedback program, so if they sent us a report, we made sure that we got back to them and told them as much as we could about what we were doing with it. And then we did some other sort of patient safety supportive projects. So, the pilot study got us reports, certainly more than we already had in the system. This was with 25 hospitals.

So, then we started looking for money. And I don't know if you remember the big splash that was made with the publication from the Institute of Medicine on patient safety, but the report said there's over 95,000 patient injuries every year caused by medical error. And so, AHRQ, the VA, and CDC and others realized that we have to do something about patient safety.

Two of us, Marilyn Flack and myself, and the contractor we were working with, got ourselves to the table, because nobody thought about FDA. They didn't see the relationship between FDA and patient safety. And it actually put in context, I think, what I had felt when I first came into the agency. Why aren't the clinical people on our side?

This also has to do with the FDA concept of whether we're a public health agency or whether we're a regulatory agency. And recently, when Dr. Hamburg came in, she and Dr. Sharfstein wrote an article for JAMA about FDA as a public health agency. I was here because I believed that FDA is a public health agency. I have always seen the regulatory structure as supporting the public health agency.

Many people in the agency over the years have seen the regulatory structures as the end-all and be-all. It's just a different viewpoint.

So we did get ourselves to the "patient safety" table and we were talking to our HHS colleagues. They were very interested in our pilot and became aware of the FDA and the importance of having the FDA as part of the patient-safety partnership group.

At the time, Dr. Henney was the Commissioner, and I remember this very distinctly because people said it couldn't be done. On September 30th of the fiscal year, she had a million dollars left, and she gave us our first million dollars. And you know

how some of these contract personnel tell us you can never do that. You can do it. We did it; we got the contract.

JS: The day before the end of, the last day of the fiscal year.

SG: That's right. We had our contractor from the pilot, so we could do it. But, again, had it not come from Dr. Henney, I don't think we would have gotten it done. So, at that point, we were off and running.

So, then we wrote a congressional report on the pilot study, and we proposed in the pilot that there be a change in the law from universal mandatory reporting to reporting of a sample of hospitals. We got funded with \$5 million, so then we were actually able to kick off the program.

So, the program has 350 hospitals in it and has had that number for quite a while. We just rotate hospitals in and out. And it really has grown.

They did a very nice sendoff for me as I was leaving. It was at one of their meetings. But I take little credit. My vision was so limited compared to what it's been. I just wanted the adverse-event reports from the hospitals.

It really has grown into a partnership with these hospitals and, not all of them, but a lot of them really are patient-safety partners. They call us up and they do work with us, and we go to them all the time and ask questions. For example, if we have an infusion-pump issue, we might ask what would happen if we recalled these pumps. And they can answer that. We do mini-surveys. We can't ask more than nine respondents without

OMB clearance, but asking the opinion of nine hospitals can get you some really interesting information. We've gone to them often to do that.

And, again, what we realized in the very beginning, that it had to be a partnership. We had to show that reporting and working with FDA is a benefit to them and will improve the safety in their hospitals. We've worked really hard to do that, and we've provided a lot of materials to train about reporting. We give them instant information on anything that we're sending out in terms of recalls or public health notifications. So, they really do work as a partner with us in the program.

RT: What is now known as the Medical Safety Network?

SG: I'm sorry.

RT: Is that program with our activity now identified as the Medical Safety Network?

SG: Oh, MedSun, yes.

RT: And it involves 350 or so hospitals.

SG: Right, right.

JS: You know, this is interesting. I mean, you paint a very interesting picture on how to change the mindset of the people at the hospitals, how they're looking at FDA as a

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public health agency versus a regulatory agency. And, interestingly enough, we developed a relationship with hospitals in much the same way in dealing with adverse events, but focusing instead on pharmaceuticals in the 1950s. I mean, it was a long time coming, that program, but it did, it did happen. And we were just as, gosh, if anything, just as much or more a regulatory agency, the emphasis on the police end of it as anything at that time. But yet there was a mindset that apparently had changed out there in the meantime. The one that you're describing is one that's quite different than was the case earlier, I think. But we also had the assistance of groups like the American Society of Hospital Pharmacists or Health System Pharmacists, as it's called now, the U.S. Pharmacopeia and others. But, I mean, the same is true for MedSun too. I mean, it's a collaboration of multiple organizations. Right? I mean, it's not just the FDA and hospitals, right, but others?

SG: It is primarily the FDA. We talked to CDER a lot about becoming part of it. They had done some studies using MedSun, actually, some small studies.

But the other thing about drugs is there's this vast network of research being done on drugs. I mean, there's so much funding, from our point of view, there's so much funding, there are so many people working on drugs. There's, again, the whole pharmacy involvement. So it's a very different kind of environment.

And devices are sort of the new kids on the block in that sense. What's become interesting about devices and why I think there's increasing attention is that it is a growing field, and I think we're, at least I've heard in the pharmaceutical world, there is more concern about the slowing down on what's new. Devices are still ramping up. And

I think that's part of the reason that we're seeing, continue to see increased adverse-event reports. I don't really know why we continue to see increases, except I just think it's a growing field, and I think that devices continue to innovate and lots of exciting things, lots of really exciting things coming up through the device world.

JS: Bigger research pipeline, which is good from the standpoint of more devices but also, as you said, more adverse events associated with those. Right?

SG: Yes, exactly.

RT: We've had a similar problem in the biologics field, where a lot of those folks were really research oriented, and at the time we had a consolidation, and there was some difficulty with those people thinking of us as a regulatory agency but more in terms of research.

SG: Yes.

RT: It was kind of a hard meld to me.

JS: Well, other entities in the agency definitely have a hard time -- within the agency, forget the outside world -- broaching those two aspects of our being, and they're both there and they always have been.

SG: Yes, but interesting also is increasingly we have combination products, and it's not just drugs and devices, it's biologics, and it is increasing and it's becoming more and more complicated.

JS: That's a good point, which leads one to wonder, when you have a combination product, when it comes to dealing with that in the post-marketing world, I know MedSun takes into account not just medical devices necessarily, but other medical products.

SG: Right. It depends how the approval, where they got the approval.

JS: So, whoever sort of has the lead in the approval would have that lead in tracking the adverse events. Okay, that makes sense.

SG: But we were always sending reports over, you know, moving them around. We could figure out, if they came into the device system and it wasn't ours; we would move them over to Biologics or move them to Drugs.

JS: Is it fair to say that the other Centers maybe haven't yet embraced MedSun in the same way that devices has?

SG: Well, it is, but I don't think they've needed to. I think it was a different thing.

We did a project for the Center of Biologics on tissues, I guess, heart-valve tissues -- I don't really remember -- for a number of years, and it was great. I mean, they participated, and then at some point, because we were really worried about funding and this program kept growing, we said, "If we're going to continue to do this, we need an FTE. We need someone to really manage it." So that kind of halfheartedly capped it, and then they pulled out after that.

Drugs has always been pretty good, but they give us a small, isolated project. "This is what I want done, and I want you to use whatever, and here's the money to do it," so it's small projects. But, again, they have so much, they just have different data acquisition than we do. I mean, they have so many research projects going on and such direct input. They just have better information than we do, very much better.

JS: Okay. And part of the confusion here, there's a database -- I'm not sure how it plays into what we've been talking about -- that's MAUDE, the Manufacturer and User Facility Device Experience database.

SG: Right.

JS: How does that tie in with MedSun?

SG: Well, the database is the place where we put all our adverse event reports, so . . .

JS: It's a tool.

SG: MAUDE was being built when I came in.

JS: In '95?

SG: Yes, it was. In '96, it was finished. And so here we are 15 years later, and we still have that same database.

Now, the plans are, and the money has been given and they were starting to talk about replacing it. But the same thing's true for CDER. That the AERS database was built the same time the MAUDE was built, and all the time that was being done, we thought Drugs had all this money and they were building this great database, while we were doing it in-house. Well, it turns out, at least what I've been told, that the AERS isn't so fabulous either.

So, there was a thought that we could have one database for all the adverse event reports (CDRH, CDER, CBER), so people spent a good deal of time and money investigating that; we finally decided we needed to go our own way. We have different regulatory authorities, and so the littlest thing – like “date of event” -- becomes just an enormous problem because our regulations are different. So we are building our database. So MAUDE is in the process of being replaced. I always felt like any day we could wake up and MAUDE would be dead as a doorknob, and there we would be. And so, it's only one of the messages I left -- and everybody knew it -- that we had to get this database replaced. Also, MAUDE is just a big filing cabinet. MAUDE is not an analytical database. It took me a long time to figure this out. So if staff want to do any

analysis, they have to pull the data out of MAUDE and put it in SAS or do something else with it. And you can imagine, at this point, it's a database that has been duct-taped and patched together and added onto here and there, and not very good documentation from all these years. So it's a mess, it really is. And I don't know if we want that in the archives, but it is. We need a new database. And so, again, it is in the process of being built, and I hope that they continue to get the funding to do it, because I think the day will come when it's just going to chug to a stop.

JS: Well, this is something that really jeopardizes the program.

SG: Oh, without a doubt. I mean, without a doubt it does, without a doubt.

JS: Okay.

SG: The other thing that was happening as I was leaving -- and, again, with many years of work -- is to move the industry to electronic reporting. Once we figured out how to do it, we wrote the regulation, we went ahead and said to industry, "We're going to pilot this. The regulation is going through, everybody; you know this is coming, but let's pilot it." So we already had a couple hundred thousand reports that have come in electronically when I left. The regulation was still chugging its way through the system. I did sign the blue sheet the day I left, but it just takes a very long time to get this stuff done.

I mean, electronic reporting is an advantage to industry, it's an advantage to us, it's an advantage to the taxpayers. You get a much more efficient system by doing it. It certainly always bothered me that it took so long to get the stuff done.

JS: Well, is part of the problem that you're trying to find a system that everyone -- I mean, not just FDA but the people that are reporting to us -- can agree on and work with?

SG: No, no. The problem is that there are so many steps to go through in the regulatory system, so it moves from here, and then it moves from there, and then it moves to HHS, and then it may move to over here.

JS: Getting the actual regulation passed.

SG: Then it came back and they said, "Well, the economic analysis is out of date." So then you do a new economic analysis, and then you start back again, although it moves a little faster at this point. And so, if there's one thing I would wish for the regulatory system, which I wholeheartedly believe in and support, is that you could speed this stuff up, because five years down the road things have changed already, and, again, you have to sort of redo it. But we are getting there. We are going to have electronic reporting, and CDER is working on electronic reporting also.

But new database, electronic reporting, and one of the reasons that the Center has to do that . . . Well, let me just talk about something else here.

The other problem with devices is that devices don't have any unique identifiers, so this barcode here . . .

JS: On the bottle of water.

SG: And every device company, most device companies have their barcode, but it doesn't mean anything to us. It means something to them, so Baxter knows what theirs is, they all know what their barcodes mean, but we don't know what their barcodes mean. Drugs has their NDA number, so they do have a system.

Devices do not, and so we have worked for several years before I left and continuing to work to get a regulation out the door to mandate device identifiers for devices and build a database so that we would be able to track better, recognize better, understand better what devices that we have. Particularly in Devices, where you get generation after generation of the same device with small changes, and your reporter is trying to tell you what it is and they don't know what it is. They may know it's a French catheter, and we don't know what lot it's from and we don't know what it is. We don't have the information.

JS: Wouldn't the GMPs for devices include some kind of identifying information, the equivalent of a drug code or something like that?

SG: No, we don't have that, no.

JS: We have PMA numbers, though, right?

SG: But they're not on the devices. The identifiers need to be in the hands of the users. So if this is a medical device, what I want is that you, as the purchaser, actually, log this in when it comes into your hospital, for example. That's one use of it. Then I really know that you have the Aqua Fina flavor rather than something else, because when I get sick after this and say, "What did you drink," you have to know what's there, and you would have it logged into your records. But there are so many reasons.

Now, the other problem is that we can't really play in electronic health records until we have unique device identifiers, because we can't tell what the device is. A patient gets a hip, and somewhere in their medical records, it may or may not be well identified. But what you really want is the device identifiers, so, once again, what lot number it was, and so you really could identify that hip. So once we get that, which will probably come some number of years, then we can really use electronic medical records for much better surveillance than we're doing now. But right now it's just very hard.

JS: It's very surprising.

SG: Suppose your patient gets your implant, and then they move to Florida.

And so their new doctor says, because, "What do you have?"

"Well, I had my hip replaced. I don't know, I guess it was like 10 years ago."

"What kind of hip is it?"

“Well, I don’t really know.” And they don’t; they don’t know.

JS: Well, I guess the same might apply if you take something, but you might have to go to the . . .

SG: I can bring you my bottle of pills.

JS: Look in the record.

But that’s astounding. It must make recalls difficult.

SG: Very difficult, and difficult for the hospitals because they have trouble finding the product in their hospitals, and you know how big the hospital chains are now.

The other problem for the hospitals is, because all the manufacturers have different bar-coding systems, they have to adapt to that somehow, and they all do it differently. I mean, some of them adapt by saying, “You have to use my system,” and so they just slap something different on.

So that’s an extraordinarily difficult task, I can tell you, for devices, because, for example, we regulate software, and you can think of a whole bunch of devices that we are going to have to decide what to do in special cases, but we just had to start taking these steps and we have to get it done, and so it’s on the way. And with quite a bit of support, actually, in the medical community, certainly in Congress, and I think the manufacturing community are okay.

JS: Can you point to any examples of public health problems we've had because of this lack of accountability with devices?

SG: Well, we can use hips as the example, and you would be surprised how little we actually know about hips, which I think in general work pretty well. But there were concerns, as I was leaving, for example, about the metal-on-metal hips, whether metal-on-metal in hips increase ionization in the body and whether people actually are having adverse reactions because they have a metal-on-metal hip and there's increased ionization. And let me just say the jury is still out on that, although I believe the Canadians have put out a health warning. And so there is concern.

So we might actually realize that we have real concerns about metal-on-metal hips. We might tell the medical community, we are concerned. Here are the symptoms that happen if people, if this is happening, too much ionization. But you'd want to know who has a metal-on-metal hip, and we don't know. I mean, nobody really has those records. Some people may know, but universally, people don't know. They get their hip, it works well.

JS: This isn't a line that we had anticipated talking about, but I'm really glad you brought it up, and it is quite surprising that we have an industry that is in a state like this.

SG: Well, you know, historically, you're hoping that if someone listens to this 10

years from now, they'll say, "Wow, really, they never had unique device identifiers?" because we really need to get this done. We really need to get it done.

JS: Well, even with produce, at least we're heading in a direction where we're assigning lot numbers so, when we have problems, we can track these things and find out where it went. We can't do that with heart valves or with artificial hips or pacemakers or . . . That just seems incredible. Even some sort of coding system. I mean, I have a chip in my dog and I can track where he is, but I can't track where . . .

SG: Yeah.

JS: Okay. Thank you.

At the time -- I know there are other issues here; we certainly can talk about those too -- but I know that at the time you left, and long before that, you were the senior Office Director in the Center.

SG: Yes, yes.

JS: Right. So, it would seem that experience like yours would have been a great asset to all the Center Directors that you served under. You mentioned Bruce Burlington. Of course, there was also David Feigal, whom you served under as -- he was the Director.

SG: He appointed me as Office Director.

Dr. Kessler took a year sabbatical; he went to Seattle. When he told me he was doing it, he said, “Do you want to be Acting Office Director?” and I said, “No, I don’t. I never came into the job to be Office Director and I really don’t want that responsibility.”

So, Dr. Feigal called me in and he said, “Well, remember, if you don’t do it, I’m going to appoint somebody else to do it.”

And I thought about that and I thought, well, I’m not sure I like that idea either. So I said, “All right, I will do this.”

I’ve always had just incredible staff. I mean, honestly, I got huge support, and it was fine, as it turned out. But it was not what I anticipated.

And the other thing I didn’t anticipate was that I would be reluctant to give up the job. But, in life, it’s hard to go back, it really is. If you take a step forward, it’s very hard to go back and be deputy again because, unless I put my heart and soul into doing that job, I wouldn’t have done it well.

And so I did. I spent the year working as hard as I could to be Office Director, and then Dr. Feigal said that he wanted Dr. Kessler to take over a different office when he came back, and asked me if I would stay permanently as Office Director. So it was a bit awkward, but it all worked out fine, because Dr. Kessler came back and took over our science labs and did an incredible job of just restructuring the whole program, an incredible job of doing that.

So then we were fellow Office Directors, and that was really nice.

JS: Well, I want to talk about the Center Directors that you worked under. But, actually, instead of going to that, let’s talk a little bit about once you became Office

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Director: how you saw what the needs of the office were, and organizationally, how you dealt with that, considering what your priorities were, what you sensed the priorities were. Because, obviously, the patient safety issues were huge.

SG: You can sort of look at OSB in five parts. First of all, we have the statisticians, and I will tell you that I am not a statistician. Dr. Kessler is a much better statistical thinker than I am. He hired Dr. Greg Campbell as a Director of the Division of Biostatistics, and Dr. Campbell is still there. He is really one of the most respected and renowned statisticians around. And he has done a great job of building our statistical group. They are very well recognized.

Device statistics, again, lag way behind drugs because the device industry lacks a lot of the sophistication that pharmaceuticals do. Eighty percent of device manufacturers are small businesses, and they're developing devices in the garage or wherever. They don't have consultants with varying talents. Now, if the small businesses succeed, they often get bought by the Baxters or the Medtronics or some large device manufacturer. But we always have to think about the small manufacturer because they're such a big part of devices. Many companies tend not to be very sophisticated in their methodologies, in their approach to clinical trials. And we have built, under Dr. Campbell, medical devices into the statistical world. Now the American Association of Statistics has a whole section that's devoted to medical device statistics. Dr. Campbell brought Bayesian statistics to the Center. They were the first to bring Bayesian to the agency and start using Bayesian statistics. This is using prior data in the analyses. We wrote the guidance document for Bayesian statistics. It's a program I'm very proud of, but, honestly, Dr. Campbell gets all

the credit for it. I supported him, I tried to get him staff, and all of that, but he's really the genius behind the program. They've made huge strides.

The second piece of OSB -- and, again, this changed over time -- is our Epidemiology Division. And while they were once a part of another division, they became a division on their own when we took over the post-approval study program. This was a program that used to be in the pre-market shop. There are two kinds of post-approval studies. One is, when a PMA device is approved, CDRH may order a post-approval study to get the long-term follow-up data and answer any questions that are outstanding. And, uniquely, the Center for Devices has the ability to order a post-approval study for devices already on the market.

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SG: So, the post-approval study, both the conditions of approval and the mandated post-approval studies, were moved into the epidemiology group, and so we were able to get additional staff. And the reason we took over the post-approval studies program was because we did a study and found out the Center really had not followed up on these studies, and we couldn't find them and the companies weren't doing them and they weren't being monitored. And that's because the folks doing pre-market are just overwhelmed doing pre-market.

JS: Post-approval was in the pre-market area before?

SG: Yes, at that time. And so, once the product was approved, they would go on doing tons of other things that were coming in the door, and they really didn't have the time, I think, for the most part, to pay attention to post-approval studies. And in addition to that, these studies really needed an epidemiological perspective. The methodology is really important. After we took over the program, we would find a previously ordered study and the questions made no sense or they weren't asking questions that we could really answer, or it was just not worth doing.

So once we found out about that, we did a report, and Dr. Schultz was then the next Center Director at the time, and we laid it out. And he said, first of all, "This is hugely embarrassing to us, and it's a real public health issue. These studies have to be done. They're really important." So we took them over in the epidemiology group.

We probably had 180 post-approval studies ongoing when I left. And we have all the data on the Web now. One can go on the Web and see what the study is, whether it's being done on time, and whether they're meeting their recruitment goals. It's all public. And we actually, we used the CDER model for that. CDER has their post-approval studies on the Web also. So that's become a very robust and healthy program, and I think any scrutiny from the outside, which there has been, we're doing a good job with that. So that's the epidemiologist program that we have.

The epidemiologists also do research. We have very little money to put into epi research, but they've been pretty inventive about finding ways to get things done and forming collaborations.

And, again, as I was leaving, we were starting a program called MDEpinet, which is Medical Device Epidemiology Network, and they're forming partnerships and collaborations with academic centers, and they're going to try to collaborate. It's a way to get staff both on an ongoing basis and also to recruit people after they graduate. And, second of all, it's academic collaborations where you get some really good minds working on some of these problems. So we were getting some funding for that as I was going out the door, so I hope that will be a successful program. And that's directed by Dr. Dancia Marinac-Dabic, another excellent leader, certainly, in the field. So, that's the epi program.

And then there's the adverse-event piece of it. Thousands and thousands of adverse events come into the Division of Post-Market Surveillance, and the staff there are busy looking for the needle in the haystack, really.

JS: So, the Post-Marketing Surveillance Division?

SG: Division of Post-Market Surveillance.

And then the fourth division is the Division of Patient Safety Partnerships, but it's really MedSun.

JS: Okay. And, I mean, this is essentially a structure that developed under your tenure, though.

SG: I did reorganize the office at one point.

JS: So, then, let's go ahead and turn, then, to the Center Directors that you worked under, starting with Bruce Burlington. And then, so, start with Bruce Burlington, then David Feigal, then Dan Schultz, and Jeff Shuren. And I guess probably, even as the Deputy Director of the Office when Bruce Burlington was there, you must have had some connections or had a sense . . .

SG: I did. Bruce gave me \$60,000 to start MedSun. He got it right away. Bruce used to work in the emergency room part-time. He really did understand the connection, the healthcare connection.

JS: So, among the things that we're sort of interested in getting your sense of is the way they interacted with the Office Directors, your perception of the relationships they had with the FDA Commissioners that they served under. That might be something that maybe you've done, but, surely, things must have sifted down a little bit about that. But also, I guess, maybe most importantly, your sense of what their philosophy of regulation as it was shared with you, particularly in the light of what we already talked about. This sort of distinction, whatever you want to call it, between a sense of regulation and a sense of public health. And you have your own sense about that, I'm sure, and we'd love to hear about that, but also that which was manifested by the Center Directors to the extent that you were privy to that, and maybe you weren't and maybe you were. I don't know.

SG: The Center for Devices is small, and so Office Directors, for all the Center

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Directors, we had frequent ongoing interactions with them because there are now seven Offices, there were six, so it's just six Office Directors.

So, Bruce wasn't there very long when I was, I don't think, but, again, he was the one, certainly, that believed in MedSun and gave me the initial funding, so I always am grateful to him for that.

Dr. Feigal, he tended to be -- it's funny what I remember about him. We did a lot of strategic planning, and he really loved it. But I think one of the concepts that he brought, which was really important, is he wanted us to think about how we could have a more flexible staffing structure because, of course, like all of FDA, we were always fighting for FTEs. And then occasionally you'd hire somebody and it's not the right person or you don't need that skill anymore, or it turns out not to be a good employee or whatever. That's not that frequent, but when it does, it's scarce resources, so how could you build a more flexible workforce.

And under his tenure, they started the Medical Device Fellowship Program, which is very alive and well in CDRH. So he took a pot of money and he set it aside for this program, and they brought in either people that were specialists for a short term. So, for example, we needed someone with a particular neuro training, you would bring someone in. The tenure starts at one year and can only go up to two years, and then they have to either get hired or they leave. And we also used it to bring in students, young people. In my office, in particular, we brought in a lot of young people through the Medical Device Fellowship Program, right out of college, right out of graduate school. When we'd get money, we could bring them in. And we could use the pot of money that was set aside, depending on what kind of year we were having; or, if I had money in my own payroll

and I wanted someone to hire through that program -- which sometimes I did, because, again, you have a choice. It's easy to let people go at that point at the end of their contract or go ahead and hire them. So we tended to use the program to bring in new, young staff. We brought in a number of young people that were just fabulously poised and hired them into the Office. So, Dr. Feigal did a really good job, I think, in helping us to think a little more out of the box rather than the standard, okay, you're hired, you're permanent.

JS: So it sounds like you actually hired a lot of the fellows that came in.

SG: We did. I think other Offices did also. Or if the need shifted, then you don't have to keep them anymore. So it gave us a lot of flexibility, and it is hard to get flexibility in this kind of a structure. As you know, it's hard to get rid of people.

And he also had us look at what we called at the time the shared-hire program. And we developed under Dr. Feigal the concept of the total product lifecycle. From the beginning of product development to end of life for the devices, it's our responsibility, and how do we internally communicate that, because we all work in our little silos: just pre-market compliance or post-market, for example. And I will say the total product lifecycle lives in CDRH and it is something they continue to strive for.

Dr. Feigal wanted people in the Center to be moved more from Office to Office so they became more familiar with the compliance structure and more familiar with whatever, and sometimes that worked and sometimes it didn't.

It turned out that being what we called a shared hire was very difficult. It was administratively difficult to do. These shared hires ended up working a lot of time because both Offices really thought they had them full-time. And then there were administrative issues about the PMAPs and the reviews or whatever, but it's still a concept that I think was important to us, and people did move around a little bit more in the Center. It was a huge advantage, actually, to have people moving. It really is when you can do it. You can't take a statistician and have them do adverse-event reviews, so it doesn't work for everybody. But a compliance officer and someone doing adverse-event reports can easily.

JS: Was this an approach that was unique to Devices?

SG: I didn't know that it was any other place. I only knew it when we were doing it under Dr. Feigal.

JS: That's interesting. And I could see where it's sort of a blessing and curse if you're the person so selected. If you do a good job, you might be pulled in different directions.

SG: Yes.

JS: So, obviously, that stands out in Dr. Feigal's tenure.

SG: Yes, the Medical Device Fellowship Program, and he really worked very hard on that concept. And, again, the total product lifecycle was under David. And we have this logo that gets shown all the time with these circles and these lines. And so, again, it's a work-in-progress always. But it remains to be something that we struggle for, and we just, under Dr. Shuren, did strategic planning. We still talk about and talked about reorganization, and still the concept of total product lifecycle was there, so that's really Dr. Feigal's very good legacy, actually.

And then Dan Schultz was the next Center Director. I don't think there's anybody else. And it was under Dan that our office took over the post-approval studies. And, again, he really saw the need to have that program to be a solid program to make sure that industry was doing what they were supposed to do, a program that would stand up to scrutiny, and a program that was worthwhile in terms of the public health. It's just no point in doing a study that no one thinks is important or is not going to get done.

We did a lot of clean-up work. We closed down, when we took over the whole program, a lot of studies. And some, there just wasn't any point in finishing them at that point. They weren't worthwhile, they weren't hypothesis-driven, so we just closed them down and started anew doing everything under new hypothesis-driven studies.

Now over 80 percent of companies are on time doing what they're supposed to do. The added scrutiny has made a huge difference, actually. We really are watching, and all the studies are on the Web also, so everybody can see whether these studies are being done. Those are the data. And when the study's done, then the information on the results gets posted.

JS: So, since this has happened, you've truly seen a little bit of a turnaround?

SG: Oh, absolutely! It's completely different, actually, completely different.

Our legal authorities, when they don't do the studies, are not as robust as we would like. But we're working on that.

JS: Truly, under the various laws that devices operate under, if FDA says there's a requirement under the approval that you have to do such-and-such in the post-marketing phase, that's not . . .

SG: We're really pressed on what it says in the law. Our lawyers have always been a little bit worried whether they really could have the authority to pull the PMA.

JS: Maybe someday we'll find out.

SG: Yes. We hope not to come to that.

JS: Right.

And then, of course, Dr. Shuren, and he's the last Center Director you were under, I trust as supportive as his predecessors of the function of the Office.

SG: Absolutely. In fact, we did this whole reorganization, and my office came out, my former Office came out virtually unscathed.

But the Center for Devices has had some troubling years, and how much of that is politics and how much of it is making a mountain out of things that really are not important is hard to say. As I said, the 510(k) program has come under tremendous scrutiny. Industry says that we have to be able to get these products cleared quickly for the safety of the patient and get the devices into the hands of physicians. I don't disagree at all. On the other hand, the question is, is the program still in balance, and are there products that are coming on the market too quickly? There have been problems and we have all these adverse-event reports.

So, we did our own internal look at the 510(k) program. The Institute of Medicine (IOM) is doing a study on the 510(k) program. As far as I know, that report is not out yet, so that might have implications for the future.

JS: Do you have any suspicions what the IOM report might say?

SG: I think it'll be very balanced. The committee is -- I know a lot of the people who are on the committee, and I think they're probably have a very balanced look, so I don't know. I would guess that there will be some recommendations for better clinical data for some products, and how we would decide what those products are, I don't know. But that's my suspicion.

There's been a suggestion that there be a different gradation of products within the 510(k) structure. There would be products that would be seen as high risk or higher risk than others, and those products might have different requirements, for example. It might be something like that coming out, but I don't know.

JS: Okay.

We've covered a lot of bases here, but are there any other issues or product categories or something that points out our improved ability over the last 15 years to track devices after marketing, our ability to recognize those problems and use that to promote solutions to whatever those problems might be? Are there any other things that stand out in your mind that demonstrate why our ability to develop programs like MedSun have been really of benefit to the public health?

SG: Well, I think, as I mentioned, that it could be within a year or two, but the face of post-market surveillance devices is going to change, let's say in five years. So the new database, the electronic submission of reports, and unique device identifiers, along with what's happening on the outside world with electronic medical records, which, as you know, is the big push for this Administration. That will change the face of surveillance for devices, and it will just be a very different look. And what I think is going to happen is that this glut of adverse-event reports coming, which right now the primary source for adverse-event reporting will become a more secondary source, because we will be able to search medical records and we will have MedSun. And so what you have is this puzzle.

This is data from adverse-event reports, which, frankly, in general, are not very well

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written and have a lot of identifying information missing from them, so you have that as a source. But you will also have electronic medical records with unique device identifiers, and you will have your MedSun community reporting and looking, and we're going to have better epidemiology research, and we're going to have MD EPINET set up. So I actually think in five years we will see a much more sophisticated and very different post-market surveillance. I just don't think I can stay around that long.

But I think that things are in place, and hopefully, you know, part of it does mean that we have to have funding, they have to continue to fund these efforts and get them done. But it's so cost-efficient to do it in the end. I mean, it just makes a huge difference in the end, and it's a huge savings in the end if they do it.

The other thing that my office did for quite a while and is really important to me is the communication piece.

I was sitting in the airport with a friend of mine 12 or so years ago, and we were watching the screen. It was CNN or something like that. I said, "Wouldn't it be great if they had little clips on medical devices?"

So we came back and we talked to our studio at CDRH, and eventually we put together a program called "Patient Safety News." And we had two co-hosts, one being Mark Barnett and one being Anita Bayner, who was in my office. It became an agency program. We put together a group of colleagues from CDER and from Biologics who contributed heavily to the program. Everybody pulled their weight. Everybody contributed financially. It was really tremendously successful, and we had something like 4,500 hospitals viewing the program.

As I was leaving -- well, first of all, Mike Barnett retired, and as I was leaving, they were at least talking about how they may or may not change it.

JS: It seems like a natural for the Web. Did they put it up on the website?

SG: We put it on the Web; we have it on YouTube.

JS: Okay.

SG: Within CDRH, there was some push and pull about who owned communications after a while, because we have an Office of Communications and Education, and that became a problem. I actually think we lost ground in our ability to communicate because we went back to, it's not paper based, but it's this electronic communications when the rest of the world is on video, and the rest of the world is on YouTube. So, they were taking a step back to think about it again, but I hope they move forward again because it's important. With Patient Safety News, the risk managers in hospitals could pull out the pieces they want and send them to the departments that they wanted. It was really a great little program. So, I'm not sure what's going to happen next, but FDA needs to continue to work on the communications.

JS: Is what you're talking about, though, something strictly that Devices, the Center for Devices developed?

SG: We did develop it, but Drugs and Biologics became partners with us. And I think most of the stories, more stories for drugs than anything else. They would have information about recalls and then there's safety messages. It's really well done, very, very well received. We always got great kudos on it. So I hope that they're able to reconstruct it in some way because I think it was important.

JS: Well, I only have one more question, and I have to ask, what's the Holy Cow Award?

SG: Let's see. Where did that come up?

Well, you know, it's very hard to, in our system, to reward . . .

JS: There is such an award.

SG: Yes, there is. . . . to reward our OSB star performers. We used to have on-the-spot cash awards, and then the PMAP system came up, so we didn't have that anymore. And I always looked for ways to reward my staff. How do you really thank those people? I know what hours they work and I know what time they give up from their family, and I know a little bit of praise makes a difference. And, honestly, you read every management book, and I know it works for me and I know it works for them, but someone recognizing and saying thanks is a really big deal.

So, I have these little rubber cows that I got somewhere, and when people did something that was great, they might get a Holy Cow Award. Sometimes we brought staff from other offices in. The manager would say, so-and-so did a great job on this, and told what they did and why it was special. It's a model for the rest of the staff. Then the staffer got this little rubber cow and lots of applause. It really made a difference. I think it made a difference. And so, again, it was just one of the ways I tried to tell my staff what a great job they did. Again, I have a great fondness and love for the folks in OSB -- tremendous, tremendous staff there. It was very, very, very, very hard to leave them. It really was. So that was the Holy Cow Award.

JS: Well, someday we'll probably have to, if we have somebody who's retiring that has one, maybe we'll try and get it for the history collection, put it on display someday.

SG: And, you know, I had some left, but I had a lunch for all my senior staff, and as part of that, I just gave them all away.

JS: Oh, they all got them.

SG: So they are floating around somewhere.

JS: Okay. We'll keep our eyes open for them.

SG: Although I was up in New York visiting my great nephews, and what do you know, they have these little rubber cows.

JS: Holy cow!

SG: They exist somewhere, yeah.

RT: Well, perhaps that's a good point to close the interview.

SG: The time actually went really fast. I was really struggling at times to recall. I hadn't thought about any of this since April 30th.

JS: Well, we try to do these not too long after someone leaves, partly because people go on, you do other things, and that FDA mindset isn't quite, you know, what it is two years after the fact.

SG: Exactly.

JS: Thank you so much.

SG: Well, you're welcome, you're welcome.

JS: We really appreciate this interview.

END OF INTERVIEW