

History
of the
U.S. Food and Drug Administration

Interviewee: Robert J. Cangelosi
Peter B. Carstensen

Interviewer: Suzanne W. Junod, Ph.D.

Date: March 3, 2009

Place: Darnestown, MD



National Institutes of Health
National Library of Medicine
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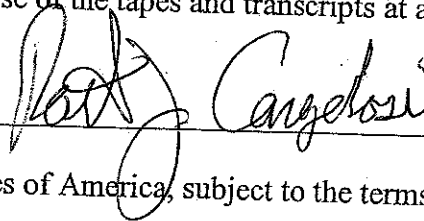
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CASSETTE NUMBERS

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

DATE: March 2009

PLACE| Darnestown, MD

INTERVIEWEE:

INTERVIEWER(S):

NAME: Robert J. Cangelosi
Peter B. Carstensen

NAME: Suzanne W. Junod, Ph.D.

ADDRESS: N/A

ADDRESS: Food and Drug Administration
10903 New Hampshire Ave.
WO 32, Rm. 3320
Silver Spring, MD 20993

FDA SERVICE DATES:

Robert J. Cangelosi
Peter B. Carstenson

FROM:

September 1971
June 1974

TO:

April 2006
April 2008

TITLE:

Robert J. Cangelosi

Branch Chief – Human Factors
Engineering, Science Branch,
CDRH

Peter B. Carstensen

Mechanical Engineer

INDEX

<u>Tape</u>	<u>Page</u>	<u>Subject</u>
1-A	1	Professional background – FDA employment
	2	Medical device inventory – Bureau of Medical Devices (BMD)
	4	National Standards Association
	5	Electric Safety issue
	5	Defibrillator – electrocardiograph standards
	7	Device lead wire concerns
	8	Device amendment opponents, e.g., Dr. DeBakey
	9	Mechanical integrity standard
	11	Perfusioinists in device manufacturing industry
	11	Problems with anesthetic devices
	15	Interviewees’ pre-FDA employment in the aerospace industry
	19	Experiences working with David Link and Larry Pilot
	21	Ted Cooper Commission Report
	22	Office of Medical Devices
	22	Activities of Device Standards Group
	27	Systems engineering

INDEX

<u>Tape</u>	<u>Page</u>	<u>Subject</u>
	28	On-site defibrillator battery maintenance checks
	29	Pacemaker issues
	31	Impact of Medical Device Amendment on FDA devices staff
	32-33	Mergers of Bureau of Devices and Bureau of Radiological Health
1-B	35	HEW appointment – Deputy Director of Bureau of Radiological Health (BRH)
	37	HEW’s designation of Deputy Director, Medical Devices
	37	Emergency Care Institute Research (ECIR) contract
	38	HEW Secretary’s admonition to industry representative for smoking in restricted conference room
	41	Secretary Califano’s anti-smoking campaign
	42	Device Director David Link’s management style
	44	John Villforth’s role BRH-BMD Merger
	45	Office of Medical Affairs Director Marlene Haffner’s modus operandi
	47	Congressional hearing on anesthesia devices, etc. Investigation of hospital deaths linked to anesthesia devices (Puritann Bennett Medical)
	53	Removal of deadly anesthesia devices
	57	Villforth & Gundaker testify on gas machines
	58	Dingell-Gore Reps. – Congressional Oversight Committee
	61	Anesthesia Patient Safety Foundation
2-A	64	Testing Anesthesia Machines
	67	Serious Injuries & Deaths – Human error in the use of medical devices
	68	Pre-Good Manufacturing Processes
	68	Pre-Good Design Practices
	69	Commissioner’s Special Citation – Ellison Pierce
	73	Voluntary Standards
	76	The Apnea Monitor
	77	Sudden Infant Death Syndrome (SIDS)
	79	National Institute of Standards & Technology (NIST)
	84	Sidney Wolfe
	86	Concluding Remarks

Robert J. Cangelosi and Peter B. Carstensen

TAPE 1, SIDE A

SJ: . . . March 3rd, 2009. I'm here at the home of Robert Cangelosi, and we're here with Dr. Cangelosi and Peter Carstensen.

RJC: No doctorate. Professional engineer.

SJ: We're here today to talk about the early days of the regulation of medical devices, and so I'm going to let you guys introduce the subject by telling us a little about how you came to FDA and some of what your background was.

RJC: I guess I'll go ahead and kick it off.

I came to FDA in September of 1971, was hired by Dave Link and Larry Pilot, who were at the time the two medical device folks on the Commissioner's staff. I was introduced to them by Joe Mammanar, who was, I believe, the Associate Commissioner for Planning and Evaluation at the time.

The day I reported, the medical device group grew. I was the first hire, and then they (Link, Pilot, and a secretary) absorbed Dr. Davis, Dr. Joe Davis's group, from the Bureau of Drugs at the time, which consisted of Joe Davis, Bob Kennedy (Short Kennedy, as we used to call him), and Dr. Scuffa, and a secretary. That was the group the day I reported.

I was supposed to report to the Parklawn Building, and they said, “No, you’re not going here, you’re going over to the Chapman Building,” and so I reported to Chapman Avenue, and was there for several years doing basically whatever they asked at the time, but I did work on the medical device inventory, which was one of the first items that was underway at the time. Larry and Dave had gotten with, I forget the acronym at the time, but it was the Medical Device Manufacturers Association. And I think Vance Bryfew [sp.], I think, is the name I remember as heading that group up.

They sent out to all the device manufacturers an informational package with the inventory sheets, and the folks came back with the inventory sheet filled out and I had to review it and make sure that it was at least usable from a computer standpoint and get a printout inventory of the medical devices.

SJ: Do you remember what kind of devices? I believe heart valves were included, but we haven’t been able to find the inventory. I’ve been looking for it.

RJC: Oh, really? I had the blank sheets. I didn’t have the filled-out inventory sheets.

SJ: But you think that they were computerized?

RJC: Yes, they were computerized. I can tell you why, because Dave had given me the assignment, and I tried to deal with the, I don’t know whether we were in HEW at the time; I guess we were in HEW at the time. And I had to try to deal with the HEW

computer folks downtown at the time, which was mission impossible, for some reason. Of course, we worked for the same government department, but . . .

So I came back one day and I found out on the top floor of Chapman Avenue, in the Bureau of Radiological Health (BRH), there was a guy named Neil Goldstein who headed the computer group. And I went up and talked to Neil. We got along really well, and I told him my problem. He says, "I'll take care of it for you." And from that point forward, all the medical device inventory was then put onto the BRH computer. So, maybe Neil Goldstein might remember where those original tapes are.

SJ: I will certainly check, because, as you can think, it's valuable to know what the state of the field was when we came in.

RJC: Yes.

RJC: You know, I think there was, I remember seeing a printout. I didn't send that last printout of all the devices? Somewhere there is a printout.

SJ: I will double-check your records, but I think something that big I would have noticed.

RJC: Yes. It would have been a pretty big package. It would look like the old-fashioned computer printout, too. It would have been . . .

SJ: On the sheets.

PBC: Yes. You might check with Larry, too, because I did send him some stuff at one point. He was going to make a speech or something. It might have been blank sheets.

SJ: What do you remember about that inventory? You said it was pretty massive.

RJC: It was, and that was, of course, used by the original panels then. It was divided into the original medical device classification panels, and that was the information that they used to try to put them in device categories.

SJ: Yes. And talk about the development of that panel. Was it conceived as an advisory committee?

RJC: I believe it was. I wasn't too totally involved in that portion of it because I went on to do standards work and did a lot of it -- I did some contract research type work toward standards development and, after the inventory. And then I was involved with Dave Link in the American National Standards Association Institute, (ANSAI) where we got the Medical Device Standards Board going. So I was involved more with standards, a little bit with the American Society for Testing and Materials (ASTM). Peter was involved with ASTM more than I was.

PBC: And Association for the Advancement of Medical Instrumentation (AAMI).

RJC: And AAMI, yes, AAMI. It was a lot of speaking to these groups to get them going on standards, particularly AAMI and the Medical Device Standards Board.

SJ: What were the priorities? What devices were the priorities at the time?

RJC: That's a good question.

We kind of developed our own priorities, I guess. I mean, defibrillators was one of the initial ones. I was involved in the contract with Utah Biomedical Test Laboratory. We did some environmental work. Pete was involved with that. Electromagnetic interference with medical devices and electrocardiographs were work items.

We tried to do an electrical safety contract. One of the first ones I did, and I remember it was one of my frustrating parts of government work because I put out this proposal to do this electrical safety, where there was a lot of contention at the time how much . . .

PBC: Electrical leakage.

RJC: Yes, how much leakage actually was harmful to a person, and in what condition. And I remember, I went through the government contracting procedure, put the RFP (Request for Proposal) out. I got 56 proposals back that I had to evaluate. And I got

them all evaluated. I was ready to award the contract. And this little guy downtown with one office and one telephone protested the award, and I never got the contract out. So . . .

PBC: Someone in the government.

RJC: No. This was some private guy downtown that thought he should have gotten a contract, against these bigger organizations. I never got that contract out. That was a learning experience.

PBC: We also were interested in international standards organization.

RJC: I remember when I was working on the defibrillator contract that we talked to the Biomedical Test Lab. We subsequently went to AAMI to get it out into the public.

SJ: Define AAMI.

RJC: Association for the Advancement of Medical Instrumentation. They're located in Virginia, still going strong.

I remember at the time that the International Electrotechnical Commission (IEC) was working on a defibrillator standard also, and I was able to write to them and get them to incorporate some of our research and standards work into the IEC standard, which mainly had to do with human factors, had to do with putting all the critical controls in a placard area. That was one of the first efforts in human factors that we did.

There was an electrocardiograph standard. I worked on leads and cables for electrocardiographs and cardiac monitors.

SJ: So, a lot of the work was components of medical devices rather than a lot of the devices themselves.

RJC: No, they were pretty much devices, but when -- the lead work was done because typically in an emergency situation, you have leads on somebody in the ambulance, and you want to transfer them in the hospital without taking those leads off, undoing the paste, redoing in an emergency situation. So we were trying to work on compatibility and being able to move fast in an emergency situation.

I was the guy who ultimately ended up as the co-chair of the AAMI committee that got the American National Standard published on lead wires. But that was quite a few years later. It took us a few years to hammer that out.

SJ: And do you remember working with heart valves at all? That's my personal interest.

RJC: Yes, very little. I remember Dr. Huffnagel -- it was either Georgetown or G.W. I met him; I was always impressed with the guy, and he's quite a guy. And then I knew Art Beall, pronounced "bell." He was from Texas. He was quite a guy. I knew him from AAMI because we sat on the same committee, and we discussed the Medical

Device Amendments as they were going through Congress at the time. There were some heated debates.

PBC: Yes.

RJC: And I remember he got on me really bad at one meeting, and then he comes up and apologized, and it's only politics, only for the show here. So he was a good guy.

PBC: He was in rabid opposition to Device Amendment.

RJC: Well, DeBakey and Art Beall were partners in crime down in Texas.

PBC: I think [unclear] coming to work for him, right? And he said [unclear] some speech, some general description of how we didn't have to do it. And DeBakey got up to speak right after he was seated and addressed the American Chemical Engineering Society.

DeBakey gets up and he deviates from his little presentation to tell the audience what a disaster FDA is, you know, what the impact is going to be on the medical device field and how they're going to ruin everything. He said, "All the progress we've made over the last decade would not have been possible if FDA was implementing the medical device amendments. They're going to kill more people!" Okay.

And I'm thinking to myself, "My God, why me? Why do I have to take this heat?"

SJ: I can see how they would have argued that it might stifle.

RJC: Oh, yes.

SJ: But I can't imagine why they thought it would kill more people. They'd been doing a lot of that with the heart valves.

PBC: Well, they say because we're going to slow down progress in new device development.

SJ: Oh, okay. I've got it, the traditional argument.

RJC: But both Pete and I came from an aerospace background, where we dealt with spacecraft, and the last job we had there was the F-14, which was an advanced fighter at the time. And we got to work on medical devices, and they were so far behind on it, I mean, so many, so much technology. I mean, human factors was just one part of it. But as far as electromagnetic compatibility, they never even thought their device was going to be interfered with or interfere with something else.

We worked on the standard for mechanical integrity, you know, shake, rattle, and roll. They never thought a medical device could be damaged. I had personal experience with stuff being damaged because it really wasn't built to withstand even rolling on a cart

down the hall, which is an environmental defect from a mechanical standpoint back in the old days.

PBC: I remember my same reaction when I first -- that was my introduction to medical devices working for FDA. And just seeing the general maturity of the technology, I was appalled. I'd never seen such poor quality the first time. And I'm going like, "My God, this thing is an accident waiting to happen," and I was absolutely right. It took literally 10 years before the quality information came out. Just as an engineer looking at the technology, I'm going like, "This is so crude." And now it's sort of like an erector set. The individual anesthesiologist would buy the machine, and then he'd buy somebody else's vaporizer, and someone else's ventilator, and he'd cobble this together. So now you had a physician, no training in engineering, being assistant engineer, you now, deciding now how to configure this machine. And I'm going like, "This is absolute insanity." Okay? You know, people in the aerospace business would be appalled to see this.

RJC: And that was without, that was pre all the monitor that added the safety to the device machines.

PBC: Oh, yeah.

SJ: I was going to say, what do you remember, if anything? By this point, by the time you came on, I'm sure that they were all under better control, if you will. The frontier

period had kind of passed. But one of the things that made cardiac surgery, in particular, possible is heart-lung bypass machines.

RJC: Right.

SJ: If you look at the early ones, what you see is gorgeous machine work. I mean, these are gorgeous pieces of machinery. But, as you said, the ideas for how to accomplish bypass then go all over the place mechanically

RJC: It was erector set; it was an erector set.

SJ: Bubbles and doubles versus columns versus all sorts of things.

PBC: At least in that field, they had really, people with, they were called perfusionists. Right? They weren't medical doctors, but they were sort of better trained than a nurse, so somewhere between a medical doctor and a nurse. But they were into the technology, and they were very well disciplined. It was a refreshing group, I think, certified and whatnot.

They were able to put these things together correctly most of the time. Right? So I don't think there was a lot of problems with errors putting things together and figuring the system. They had a pretty good track record because they had experts dedicated to one function.

RJC: Right, exactly. And usually they were teams. Right? So it was the same, say, four people that were working together, you know, so, through experience, they sort of perfected it.

SJ: What state was anesthesia? You talked about anesthesia. You talked about the gasses. You talked about actually working with them. What state was that in at the time?

RJC: Pete's probably better to talk to that because even today, even the gas cylinders in the U.S. and elsewhere are differently coded, pin indexed, and so . . .

PBC: Color codes.

RJC: Yes.

PBC: Well, the mechanical connection diameter indexing to make sure you don't cross, hook up nitrous oxide to an oxygen line, you know.

SJ: They have different sizes?

PBC: Right. They're indexed. And the gas cylinders have pin indexes. Right? Most of the time. And now, with the advanced technology in monitors, now they sample the

gasses so you know what's coming out. So if you do inadvertently mix things up, you know it's going to go off oxygen. That kind of thing.

The thing that really mattered was development of these pulse oximeters, where they put that little clip on your finger. They actually measure the concentration of oxygen in the bloodstream.

SJ: And when did those come out?

PBC: It was like the mid-'80s.

SJ: I thought they were much more recent.

PBC: Yes. The first one, I think, was Elcor. Bill [unclear] medical doctor; he was an anesthesiologist and started this company and developed the Elcor pulse oximeter. But they were expensive, and they weren't in widespread use. It was only after -- we're going to date ourselves now, but it was only after Jeff Cooper from Harvard had done a critical instrument study of the five Harvard hospitals. Right? They self-insure. And he set up a system where he hired professional psychologists to run these one-on-one interviews with the anesthesia group in five hospitals, basically asking them, "Have you ever killed anybody? And tell me the details." Right? And with the promise of anonymity. And he got away with that because Harvard is self-insured; they absolutely guaranteed that they would not, if word got out, they protected to make sure. There were only three people that could identify, would ever know who the individual was that told

them whatever. Right? And then this worked. So if they got a court order, right, they'd go like, "Sorry, the information has disappeared, and my memory is not very good."

Okay?

And they, based on what they discovered in that study, extrapolating across the entire United States, saying, "This is our experience in these five hospitals, and there are X number of hospitals, that this is representative." If this result is representative of what you'd see across the country, in other words, those five hospitals were not different than hospitals across the United States, there would be somewhere between 2,000 and 20,000 deaths every year from anesthesia mistakes, and almost all of those would result from human error, you know, somebody made a mistake, the anesthesiologist, whatever.

So, that came out. Right? And there was a major push to address, and I think it was astounding. Right? The numbers, people who had no idea it was that bad. And that was a pretty definitive study.

RJC: Oh, yes.

PBC: It was a scholarly study. And they were, you know, being academics, they were very careful not to exaggerate. They wanted to be able to defend what they said, so it was at least that bad.

Because Cooper talked to me personally, and I said, "Jeff, I'm having a lot of trouble translating this information to our Center management, to Link and other people.

RJC: Right.

PBC: I think Villforth at the time really came out concerned. Villforth claimed that senior management is very troubled with the idea of two to 20? You know, why are they so uncertain? They just couldn't grasp why this huge range. Right?

And I remember talking to Jeff Cooper privately, and I said, "Jeff, can I get your help? They just can't seem to deal with this wide range. They seem to translate that into, 'Gosh, they have no idea. They're kind of winging it.'" Right?

And he says, "Well, I can tell you confidently, I'm pretty certain, and not just me, other people involved, other academics who have looked at the results. We think it's probably in or around 10,000 plus or minus 4,000, right, you know, that range. But I can't say that in scholarly work because I can't defend it." So, to say, in a scholarly way, it's at least two, could be as high as 20, somewhere in that range.

SJ: Okay. This is great stuff and I want to keep all of it, but I want to make sure we don't forget anything.

So, we haven't gotten your background and how you came to be at FDA.

PBC: Well, I first met Bob when I joined Grumman Aircraft back in 1964. He had just gotten out of school. I had worked for aerospace before that, space aircraft. And we bumped into each other, two young system engineers, and dealing with these older subsystem engineers who resented system engineers in general because they were sort of more elite. Okay? And here these kids are telling us what to do? And we worked two different systems organizations. Bob worked for systems tests and I was working for

systems analysis, which basically, there was a lot of overlap. He was assigned a series of subsystems to sort of get smart on and do the systems work on. I was, you know, there was a lot of overlap. I was dealing with some of the same subsystems.

We bumped into each other, and we decided like we, you know, sort of comparing notes and finding out how difficult it was to deal with these older guys who were not cooperating. Okay? So we decided to pool our information. Like, you know, here's what I've got; what have you got? Right? And we had to keep it a secret because our two organizations were rivals. So our bosses knew we were sharing information, and it was nothing good politically. Okay? So we just did this to survive. Right? We're just trying to get our job done.

So we'd bump into each other, and I was working with a group that was sort of supporting the lunar module test team of engineers, sort of a liaison, and Bob was on testing, so we had a lot of contact, we'd run into each other.

And then we both sort of like specialized in guidance and controls in the SCS, you know, stabilization and control systems.

RJC: Right.

PBC: Which were very interesting. [unclear] changes and stuff. And I can remember -- you should tell them the story about the selling of the lunar module number five. That was the one that actually landed on the moon. Bob was involved with this.

SJ: Okay. Hold on two seconds; I forgot something.

Where did you get your degrees?

RJC: I got my B.S., electrical engineering, at the University of Maryland, my M.S. from Brooklyn Poly, Polytechnic Institute of Brooklyn.

PBC: Polytechnic Institute of Brooklyn; that's where I got my undergraduate.

SJ: Okay.

RJC: So, being systems engineering, we also had interface with the ground support equipment people that interfaced with the spacecraft and checked it out, and we were the only people looking at how the subsystems actually got married together, and we were able to come up with some irregularities that the subsystem people really didn't want to hear about but had to fix, and we found them during tests.

I remember one of the first test things, I was down on the floor running a test on the descent engine, and I was asking them to make some, the descent engine move, and I'm looking at the thing saying, "Guys, this is going in the wrong axis." Somebody had screwed up the wiring on all the drawings. It was just a few of the things we, you know, line voltage drops that couldn't be sustained because of the wrong wiring system, like that.

But anyway, we got around to LEM-5, something that Pete and I ended up on, LEM-5. It wasn't supposed to be the first lunar lander. I ended up on there because I asked for a reprieve from 24/7 work to finish my master's thesis, and they pulled me off

LEM-3 or -4 and onto -5, and somehow LEM-5 turned out to be in the hot seat, and I was in charge of guidance and control subsystems. And it was a couple of nights before Christmas and everybody was sick with the flu.

PBC: It was Christmas Eve, wasn't it?

RJC: It was something like that. I ended up running the night shift, attached on the night shift. And the vice president said to me, "You've got to sell this to NASA tonight, have them sign the DD-250 and get this thing off our books."

So we reran some, the profiles that demonstrated that the spacecraft was good to go. About four o'clock in the morning, we had the NASA engineer buy the spacecraft, so Pete and I were there. So it was the LEM-5, which went on Apollo 11.

PBC: I think it was close to 10 or 11 at night, and it's basically, he was assigned to the test team. I was just there from engineering as a support. Right?

And I remember heading for the door to get my coat, and Bob says, "Where are you going?"

And I said, "I'm going home. It's Christmas Eve."

And he said, "Didn't you hear what the vice president said? You guys aren't going anywhere until you sell this thing."

I said, "He said it to you. He didn't say it to me. I'm not part of the test team; you are."

And he goes, "Come on."

And I'd go -- it was like sort of loyalty to a friend, but also fear that maybe he'll tell the vice president and I'll get fired. I remember thinking, "God, I almost made it out the door, came that close, that close."

SJ: Well, I want to go back just a little bit just because, you know, this is great.

Tell me a little about, what was the atmosphere like when you first came? It was so small, it must have been fairly collegial. What was the leadership under Pilot and Link like? Obviously, you were impressed enough to come work for FDA, so . . .

RJC: It was pretty collegial. I think Joe Davis's group pretty much continued doing their thing and irritating Dave.

PBC: Dave Link.

RJC: Yes. They didn't -- you'd have new guys come in, new political appointees. I guess Dave and Larry both came in as an original staff, because Larry ran the Pharmacists for Nixon campaign, I remember. Dave came -- well, whatever. But it was pretty collegial. Yes, they were kind of an individual group.

Somewhat off the record. It was funny. Dr. Davis had a secretary who took very good care of him. I made the mistake of trying to go see him after lunch one day. He took a nap after lunch every day. And I started to open the door, and this lady hit me with a body block I'll never forget. Almost knocked me on my can. But it was just a funny story.

But then, Dr. Davis was a character.

I remember one time he went to sleep in a meeting we had with all these other government agencies. It was a round table. And I can remember Dave Link's face just getting redder and redder.

PBC: It was embarrassing to him.

RJC: Yes.

But they did their own thing, I guess.

SJ: Well, you probably weren't that involved in the evolution of the Medical Device Amendment, but the Cooper Commission Report was supposed to be such an important piece of mapping out, I know, the classification system, but maybe other things as well. But the problem is, the Cooper Commission Report is 20 pages? I mean . . .

RJC: I thought there was an appendix to it. I think it's a little larger.

SJ: Okay. Well, the most obvious part is so, is almost startling in its simplicity, and lack of specificity. But you're right, maybe I am missing that part of it.

RJC: It's almost like any of the bills you look at. You've got to go back and look at the committee report to get the intent of what they said in the bill. Maybe it was [unclear] discussions.

SJ: Well, did you know Ted Cooper or have any interaction with him?

RJC: I did not. He was at NIH.

PBC: Yes.

SJ: Yes. Well, that was . . .

PBC: They claimed that there were like thousands of people dying from electrical leakage problems, and it turned out to be totally . . .

SJ: Wrong?

PBC: Totally wrong.

RJC: Somebody, a research institute wrote an article, or somebody hit the airwaves with it. I'm not sure it was the Cooper Committee Report.

PBC: Emergency Care Research Institute (ECRI).

RJC: Yes, somebody hit it.

SJ: ECRI?

PBC: Yes,

RJC: And that's why we tried to do that research study that I talked about earlier and that had all these proposals. Then I got held up and shot down by a one-man show.

SJ: Well, tell me a little bit about the growth of the office that was started and then into the Bureau of Devices, and then later with Rad Health.

RJC: It became the Office of Medical Devices, and we gradually grew in the classification area. Carol Brook. That name rings a bell. He headed up that part of the group when we started putting classification panels together. We started putting on more people in my group and the standards group. There was a, we were Medical Device Standards and there was another part called In Vitro Diagnostic Products under Eloise Evans that was a parallel group to Medical Device Standards.

We had the bulk of the contract money at the time.

SJ: What was her group doing?

RJC: In Vitro Diagnostic Products.

SJ: Examples.

RJC: A list of the wet chemicals we used to . . .

PBC: Diagnostic tests.

RJC: Diagnostic tests outside the body, blood samples, blood plasma, any test you would do.

SJ: Pregnancy tests?

RJC: Yes. The reagents and other things that go into, the raw chemistry, microbiologists and chemist, primarily. It came from down south at CDC.

PBC: Yes. It was a rivalry between the CDC and FDA. The CDC kind of resented the FDA role.

RJC: Probably.

PBC: She was sort of forced on, I think.

RJC: Yes. I think there was somebody else that had, in fact, there was a guy that

headed that group up before her, and I can't remember his name. So, again, I don't remember the politics of that, but I know there was always a suspicion that she was working behind his back to transfer the whole thing back to CDC.

SJ: You can go back to your part.

RJC: Yes. So I'm in the standards group. We grew to 10 or 12 people at the time, I think. We were doing what I call quotes, unquote, a lot of research work, what we used to call them problem definition studies where we'd look at a medical device and try to determine what the problem areas were, and then try to translate those into recommendations for which standards could address those problems.

Then we tried to get that information out to organizations like AAMI, the Association for the Advancement of Medical Instrumentation; ASTM, the American Society for Testing and Material, and hopefully get their standards groups working on those problems. And I think we were pretty successful. We had quite a few standards going back to the early days.

And the classification panels grew at a much more rapid rate. They grew because they -- was it 13 panels including the in-vitro panel? I forget how many there were.

PBC: That sounds right.

RJC: It seems like there was a large number of panels. And they started the work on

the medical device inventory and tried to divide those up into panels and then classify them.

SJ: And that was the basis of it.

RJC: Yes. And then there was a lot of contention over whether standards could really do the job because there were so many devices that would end up in Class II, which was a standards category that would have taken millions of dollars and many years.

PBC: At least.

RJC: Class I was general controls. Class III was pre-marketing. It was a fair number of devices that we needed to do pre-market approval.

PBC: The higher categories we later realized/

SJ: That's another thing I wanted to talk about, is, obviously, the '62 amendments had had a profound influence on the agency in terms of setting up a process of notifying the agency of trials that they wanted to have done, and then monitoring the trials or having the results of the trials reported as part of the NDA process, the approval process. How much did Devices conform to that model or deviate from it, or learn from it, or change it or . . . What was the influence, what was the status of clinical trials under that, 1976 to the present time?

PBC: That was -- I never, never really got involved with clinical trials.

SJC: The device part of the industry that FDA regulated was much opposed to a drug model for devices, and I know from a personal conversation I had with Dave Link, that he was very sympathetic to what industry was saying. He was sort of like fighting off the FDA drug people, you know. And even to this day, drug reviews dominates the agency, no question about that. And the new upstarts, you know, device people, and I think there was pressure on Link and company to follow the drug model. So it was a fight to keep it more reasonable and sympathetic to device approvals, and I think he was right.

SJ: And we've heard a lot more recently about lifecycle. Is that something that you, something, a term that was used, or is that a much more recent term. The concept of a lifecycle, they've argued, is fundamentally different from that of a drug. Whether or not that's true or not is apparently up for debate. Was that something that you kind of intuitively knew? Or is it something that was expressly discussed?

PBC: Well, it's interesting. Bob and I were the only two -- there's one other person with experience in aerospace.

RJC: Dave Seegers?

PBC: Yes. Well, Seegers was working for Bob. The only systems engineer in the

device program -- we're like half a dozen people or four people working for Bob. Right? And we certainly understood the concept of a life cycle. System engineering, that's the lead thing.

SJ: I was going to say it sounds just like exactly what you were doing.

PBC: And we were never successful in educating our superiors. They hear you, you know, they nod, but you realize that it's not registering. And it was only when Figel came along that they came up with this idea of life cycle. Right? It was nothing new for us. We're going like, well, finally, finally one of the senior managers gets it.

RJC: We did do some work that might have highlighted some of that was a lot of money to spend with the states and state regulatory people, and we used to put out state contracts.

I remember one of them, we did a state contract with several states to study the, basically the liability and maintenance of defibrillators that were actually used in the field. That was a very interesting set of contracts because we asked them to actually go out to look at these defibrillators in actual use now as part of the life cycle.

PBC: Didn't they actually go out and test the batteries in them?

RJC: We went out, and I was on a team -- I went out with them several times, and we'd go out into rural areas, to cities, and actually asked the user to do certain normal functions

with this defibrillator using a test load, not a person. It was surprising. Sometimes a user couldn't even set the device up, which gave us a clue that there were some problems. A lot of times the device wasn't ready to use. I remember one rural fire station, the guy went out and we asked him to test the device on this test load. It wasn't working. The next thing, he's jiggling the cable. "Well, I always have to jiggle the cable, push it in to get it to work," you know. So we found some very interesting stuff.

And battery maintenance with the early defibrillators was a real problem.

SJ: These were portable.

RJC: Yes.

I remember I got a call which came down the chain from the Veterans Administration Medical Center (VA) Inspector General's office. They had several deaths due to inoperative or unusable defibrillators and asked us to go down and look at all their defibrillators with another engineer. And I went down and we tested all their defibrillators, and they had a variety of defibrillators with a problem. They had some old General Electric (GE) that were like antiques, you know, and then they had some newer devices, but they weren't properly maintaining their equipment, and it was a biomedical engineering problem which we tried to highlight.

In fact, a little aside, one of other last defibrillators we tested had a dead battery in it, and it was on a floor, it was on a ward. So we asked them to take this back to the biomedical engineering shop and take that battery out and put a new battery in. And

when we got back, we were kind of being debriefed, and I said, “Can I have that battery? I’d like to take it back so I can take it apart.”

And so the guy went running to get the battery. Not coming, not coming, and our plane is going. I said, “Well, we have to leave.”

And they finally came running down the hall, and he said, “You won’t believe it.” He said, “The defibrillator and that battery are back on the ward.”

We said, “Well, we think we’ve got part of your problem there.”

But that’s typical when you get out and look at the life cycle of the device: when it’s put in service, do these people get the proper training? While it’s in service, is it being maintained? What happens when it gets to end of life? Somebody, budgeteers take over and say, “You can’t replace that device?” A lot goes into it.

SJ: In going through some of the records more thoroughly, my earliest records having to do with Link’s stand on some things that has to do with a problem they had with internal pacemakers. Did you have any involvement with them?

RJC: I was involved with pacemakers a little bit back in the early days. In fact, some of my papers were on that subject. We found a couple of memos in there dealing with pacemaker problems. I’m trying to recall.

PBC: Early on, they were implanted.

RJC: Oh, yes, they were implanted, some of the original ones. But we used to deal with

things like the New Jersey officials would call up and wanted to put signs up because pacemakers were in use around microwave ovens. We'd get those kind of questions.

SJ: Now, was that later?

RJC: That was the early days of pacemakers, in the early '70s.

SJ: Yes, exactly.

RJC: And then I recall a case where a doctor implanted a pacemaker without putting leads in and wondered why it didn't work. So, there was a lot of odd stuff going on.

SJ: You obviously weren't involved in the legislative part of the 1976 Devices Amendment, but what changes do you remember taking place as a result of it, aside from the emphasis, more of the emphasis on standards? Were you bringing more people in? Was there additional funding? What kind of regulatory actions-- did you notice any changes around that period?

RJC: You mean after the amendments passed?

SJ: Yes.

RJC: Oh, it exploded, you know, very rapidly.

SJ: So, there were 50 or 60 staff members in the Office of Medical Devices?

RJC: I think so, yes, probably. And it exploded.

SJ: So, we're talking about from 1971, when you came in, to roughly 1976, '78, somewhere around then.

RJC: I'd take a guess. Dave Link would have a better number, or Larry Pilot. I think it was maybe 60 people in '76, less than a hundred, I'm sure, because we had Compliance folks on board too -- not too many, but . . .

PBC: When I came in 1974, for some reason I remember 75 or more people were on board.

RJC: I don't know. That number really escapes me, but I know after the amendments, we exploded, because that was when we moved to Silver Spring because we needed more space. And we moved to Silver Spring in '76, I believe, right during the amendments because big tower was down there next to the Holiday Inn. We had like three or four floors there, so I guess that was a time of building up.

SJ: And were Link and Pilot still there even after the change in administrations?

RJC: For a while. I'm trying to remember when Dave left.

PBC: But he converted to civil service.

RJC: Yes.

I don't remember when Villforth came in to Devices -- it was in the '80s when the two bureaus were combined to become the Center for Devices and Radiological Health. It was like '83.

SJ: It was '82.

RJC: Yes. It was in the early '80s, because we had moved back to the Chapman Building at that point.

TAPE 1, SIDE B

SJ: We left off talking about the merger between the Bureau of Devices and the Bureau of Rad Health that came over from NIH.

RJC: Originally, but they were in the FDA for a while.

PBC: Didn't they have their beginnings in Consumer Product Safety?

RJC: No.

SJ: No, because we had our beginnings, we pioneered work that later became transferred to the new Consumer Product Safety Commission(CPSC).

RJC: No. They were kind of, they did come to FDA, though.

PBC: Someplace. The Public Health Service.

SJ: I wanted to talk a little bit about that merger.

We've heard from other people that they felt like it was John Villforth who was instrumental in getting that merger accomplished in a way that minimized ill feeling and maximized the merger because it was quite clear from the beginning that medical devices were going to be . . .

PBC: Subsumed.

SJ: That Rad Health was going to be subsumed with the regulation of devices. Do I have that wrong?

RJC: Okay. But the fact that . . .

SJ: So, I just wanted you to comment on that.

RJC: Yes. The fact that Villforth was asked to take over as head of the new combined organization, there was a lot of anxiety on the part . . .

SJ: Was there somebody in between Dr. Link and Vic Zafra?

RJC: Vic Zafra was Link's deputy, and when Link left . . .

SJ: After Pilot.

PBC: Pilot was Compliance.

SJ: Oh, I've got it.

PBC: So, when Dave Link retired and left the agency, Vic Zafra, being his deputy, just moved up to become the, I guess, acting bureau director.

RJC: Yes. I don't think he was ever a director, was he?

PBC: I'm not sure. I think he was not. I think you're right, Bob. I don't think he was ever named permanent director.

In fact, it's kind of interesting. The story I heard was that Zafra was imposed on Dave Link at a time when Link was out for a couple of weeks on vacation, came back, and walked in early morning, and as he's going to his office, he noticed the empty office next to his was now occupied by Vic Zafra. And he came out and talked to his secretary and said, "Who's that guy sitting in the empty office?" supposedly empty office, and she says, "Oh, that's your new deputy."

And the story was that Zafra had been working in OMB, and in OMB he was responsible for the FDA budget, I think maybe all of HHS's budget. I'm not sure. In fact, it was all of HHS's budget because, at the time, Califano was the secretary of HHS, and Califano and his underlings there were having a lot of trouble with OMB over budget, and it was Zafra who was giving him all of this anxiety. And Califano went, I guess, to the White House and said, "We want to get this guy replaced," or he might have gone to the head of OMB, you know, probably, and, "We've got to get him replaced, got to get somebody else to handle it. We can't deal with him."

And the story was that they said, "Fine. He's a GS-15. Go get him a GS-15 job, because if we move him out of this position, we don't have anything, any GS-15 slot for him."

So Califano looks around his own organization or somebody, you know, his superiors, and they find there's this empty slot. Link had never filled the deputy slot. Okay? Big mistake.

RJC: That's why he had appointed only division directors.

PBC: But there it was on paper, you know. There was this organization. Take it. And it was a 15 position. He goes, "Good." There goes Zafra.

RJC: He was -- I'll say it on the record. He wasn't well respected because of where he came from. He didn't have any background technically. He was a number cruncher.

PBC: I think he was trained as an economist or financial, but he had no science background whatever, and it showed in the decisions, dealing with him.

SJ: Well, how did he get elevated to, I mean, politics.

RJC: Yes. Somebody had a slot and it was an open slot.

SJ: No. I mean when Link left.

PBC: Well, I think it was a change in administration.

SJ: Oh. So you think he was just acting.

RJC: I think he was acting. I don't think he ever was a permanent director.

PBC: I think you're right.

RJC: Pete, tell the story of your run-in with Califano.

PBC: Oh.

RJC: Remember the smoking? This is funny.

PBC: One of the first assignments Bob gave me after I came to work for him in June of 1984, he says, "Take over." He had already issued this contract to Emergency Care Research Institute to develop a standard, an environmental performance standard. That's mechanical shock and vibration, temperature, humidity, and electrical line voltage variations. Right? So it was what we call one of these baseline standards that will apply to everything.

So the contractor, ECRI, had a public meeting at the end where we were going to get public comment on their work. And we held the meeting down in the HEW conference room down at the Califano Building down there at the Mall. And it was a disaster, I mean, comments to the industry were pointing out the flaws in this thing, and I'm just, you know, just holding my head, "My God, I've been put in charge of this thing? What a disaster it is." Right? And I'm going to get blamed. And the meeting is over now, and we were, there were maybe a dozen of us sitting around sort of going over the events of the day, including not just me, there was a couple other people from FDA, Don Marlow, who's running the lab, and I think one other person. My secretary was down there. I asked her to come down and record the meeting minutes with a tape recorder like this. And we're all sitting sort of with our chairs around

in a circle, and we're going over the events. And we're saying, "Okay, what do we do now?"

And in one of the divisions there was Marty Curick. He was vice president, senior vice president of a medical device company. He's sitting there smoking his pipe in the conference room where all of these no-smoking signs were all over the place. I didn't even think anything of it, I was so absorbed in, my God, what are we going to do now?"

SJ: Substance, substance, yes.

PBC: Right. And I see in the far, 150 feet away, a door opens, and this guy waddles in like a bear, and he's about halfway across the room before I realize I've never seen him in person before, but I've seen him on TV. It's Califano. And I'm thinking to myself, "Well, this is going to be interesting. He's probably going to come in and say, 'Hi, how's it going, gang?'" you know, and "Keep up the good work." I'll have a nice little story to tell the next day when I go back to the office, "Well, Califano came in," actually patted me on the shoulder, said, "Keep up the good work." Right?

He walked right over. I see him. He makes a beeline for Marty Curick, who's sitting right next to me, and he puts his face in his face and screams at him, "Can't you read?" And he points to the signs in front, "No smoking. What's the matter with you? Can't you read." Right? And Marty Curick didn't even realize it was Califano. Califano is so intimidating that he took his still-burning pipe and stuck it in his pocket. It was still lit. And some of the other people put two and two together and realized it was Califano. They go, "Oh, my God."

And Califano asks, “Okay, anybody here from the government?” And I noticed Don Barlow, who’s the more senior person, he was a 14 and I was a lousy 13 or 12 at that time, and he doesn’t say a word. I kind of looked to him and he’s looking at his shoes. And I stand up and I say, “Well, I’m here from the government. It’s my meeting.”

And he says, “What program?”

And I said, “Well, I work for the Food and Drug Administration, for the device program.” And I still hear his words in my ears today.

Califano says, “My God, a public health program. You ought to be ashamed of yourself. Can’t you see these signs all over the place, and you’re letting this guy smoke here?” And then he asked me, “What’s your name?” and then, “How do you spell that?”

So I spelled it out for him, and he just turned around and he says, “My God, this is disgusting,” and he marches out of the room.

And I remember everybody realized that it was Califano, and they’re going like, “My God, what are you going to do now?”

Marty Curick didn’t realize it till somebody called him up a day or so later, and I get this phone call that says, “Peter, I had no idea you were in this kind of trouble. I didn’t know he was the secretary of HHS. Geez, are you going to lose -- I really feel responsible. If you lose your job, I’ll give you a job. You can come. I’ll get you a job at our firm. I owe it to you.”

PBC: I go like, “No, don’t worry about it.” I immediately said . . .

What I did the next day, I went in to talk to Dave Link. I actually called him up early in the morning when I was having my cup of coffee, and I said, “Dave,” and he was like a couple of floors away. “Dave, this is Pete Carstensen. We had a public meeting

with Emergency Care Research Institute on the environmental diplomacy.”

“Oh, yeah, yeah, yeah, yeah. How’d that go?”

He hated Joe Noble. There was a personality clash between Dave Link and Joe Noble.

RJC: Joe Noble was head of ECRI, Dr. Noble. He’s a character.

PBC: I mean, an ego as big as this room.

He had a pretty healthy ego, too. And they sort of clashed because Noble used to go down to testify to Congress, saying, “You don’t need this medical device amendment. I’m taking care of all this stuff.”

RJC: You’ve got to know Joe, short, bald, showing up in scrubs.

PBC: Right. Playing the game, playing the game, a real political animal, and very jealous or threatened by the existence of this new organization that’s going to regulate medical equipment, when that was his whole purpose for being, ECRI. They put out the equivalent to Consumers Report on medical devices.

RJC: It was a good publication.

PBC: Yes, yes. So he felt threatened by the existence of this new organization. They were going to take care of the problems. Why would anybody want to buy his

publication when FDA is taking care of that stuff?

So I said, “Yes. We had the meeting. Let me just give you the . . . Califano was in, by the way, dropped in the meeting.”

“What? Joe Califano?”

“Yes, yes. Let me just give you his parting words. And his parting words, Dave, were, “God, this is disgusting,” and he marched out.

And he goes, “Oh, my God.” He said, “Get up here. Come on up to my office.”

So I purposely finished my coffee and let him stew for about 10 minutes, took my merry time just to let him, you know, just to agonize, you know. So I walked in, and he was really anxious.

“Tell me, tell me, what happened, what happened?”

And I told him the whole story. And he goes -- I remember that, I knew he was going to be sympathetic. He says, “Well, isn’t that something. Califano. You know, secretary of HHS, and that’s how he spends his day, intimidating little bureaucrats?”

And he says, “Well, I guess if I was the good little bureaucrat now, I’d call up the Commissioner and warn him that he might get a call from Califano, but I’ll be damned if I’m going to do it. I’m not going to be a sniveling little . . . Let Califano go make a fool of himself.”

SJ: Califano had some missteps with his anti-smoking campaign as well. They had discovered that, well, you all know, women over 35 who smoke had an increased risk of cardiovascular problems or whatever. And so he had this spread and he was going to include warnings for pregnant women in particular and other women as well. The only

problem is that it was a lot easier to give up your birth control pills than it was to give up smoking, and so it backfired. He was trying to get them to quit smoking, but given a choice, they generally kept the cigarettes because they were addictive.

PBC: Exactly. It's more addictive than, I think, any other drug.

RJC: Yes. Dave Link had a unique management style of any of the managers, I guess because he knew he wasn't going to be there a long time. He always, at evaluation time, he always had two sheets. This is how I rate you; this is what I'm turning in. So he always told you like it was. But I always enjoyed it because back in the early days he used to take all the division directors to a staff meeting with the Commissioner and Associate Commissioner, you know, Sherwin Gardner. He used to be associate commissioner when Dave has his weekly or biweekly meeting. He used to drag us along, and we got a lot of insight.

PBC: He was a good manager, Dave Link. I had a lot of respect for him. I liked his style.

SJ: If you felt comfortable enough to joke with him, then that's a good thing.

PBC: You know, he used to challenge your positions just to see how confident you were. But I can remember being in there and getting so emotional with him shouting at you. Right? And he'd walk back with a big smile and he'd say, "Well, I can see you're

really sure of yourself, aren't you. Well, okay, I'll go along with your decision." It was like he would test you to see if you were really, you know, how confident are you.

SJ: And let you just sell your position.

PBC: Right. But I enjoyed the give-and-take with him, I really did.

SJ: Well, he was a wonderful person to interview. And he's, of course, elderly now.

RJC: Did you, in person or over the phone?

SJ: No, it was in person. I went out there.

RJC: Oh, good.

SJ: But the deal was, he would do the interview only if I agreed to lecture for his class. So in order to do an interview, I had to do a lecture for his class.

PBC: Quid pro quo.

RJC: He called me when I retired to wish me well. He had an amputation

PBC: Yes, toes or something like that. He's diabetic. Or a bedsore. I don't know what it was.

RJC: His toes, I think.

SJ: Okay. Well, we were talking about the transfer to Villforth, so let's get back to talking about Dr. Villforth and the future of trying to merge two such different organizations.

PBC: Obviously, he put a lot of effort into engineering this merger, and he wanted to make sure that both staffs felt that they had an opportunity to influence how the organization was going to be structured and the setting out the philosophy or approach. Right? So it was what you call participatory management, you know.

Linda Suydan was a special assistant to him at the time, in a senior position.

And I think she had a lot of influence on Villforth and Vincent Zafra, but I think they were inclined to be very receptive. But she was laying out sort of how they were going to engineer this collaborative marriage of these two organizations.

I know there was a lot of anxiety on the part of people -- you know, I consider myself a bit of a device person, but I wasn't high enough up that I was worried about losing a political position. But I know the people who were, and most of the really good assignments went to Villforth's people. I expected that.

SJ: He knew them.

PBC: He knew them, and had performance history with them. But he made sure that there were a number of positions that were not formally held by Radiological Health people. Like Marlene Haffner was brought in to head up the Office of Medical Affairs, where he had Gordon Johnson there, who was already a senior medical person, so Gordon became deputy and resented it greatly. I don't blame him. Right?

And Haffner had some political pull at the time. She had been a two-star admiral in the Public Health Service in charge of, I think, the whole Indian Health medical health program out in the Southwest, and had overrun her budget for two years running and was almost arrogant. She would run the money, spend all the money, and then she'd say, "I need more money," because they didn't have any choice. What are you going to do, shut down a hospital? So they had to give her the money.

They said, "Don't let that happen again."

She did exactly the same thing the following year, and that's when they pulled her. And she was downgraded to a captain. And the only reason that she survived at all was that she had helped this person, a rabbi, somewhere high up in HHS who sort of looked after her. Never heard the person's name, she never identified it, but she had a connection who protected her. And I think that's how she ended up sort of being forced on, you know, Villforth had to take her on. And they had to give her a job that was worthy of her captain status or something.

RJC: Well, she made it back to admiral.

PBC: She did.

RJC: Retired as.

PBC: Yes, she did. She headed up the Center, she headed up the Orphan Devices, Drugs, or . . .

SJ: Orphan Products.

PBC: Orphan Products. That's right, yeah. And she managed to capitalize that.

RJC: Bring a case of wine.

PBC: Oh, yes. Tell you the wine story.

I'm going out to San Francisco for a meeting, and she says, "Pete, do me a favor. Would you stop off in this wine store -- they're not allowed to ship this stuff to Maryland -- and just pick up a couple of bottles of wine for me." Right? Purchased already. "Just bring them back." Right?

A couple of bottles? Two cases, 24 bottles. I arrive here and I'm going like, "How am I going to . . ." You know, I've got luggage, I've got my briefcase, and I've got two cases of wine I've got to get in the airport. And I convinced Dave Segerson, who

was out at the same meeting, “Give me a hand, Dave.” So we meet the next day, and he says, “All right, I’ll take one of the cases.”

But that was typical of her, to abuse her staff.

She had a secretary picking up her laundry. When she was away with her family or on her ski trip, her annual ski trip, her secretary was going there, watering the plants, taking care of the house when she’s gone, running errands for her. I mean, that’s abuse. That’s . . .

RJC: Well, one thing you might want to talk about, during that Villforth transition, Pete was involved with the Puritan anesthesia problems that we had, a couple of deaths. You might want to cover that and then take that to how we worked with the anesthesia folks, with a checklist, an anesthesia trailer I can add in.

PBC: What happened here was there were two deaths at Puritann Bennett Medical, a pretty high-up, classy hospital in Denver, about one month apart, same manufactured machine, but different serial numbers. So they were identical machines, but two different serial numbers. And they didn’t put two and two together in the hospital after the first death. It was the second death. That would often happen. It was a usual pattern back then, it was pretty clear that there were a lot of deaths that were probably the result of medical devices that never got identified as a device killing somebody because they, you know, it’s a dead person. Right? So if it happened in the OR (operating room), it’s not unusual for people to die during an anesthesia procedure.

But the second one got their attention, and the FDA district office was called in and started to investigate. And the problem is, the press got hold of this in Denver, and it was the *Denver Post*, and there were two young, eager, ambitious reporters there who were doing a series of investigative reporting. They told me this later. They were hoping that they would be, if they did a good enough job, they might have a shot at getting a Nobel Prize, I mean a Pulitzer Prize or one of the other lesser.

RJC: The Pulitzer probably.

PBC: Yes. They were really going for the Pulitzer. Right?

They did a whole series, like almost every other day an article following up on this thing, and then they got the local TV station stirred up.

And the district, very unusually -- you know, the district, after they had become independent of headquarters and they could make their own decisions, they guarded that independence jealously. So they were very reluctant to ask for headquarters' help on doing an investigation, but they had an exception on this one. And they got a hold of our Compliance people, requesting them to send somebody out who has some expertise in anesthesia gas machines. And I had the reputation, working for Abner, and Abner comes to me and says, "The field would like a little help. Can you go out there and give them some assistance while they investigate these deaths involving the anesthesia machine?"

I said, "Sure, no problem."

And I get out there, and we're on the way now to the hospital, and I'm in the car with three other people from the district, and I'm sitting in the backseat. I hear them, as

we're approaching the hospital, and they're talking in a very low voice, "No, don't go in the front door, go in the back."

And I see this, all those TV trucks with the satellite dish. I think there were two of them there. And I'm going like, "What is going on here? We're sneaking in the back because we want to avoid the reporters?"

So I get in there and I find the room is -- I never saw so many lawyers in one room in my life. I mean, everybody was lawyered up. Some of them had more than one, two, maybe three lawyers representing their interest, and they all want to come in and witness me looking at the gas machine and doing testing or whatever.

And I remember saying, "This is chaos. Stop. We cannot have all of you people coming into that small room while I'm running testing with the manufacturer's technician. And I said, "Okay, let's identify who's who here."

So the technician from the company and an engineer, and the guy from Regulatory Affairs Inspector Erickson. I say, "Okay, you three guys from the company, I need you there and I want you there. You have all the drawings and technical expertise in the instruments and whatnot."

And the hospital had hired Charles Goodyear, who I knew from the Standards Committee because he had once been the chief engineer at Fraser Harland, and I knew his reputation.

"And a hospital engineer, you're representing the interests of the hospital, you can come in."

"And all you lawyers, you guys, no lawyers. We don't need any lawyers here."

And the hospital vehemently objected. They wanted their lawyer to be there, and also the director of the hospital. I go, "Fine, one lawyer. You're the only one."

And so we all march in there and start testing the machine and discovered very quickly that a massive overdose had been given. I remember the manufacturer producing these drawings, sort of schematic drawings -- they weren't engineering drawings; they didn't have dimensions on them. They were just a functional schematic layout of how the plumbing works, how the valves work.

I remember taking one look. I mean, I had spent five minutes looking at this, and I go like, "Gentlemen, this is really not representative of how you designed this. You're not actually using -- here I see a spring and a shuttle valve, and the shuttle valve gets pushed back and forth with this cam, so when you move the cam off, the spring pushes it back to the right position. You're not really relying on a spring to return this to its proper position, are you?"

And they kind of looked at their shoes and go, "Well, yeah."

I go, "Okay. I think I know what happened here." I said, "I cannot believe what I've seen here. Any engineer looking at this, this is a fatal flaw, and you can't tell what position it's in buried in the machine. And there's no way to know whether you've overdosed a patient and killed them."

There were no routine gas monitors. They had this thing called an inferometer, where you could take samples out, and it was an optical instrument, and you didn't know what was coming out. But if you knew what the gas, the anesthetic vapor was, you could use this machine to determine what percentage of the anesthetic agent was in the total gas. Was it 4 percent, 3 percent, or 2 percent? So we used one of those machines, one of

those devices. It went off the scale. And I think it read up to about 18 percent, you know. This thing just pulled the needle. I mean, it was like off the scale. So I'm going like, "Whoa!"

And I'm not an anesthesiologist, but Charles Goodyear said, "Peter, I've worked with anesthesiologists." And he says, "If it's off scale, higher than 18 percent, I guarantee you three breaths, three breaths, the patient's gone, and you can't pull them back. I mean, that's a massive overdose."

SJ: And this, who made this machine?

PBC: Fraser Harland.

RJC: This was a private firm manufacturer.

SJ: It was a company.

RJC: Oh, yeah.

PBC: Oh, yeah, yeah.

RJC: They were a big company.

SJ: What time frame are we looking at?

PBC: This was 1983.

RJC: Yes. The machine was probably made in the '70s. It wasn't a new machine. It was a big manufacturer.

SJ: And how many of these were across the country?

PBC: But it actually meant the old performance requirements, safety requirements, in the ANSI Standard Z79 at the time, that was in place, so, and that was a fairly recent standard. It wasn't an old standard. I think it was published in 1978.

And what had happened, Fraser Harland came to me and said it evolved in the committee that was writing the standard.

RJC: Anesthetic machine.

PBC: Yeah, but it was the Fraser -- not Fraser Harland. It was Puritan Bennett, but . . . I'm sorry, it was Fogart Division. Fogart had been a separate company that was purchased by Puritan Bennett only two years before. So they inherited, Puritan Bennett inherited this machine.

SJ: How many of these were around the country? Is this the only one that had problems?

PBC: Oh, no, no.

SJ: It was the only one that was identified at the time.

PBC: Thousands. There were thousands of them.

That was a real problem because as soon as we realized what the situation was, we had to get the word out there: Get these things out of the operating room.

RJC: And that was a problem in itself.

PBC: Because they didn't have anything else. They had nothing else to use. There were a lot of hospitals with . . . That's three-quarters of our machines. And there were two models, the 705 and the 710. The mechanism of both of those was the same. So it was all the 705's and all the 710's had this potentially fatal flaw in them.

RJC: But it boiled down to the seal expanding or something not allowing the spring to do its job.

PBC: Right. It was -- so not all would do it. What was happening was the anesthetic agent was diffusing back and stripping the O-ring of its lubricant, and then it would stick. And it's interesting because, in the follow-up investigation, we looked at the company's records. They told me during the early part of the investigation that they would often get

calls to come in and deal with a sticky spool valve, and if they couldn't free it up just by taking the cover off and putting some new lubricant in and sort of running it up and down, they would have to install what they called a spool-valve kit, which was a lot more work. It was an expensive service. They would only resort to that if they couldn't free it up the easy way, you know, the regular way.

They had records on 198 cases where they installed the spool-valve kit, so that thing was so stuck, they couldn't free it up.

I remember telling Villforth, I said, "All those 198 cases, there's a dead body behind it."

RJC: Right.

PBC: They didn't kill two people, they killed at least 200 people over, I think, a five-year span. And they got away with it because, another thing is, the service guy, they never put two and two together. They would come in, they'd get a service call, something's wrong with the machine. They would do the service work and disappear. But the hospital had no idea what these guys did. They just came in, it was broken and they fixed it and were good to go.

SJ: Never related it to a patient at all.

PBC: No. And they were so sloppy in investigating deaths, they would just go like, "Guess it was his time. He was a sick old guy," you know. It was, if you didn't operate a

lot on them, you would have died and what are you going to do. Right? These things happen.

And I think two or three other cases came out that they did investigate but and didn't link it to a death. But the vast majority of them, more than 150, 170 of them, no deaths, nothing.

So the investigative reporters were keen on following up, so they came to headquarters, they got a meeting with Villforth and Benson and me and Walt Gundaker. And in this meeting, Villforth and Benson I think were a little naïve about devices and the press and whatnot, but they had the attitude, "Let's be open and cooperative." So they revealed a lot more information than they probably should have legally while it was an open investigation, including the -- Villforth instructed me, "Well, Pete, why don't you take him back to your office and show him the pictures of the . . ." You know, they were trying to sop up everything they could get. And so I'm instructed now to go back to my office and show him the photographs of the disassembled machine, spools out and all, which I don't know why that was so important to them, but they wanted it, fine. Okay?

And while I'm there, one of the guys -- there was two; Farrell was his partner; I can't remember the other's name. It doesn't matter.

And so we're here in my office, it's just he and I alone, and he's trying to read the investigative report, this big, thick report. It's upside-down. I'm sitting across the desk, and I realized that, and I'm going like hey, you're reading it wrong. And he says, "Say, Pete, you look like you could use a cup of coffee. Why don't you go down and get yourself a cup of coffee, take your time. I'll wait here." And I'm going like, "No."

So he disappears. Then he's back in my face again two days, three days, or a week later. They're having a series of articles because they're building up this case for the Pulitzer Prize.

I remember this next meeting with him, and I was so frustrated with the guy, and I've had it. You know, you got more than we should ever have told you, and this is administratively confidential. We're not supposed to be sharing information while there's an ongoing investigation, with the press, of all things. Right?

And I remember telling him, and he said, "Well, how are we going to get the story?"

And I said, "You can get it under an FOI."

"What is that?"

I said, "Well, if you put a request in now, it might take six months to a year."

"We can't wait that long."

And I said, "Well," just in frustration, I told him, I said, "Well, I've got an idea for you. Why don't you go down and stir up the Congressional Oversight Committee. Okay?"

RJC: That's what I was going to get to.

PBC: Those bastards -- I have nothing but contempt for Congress because I've gone down and testified. Later.

So, sure as heck, that's exactly what he did. About two weeks later, we get the notice, the letter from the Oversight Committee, that they're going to hold hearings on

the gas machine. And I remember going, "Oh, my God, what have I done." And I'll tell you, I never told anybody what I had done. It was just, it wasn't my intent to actually do it. I just wanted him to get out of my face, get out of my life. And I remember thinking, if this ever comes out, [unclear] this idea.

So then we prepared, weeks of preparing Villforth for testimony. And I remember he wanted me to go down there to sit next to him while he's testifying, and Gundaker and the regional director is down there. It wasn't the district director, it was the field regional director, Villforth, Gundaker, and myself, and Villforth did most of the testimony, and Gundaker did some, and I think I was the third. We determined they dug down deep into the weeds, where it was something that we hadn't really briefed him on, something that we didn't, can't give him all the details. But he was really very well prepared, did a terrific job of testimony.

But I remember driving down, and I was in the backseat. And it was Benson and Gundaker. Villforth was driving. I think Benson was in the front seat with him, Gundaker in the back with me, and the three of them are talking about making side bets of how many cameras are going to be there. And I was puzzled, and I think Gundaker said, "Pete doesn't have any idea what we're talking about."

And Villforth then explains to me. He says, "Pete, well, it's sort of our tradition. It's just a fun thing we do. We go down to testify. We make sort of like side bets on how many cameras will be there, who gets to close as witness," whatever. And I think Villforth had the largest number.

So we get down there, walk in, and it's two cameras more than the largest number that FDA had guessed. Because he told me, they knew how many, in the worst hearing,

the number was -- say it was six -- there were like, and there were two more. It was like eight cameras. I don't know exactly the number. But there were two cameras more than the most cameras that FDA ever encountered in an oversight hearing, and that kind of set the tone.

It was interesting because Dingell was the chairman, but Al Gore, Congressman Al Gore was on the committee, he turned the committee over to him to give him sort of the exposure, I guess, help his career along.

And I remember, I really got an education, and it really, how phony these oversight hearings are. They're all -- they don't ask any questions, but they don't already know the answer. The staff hasn't told them what -- if he asks this question, here's what they'll say. Right?

And one of the things, one of the staff people had come down to the Center and wanted to see the gas machine. We had moved the two to the laboratory, and I was explaining how things are, and here's the gas machine and here's how it work and all that. And they said something about, "We saw in one of the reports that there was a sign on the machine, there was a piece of paper with scrawled on there in handwriting said, 'Do not turn the T handle.'" And they wanted, "What is the significance of that?"

And I said "Well, the T handle . . ." What the T handle was, these vaporizers, there were three of them on like a lazy Susan configuration, so you could rotate, then, the one you wanted to, in position, but to do that, you had to turn this T handle to lift this manifold off so it was free to rotate. And then, when it got in the right position, then you'd turn the T handle the opposite way and it would lower it and make the pneumatic connections.

But there was a sign on this one, one of the two machines, “Don’t turn the T handle.” And he said, “Well, what’s the significance of that?”

I said, “Well, the inspector did ask the anesthesiologist the following question: ‘Why was there . . .’” The story that they got was it was to remind them, him, the anesthesiologist, not to turn the T handle when they were delivering anesthetic. All right?

And he says, “Well, does that make any sense?”

I said, “Well, just a little bit.” I said, “It makes as much sense as putting a sign on your car ignition: ‘Do not turn the ignition off while you’re driving down the highway.’” And the guy laughed.

He said, “What sensible person would have to remind themselves not to turn the ignition off while they’re driving the car? I mean, it’s kind of silly. So I don’t know what the real story is, but that’s what he said. “Oh, oh, that’s great. When you’re asked that question, will you answer it with that analogy, exactly what you said here?”

I said, “Sure.”

Well, it got to that point in the testimony, and Gore asked me, he said, “We heard there was this sign on the machine,” and he’s expecting me to answer as I was instructed.

But I decided not to because we had subsequent discussions with the American Society of Anesthesiologists, who came to us saying, “We have a real crisis in the field. We’re getting a lot of bad publicity. There was a big expose on “20/20,” you know, the TV thing about killing all of these innocent people with anesthesia. The gas machine manufacturers are talking about their product liability insurance going through the roof. They’re talking about going out of business altogether, and this is going to be a disaster.”

And we were finally driven, we want to organize this Anesthesia Patient Safety Foundation consisting of the professionals who manufacture the equipment, FDA, the Joint Council for Accreditation, the insured, the insurers, every interested party, to get together and cooperate and deal with this crisis. So I really didn't want to embarrass one of the three people in the profession by, because this poor anesthesiologist comment look like a fool.

So I just answered, I said, "Well, sir, I can tell you what the anesthesiologist told the inspector."

"What was that?"

I said, "It was to remind him not to turn the T handle while he was delivering anesthesia because it would disconnect the system."

"So, does that make any sense to you?"

I said, "Well, not to me, but you'll just have to ask the anesthesiologist directly. I can't tell you any more than what I was told."

And Gore really covers his flank, and his little staffer skittles up to him very quickly, and I hear this buzz-buzz-buzz going on for what seems like three to five minutes. I'm sure it was like a minute and a half, two minutes. Well, Gore -- the guy is explaining to Gore, "Well, I told him to say it, and I'm sorry he didn't."

And at that point, Gore takes his hand off the desk and said, "I think we have enough testimony from you, Mr. Carstensen." He didn't want to deal with me. And he turns back to Villforth because I'm not playing the game right here.

SJ: You weren't giving him sound bites.

PBC: I was not giving him the . . .

RJC: That would have been a major sound bite.

PBC: Till now, it's all so unpredictable. You know, we might ask Carstensen another question, which we thought we knew how he was going to answer, but he just told us he can't be trusted. He just demonstrated . . .

RJC: So, that was kind of the birth of the Anesthesia Patient Safety Foundation.

PBC: It was, it really was that.

They had approached me because Jeff Cooper was up at Harvard, who had done the Harvard study I told you about before. He knew me from the Standish Place committees; knew me very well. And he was involved with the small group at Harvard who was trying to organize this Anesthesia Patient Safety Foundation. It turns out that the current president of the American Society of Anesthesiologists (ASA), Ellison C. Pierce, Jr., MD, was the president of the ASA at the time, and it was his initiative, trying to . . .

TAPE 2, SIDE A

PBC: . . . with Pierce and Brownstein, and Cooper was there, and I think it was down in the ASA's General Counsel offices down on K Street, I think. Right?

RJC: Yes.

PBC: And I remember his deputy, Jim Morrison.

RJC: Jim Morrison.

PBC: Yes, he was there. And they were basically to ask us, can they get an audience with Villforth, and would the FDA be interested in being a founding member. So we did promise to make those arrangements.

And that was the meeting where they brought up the problem of the checkout procedure that Puritan Bennett had issued on that machine, which was the ASA's judgment was excessively burdensome and was really an effort on the part of the company to shift liability onto the user. So he gave them this six- or seven-page detailed "here's what you need to do to test the machine every day before use." And it was -- I forgot the name of the guy -- Zouter, I think, was the incoming president of the ASA who looked on, he was outraged. He thought it was just an effort to shift responsibility and liability onto the anesthesiologists in an unconscionable way. And Cooper had put together a much more simplified checklist and they're going to have it issued by the American Society of Anesthesiologists, but the legal offices there at the ASA objected, because they said, "Well, then the ASA now takes liability. You're going to put out a

checklist, everybody's going to use it, and now something goes wrong and they're going to say, 'It was your checklist that was flawed or incomplete,'" and it was incomplete, because Cooper made a decision that if we didn't make it something you could do in 10 or 15 minutes, they would do nothing. So better to get them to do most of the important stuff in 10 or 15 minutes as opposed to taking an hour to do everything.

And then, of course, the legal liability issue trumped everything. And Cooper says, "Do you think there's any way that the FDA could put it out?"

And I just volunteered. I said, "Sure. They can't sue us." I mean, we're a sovereign state. You can't sue a sovereign state without its permission. So I made the commitment right there that, yes, we'll issue your checklist.

Got back, and I remember Morrison coming back, saying, "Oh, you're going to get in such trouble. You can't. You have no authority, Peter, to make a commitment like that. That should have been brought back to Villforth's attention, and it should be a decision made at the highest levels of FDA. Probably even Villforth wouldn't have made that commitment without checking with the Commissioner and General Counsel."

But I remember telling Morrison, I said, "Well, I'll take my chances. I think Villforth will back me up." I said, "You know, sometimes," I said, "you just have to seize the moment, Jim. And I thought that was the moment, and I'm willing to take responsibility. If it was a mistake, so be it. You can discipline me."

And, of course, Villforth loved it; he endorsed it. That was that.

So we, the checklist was organized and it was very successful.

SJ: You published it as drafted.

RJC: Well, we did work on it a little bit to make sure it was doable.

PBC: Oh, yes, yes.

RJC: So, at that point we got together with the anesthesia manufacturers, and each one of the two major manufacturers donated us two machines, which we then took into the laboratory. We built basic faults into the machines. We actually rented a trailer, an RV trailer, 24-foot-long trailer, office trailer that had RV axles on it, a pick-up truck, and we would go to anesthesiologists' meetings and ask them to come on, check these machines out just like you do before an operation and see if you could find the faults.

PBC: And they would test the equipment now using our checklist.

RJC: Yes. We went, we would go out, and we went to a big meeting in New Orleans of ASA.

PBC: Right.

RJC: And we would attract the younger anesthesiologists. The older ones didn't want to have anything to do with us.

PBC: They didn't want to be embarrassed because they didn't know how to check out the machine.

RJC: There was one meeting in which -- my wife remembers the story because I had told her -- had a lady anesthesiologist who went through the test, checked out the machine, and left crying. She came back later, two hours later, and wanted to do it again. She says, "You know, I would have killed somebody. I couldn't find the fault." So I think it had an effect on anesthesia.

Of course, then it moved -- then the monitors started coming out, the O₂ monitors, pulse oximeters, the gas concentration monitors, and kind of shifted to the safety aspects of the anesthesia machines.

PBC: Right. But actually, we published the original version of it before we did that testing you're talking about.

RJC: Did we?

PBC: Yes. But we updated it, revised it based on the results of all of those.

RJC: Yes. We tried to shorten it up and make it more concise, user-friendly.

PBC: Yes, because we were getting feedback from people, saying, "Don't kid yourself,

people. Even though you put this checklist out, it's still not positive proof." They're winging it.

RJC: So, I'd go into a hospital and work my way around to the OR and say, "Let me see your gas machine," and I wanted to see where the checklist was, and if it was all tangled up behind the machine, I knew they weren't using it.

PBC: But it had the political value of promoting, first of all, demonstrating to the Foundation and the manufacturers and the professionals that FDA was willing to go the extra mile and cooperate and help out. We weren't just the enforcers. So it really won us a lot of trust and . . .

SJ: Goodwill.

PBC: Goodwill, it did, it really did. In fact, I was told that the American Society of Anesthesiologists in general despised FDA. It was the drug people, though, because they were so uncooperative in getting newer anesthetic drugs out that were in widespread use in Europe. It would take another five to eight years to get it through the United States, so they didn't have the benefit of it. So they held FDA responsible for delaying progress. So we didn't have, the agency did not have a good reputation, but they came out smelling like a rose from this cooperative effort, and just overnight, this switched. And I heard that from some people politically active in the ASA, saying, "You guys did yourselves a big favor, did yourself a lot of good."

But during the testimony down there at Congressional Oversight, Villforth faced serious issues. One, he pointed out the Cooper study where the two to 20,000 deaths every year, and mostly from human error, so he promised Congress, saying that now that we realize how bad it is, we think that's not just confined to anesthesia. We think there are a lot of patient serious injuries and deaths as a result of human error in the use of medical devices, and we're going to mount a major effort to try to deal with that, human-factors engineering. So he introduced, you know, that was a big push to develop a human-factors program as a result of that testimony.

And the second thing was, he got down there, and as part of our investigation, I remember being told by Fraser Harland, the former chief engineer, Charlie Goodyear, the former chief engineer at Fraser Harland, he pointed out to me, because he knew I had an aerospace background, and so did he at one point in his career, he says, "Pete, are you aware that the medical device engineering teams do not do sort of the routine design validations that you and I were used to in the aerospace industry?" In other words, they don't have design reviews. They don't do, necessarily routinely, a risk assessment and all that.

And I'm going like, "I didn't know that." I said, "My God, that's a scandal."

So, talking it up with Villforth, he went and testified that we're looking into, and we'll probably do it very quickly, we think we can modify our good manufacturing practices, which dealt only with, at that time, with the manufacture of equipment, and it didn't go back into regulating the design and development cycle. So we're going to revise that to now include requirements of the manufacturers to do design and development in an orderly way, to do risk assessments and design reviews and all that,

because, as it turned out, we came to the conclusion that this fatal design flaw would have been picked up had they done what's routinely done in some other engineering disciplines, by engineers in other fields; for example, aerospace. So it took us like eight years. He just thought he could do it overnight.

But it turns out that General Counsel had other ideas. He said, "Oh, no, no, no. You have to put out this proposal, you have to have public comment, you have to deal with the comments. And there was a lot of resistance on the part of the industry. I mean, it was a very slow, painful process to get it through.

SJ: So it was pre-good manufacturing processes.

RJC: Pre-GMP's, good design practices.

PBC: Right. So now . . .

SJ: They were named that?

PBC: Well, it was called good manufacturing practices, and it just dealt with manufacturing. And the new one was called quality systems regulation.

SJ: Ah, that's where that came from.

PBC: Quality systems regulation, which consisted of the GMP process and then this

new thing called design controls. In design controls, there's language in there, in the preamble, that talks about, among other things, human-factors engineering as an important activity to deal with making the designs more user-friendly and less accident-conducive devices.

RJC: Didn't we give an award, an FDA-level award, to Pierce?

PBC: Pierce.

RJC: And Dave Lees, too.

PBC: Yes.

RJC: There was two anesthesiologists, as a result of these programs . . .

PBC: That's right.

RJC: . . . and the anesthesia trailer and stuff that we elevated to get awards at the FDA level.

PBC: Yes, it was the Commissioner's Special Citation for Ellison Pierce for being the primary lead on the full anesthesia patient safety movement, you know, predating the

Foundation and delivering speeches. I mean, he was a master politician, Ellison Pierce, in the very best sense of the word. He was very diplomatic, he was courageous, he was . .

Some of his colleagues in the academic world were outraged at the negative image that he was projecting. He was washing the dirty linen in public. I mean, he had the guts to realize that there is merit in taking the heat because there's a nobler objective. I mean, I had such admiration for that guy.

SJ: When did the final regs come out? Do you remember?

PBC: On the quality systems reg? Geez, oh boy. I'll have to look it up.

RJC: It was in the '80s.

PBC: Well, we testified in '84, and I think it was early '90, I think maybe six years.

RJC: It took a while.

PBC: Yes. It's easy to look it up.

SJ: Please look it up, if it's not a problem.

PBC: I have it on my computer at home. If I had my laptop, I could call it up. I have the regulation and the . . .

SJ: I'm just trying to get my bearings in terms of progressions and whatever.

PBC: Yes, but it took an unconscionable length of time to get it in place, because it was a major accomplishment.

SJ: Well, that's a major change.

PBC: It was a major new regulation, oh, yes, and companies needed time to sort of plug it into their SOPs.

SJ: You're looking at a quarter-century transition from aerospace, earth space, What would you call it, standard practice into a biomedical standard practice.

PBC: Well, it's interesting, though. When Bob was in charge of the branch that the old human factors team reported to, remember, Dick Sawyer and I had put together a little blurb on, say, the design controls has four elements: design input, design output, verification, and then final validation. And it's really very short, just one page, the whole thing. The preamble is a lot longer, like 60 pages of discussion. But there's a lot of detail there. And so we decided to credit, emphasize the importance of human-factors engineering, we put up a little document on the FDA web page that says, here is the role human factors engineering plays in complying with the design controls. So, here are the human factors engineering activities for design input; here are the human factors

activities for output; here's the human factors activities and the tasks you would do to satisfy the verification requirements; and then the final validation and risk assessment. And here's the final usability testing you would do, explaining all this, put it up on the FDA web page.

Then I had the goal to go around in public talks and to clarify it as an informational document. It is not a regulation; it is information. To this day, when I left, my superiors at FDA think it's a General Counsel-vetted regulation. And the industry does too. Everybody in the world, you see it all over the place. I've seen other people giving talks, like Yvette Weingart, the head anesthesiologist down at the University of Tennessee, the chairman of Vanderbilt, and chairman of the AAMI Human Factors Engineering Committee. And I've witnessed, been there, and heard him giving talks and saying, "And it's the law." And you know what? They accept it. It is universal.

It's almost like, I think, at this point probably a legal guideline. I bet you if it went to court, the courts would say, "It's been up there so long, it is a de facto regulation." Okay?

SJ: What lawyers did you guys deal with?

PBC: Pardon?

SJ: What lawyers do you remember dealing with on all this? Or do you remember at all? Was there one consistent one?

PBC: Well, I didn't have much dealings with General Counsel. That was the Compliance people. The only time we ever really got involved with them is when, the early days, I think, when it looked like we were going to have regulatory standards.

RJC: Yes, and we tried to publish that document on standards. We went back and forth.

PBC: With Bob Stimpson, when he tried to . . .

RJC: I was involved before that.

PBC: Against our advisement.

RJC: Yes. And I was involved before that, and then he tried after that.

PBC: Well, he made a huge mistake when he tried to give official recognition for voluntary standards without going, without, you know, ignoring the fact that these, the law required regulatory standards and with due process. So, he wanted to put a list out in the *Federal Register* saying that "FDA recognizes the following voluntary standards," but there was no due process. There was no opportunity for comment and all that, and we bypassed all that, see.

What happened is, I think it was HIMA, Health Industry Manufacturers Association, saw the dangers here. There were going to be *de facto* regulatory standards without the due process, without them being able to comment on a proposal.

So they sent, one of the public comments, they sent in something that looked very suspiciously like a legal draft that was going to be submitted to the courts. I mean, it was called, "Oh, you don't want to listen to us? Well, gee, we've got this brief here now. We just have to say 'brief.' Just put the title 'brief' into the federal courts."

SJ: Intimidation.

PBC: Oh, it was obvious they had put it in a form that was very intimidating. It was like, it's called, "You want to ignore us? We'll see you in court. And we're going to win. Here's our legal argument," a lie, "you have violated the law."

RJC: We never did get anything out on standards.

PBC: He set us back.

RJC: I worked on that for years. I had a document this thick, and I could never get it over the threshold.

PBC: But we told him that this was what's going to happen. You can't do this. He goes, "I know better. I'm in charge."

SJ: And who is this?

PBC: Stimson.

SJ: Oh, Stimson.

PBC: Bob Stimson.

RJC: He wasn't there long.

PBC: Well, he wasn't long after that. I mean, he made such a fool of himself. And now, he's set the program back. He made it so they wouldn't pay any attention to the voluntary standards after that. But before, they were . . .

SJ: At least considering.

PBC: Well, you know what they were doing? They were complying with the voluntary standards with the idea that, first of all, it gives them liability protection. I mean, if I'm a manufacturer and if I get in trouble and say, "Well, I complied with the voluntary standards," I followed good advice. So I think after that, it was like the manufacturers were laughing at us: "You guys are paper tigers."

SJ: So you never really got the formal standards published, but you managed to get the human factors incorporated and . . .

RJC: Yes. We did more with human factors, kind of de facto.

SJ: Well, have the standards been specific, or more general?

RJC: No, they would have been specific, yes, defibrillators. But they were used by the classification folks.

SJ: Throughout FDA history, standards have always been fairly controversial.

RJC: Well, they tried to actually do some 514 standards, the regulatory standards.

PBC: The apnea monitor.

RJC: Yes, apnea monitor.

PBC: The apnea monitor wasn't the first. I think it was the first formal . . .

RJC: Yes. They tried to do it and they never finished.

PBC: Fell flat.

RJC: Yes. They picked an awful tough standard because how do you measure whether a baby's breathing or not? There are so many -- do you measure the chest movement; do you measure the nose, whether it's air blockage? They just couldn't come up with a test method.

SJ: And this had to do with all the interest in SIDS, sudden infant death syndrome?

RJC: Yes.

PBC: Spent millions of dollars.

RJC: This went on for six years or so, and they finally had to give up.

PBC: I think it got as far as a proposal in the *Federal Register*. I think they couldn't deal with the comments that came in.

RJC: Yes.

PBC: Well, people were pointing out, for example, like the academic researchers, pediatric researchers, saying, "You know, there is not one documented, scientific

documented case where an apnea monitor has saved a baby's life, and there's not one documented case where it's cost a baby's life. Right? There is no way to get this information. So, what have you got here? You've got a standard that's dealing with what? And it was obvious that they picked the worst device they ever could have picked.

RJC: That was drawn out of our research group, Don Marley's at the time. What was it, standards?

PBC: Oh, yeah, yeah, yeah.

RJC: They took undocumented research and whatever. We tried to warn them, but they were off and running at the time.

PBC: The laboratory staff.

RJC: Yes, the lab folks.

PBC: Science people.

SJ: They've discovered now that SIDS is complicated. It's not one thing. I think at that point they thought there was one cause, and they're finding now that it's multiple causes, including some things that we never even think about.

RJC: They couldn't even come up with a standardized test method.

PBC: I remember when the list came out. It was a short list of about six devices that they were going to attempt to write regulatory standards on. And I saw the list, and I didn't react soon enough. But I brought it to Marlene Haffner's attention, but I didn't realize it was too late. The decision had already been made to go with the apnea monitor.

I remember pointing out to her, I said, "Marlene, I know some of the history of the standards effort in apnea monitors," because one of the guys at my branch was Larry Colbert, had put a request for proposal, ECRI, and I looked at it. The proposal came in, and it was just regurgitation of the RFP. ECRI had no idea how to do this.

And I remember taking the thing over to Emergency Care Research Institute. So they put a proposal in for \$150,000. They were going to write a performance and safety standard for apnea monitors, and I was so skeptical.

I took the proposal over to National Institute of Standards & Technology (NIST), and I've forgotten the guy's name, but he was in charge of the electronics stuff over at NIST. And Oscar Peterson -- that's his name -- Oscar Peterson. He had a national, if not international, reputation of being a heavy hitter in electronics. And he was heading up, I think, the Instrumentation Division efforts over at NIST.

And I asked him, would, in his opinion, take a look at this. And he says, "Is it your opinion that we can even write a standard for a device like this?" And I left it with him and I didn't hear anything and I didn't hear anything, and weeks went by.

And finally I called him up and I said, "Oscar, are you gonna . . ."

He said, “Well, I’m working up an estimate of what I’m going to charge you to answer that question.”

And I thought like, okay, we had a cooperative thing there, interagency agreement, so I figured, what’s it going to cost, \$5000, because that would be the high side. Right? He comes back with an estimate of what it’ll, to answer that question, a quarter of a million dollars.

And I go like, huh, and I pick up the phone and I say, “Oscar, can we meet face-to-face and discuss this?”

“Oh, sure.”

So I drive over to NIST, go to his office, we’re alone. I say, “Oscar, I don’t know if you’re aware, we had budgeted \$150,000 to do the thing. I wanted to find out, are we wasting our money? So that’s why I posed the question. Is it doable? And you want to charge me another \$100,000 just to answer the question, is it doable. Why do you think I would give you a quarter of a million dollars so I could possibly say we’re wasting \$150,000? So, what’s going on? This doesn’t make any sense. I just want your professional judgment.”

“Oh, I can give you that. I thought you wanted something that we could document, that you could take up the line and say, ‘I can defend this. I’ve got this report from NIST.’ Well, let me tell you right now, it’ll cost you nothing: It can’t be done.”

So, “Thank you.” I said, “Thank you. Meeting’s closed.”

So I come back. Months go by, maybe a year goes by, and I see it’s on the list, and I told Haffner the story. I said, “This can’t be done. This is stupid.”

She arranged, she had a one-on-one, her one-on-one every two weeks, I think, her weekly with Villforth, drags me along. She thinks she's going to make some Brownie points, my new hero here. And she says, "Tell John what you told me about apnea monitors. Explain to him." And he's looking there and he's listening to me.

"You know, I don't doubt a minute the truth of what you're saying. But where were you a week ago when we circulated this list? This has already been kicked up to the Commissioner, and it's about to go in the *Federal Register*. You're a week too late."

And I go, "Political reasons."

And I remember to this day -- I think Benson was there -- and he goes, "You know, maybe this is good because this will prove to Congress," because he was trying to make the case. He didn't want to spend a major amount of effort on regulatory standards. Why? Because they had done that on the VRH (?), you know, introduced a number of regulatory standards. The money then went to the field to enforce the standards, so he shot himself in the foot. He created this vehicle for the field to get a bigger share of the budget. The budget was effectively fixed. You can adjust it up a little bit, but here's the pie, and now they're going to get a bigger slice and we're going to get less slice. So he had that experience in the back of his head. He said, "Enforcing regulatory standards. Who do you think is going to get all the resources? The field."

So he goes, "This is probably good. This is going to work out. This will fail, and that's a good thing."

And I remember thinking, "God, okay. What a lesson in politics."

But I realized that, at my level, the things I deal with, my little sphere, my minor little sphere . . .

SJ: And you go back and go, “Whew.”

PBC: Very glad I don’t have his job.

RJC: Because, I mean, if they project it on how many standards you needed and what they were going to cost, oh, millions of dollars, so we never would have gotten there.

PBC: Right. We would have been . . .

And then, you know, the biggest cost was not to produce the first version of it, it was, every five years you had to update it. Well, as the number keeps growing, more and more, as you need more and more in the budget to just maintain the stuff to get out there. And we, Dave Segerson and I had done the calculation and the analysis on the assumption that it costs us \$135,000 to produce a standard, and it’ll cost us, oh, I don’t know, \$35,000 for an update, and then we just worked the numbers. And it got clear, we were approaching what looked like the Defense Department’s budget. We were going to have the biggest piece of the federal budget just maintaining these standards. So, I mean, it made it very obvious that it was just not practical.

SJ: And this was before paperwork reduction, OMB.

PBC: I think it was good that it worked out that way, because they would have, you know, we would . . . Once you get something on the books in regulation, it’s very

difficult to get in there and change it. You have a vested interest. You have a company now that complies with the standard, and now you realize you went too far and you want to relax it. That company is going to be fining you because they don't want you to relax it. They can meet this tougher, unnecessarily tough requirement.

SJ: They want to keep their competitors from meeting it.

PBC: Right.

So, you have created this monster that would have slowed progress down. Whereas the voluntary standards, they're flexible. It's easy to change them. And most of the companies, they're not ignoring those things. They can't afford to ignore them from a liability standpoint. Plus, you know, they want to be on the cutting edge, they want to be competitive, and they want to be able to say, "I'm complying with that voluntary standard, the ANSI standard, and my competitor doesn't. I do."

SJ: And my experience has been, the people in the company, they can use that as a lot of leverage for the work they're doing; at the lower levels, they can use the leverage at higher levels.

PBC: To do the job right.

SJ: Yes.

PBC: You know, get the bosses to give them a budget to do the job right.

I remember Sidney Wolfe.

SJ: Oh no.

PBC: Sidney Wolfe had gone down and heard -- I heard about this -- that he had gone down and testified to Congress that these voluntary standards were dominated by industry, and they were just crap. They were just using it to avoid responsibility.

And I was so upset with that that it turns out, my dentist that I had was good friends with Sidney Wolfe, and I had known this dentist for, at that point, like 15 years previous, a pretty good friend. My whole family went to him. And I remember talking to him and commiserating with him.

He says, "Hey, if you want, I could arrange to -- you know, Sidney Wolfe's a good friend of mine. If you want to go down and talk to him and tell him how it really is, I could make that . . ."

I said, "Could you?"

Well, I never told my superiors. I go down and visit Sidney Wolfe at his office downtown, and he listens to me, going, "Uh-huh, uh-huh," and I think I'm making progress.

But I felt a little suspicious when he said, "Well, listen, Pete. If you ever get any documents, just send them to me," you know, "blind copy, don't put your name on it, any internal documents that I can use to keep FDA's feet to the fire."

And then I find out, it was shortly after that, I hear he made some public speech where he also was railing against these voluntary standards being dominated by industry, so I made exactly no progress with him. Okay?

And, in fact, I told him, “From my experience, Sidney, if anything, if anybody’s dominating the Standards Committee, it’s the physicians, and not for the public’s interest, let me tell you. But the manufacturers, I said, they’re trying to do a decent job, with my experience. They’re really doing the journeyman’s work there. The physicians are the ones that are screwing it up. They’re asking for requirements, unnecessary requirements they don’t need. For example, I’ll give you an example: the anesthesia gas machine. The accuracy of the anesthesia flow meters”

And what they are is a little ball in this tapered tube, so as you increase the flow, the ball rises and then stabilizes because there’s a bigger opening around it. Okay? So a good plus-or-minus 10 percent of what the actual flow is, plenty accurate for what, the way an anesthesiologist uses a gas machine. They really sort of use the machine to sort of get them in ballpark, and then they titrate on the patient. They’re looking for a patient’s reaction and adjusting it accordingly. Ten percent is fine. Meantime, these manufacturers are demanding plus-or-minus 3 percent.

RJC: The physicians are demanding.

PBC: I’m sorry, the physicians demand it, but they don’t know what they’re talking about.

By the way, they're the ones who told me this is how they operate the machine, but they can't put two and two together. Well, what do you need this accuracy for?

So I would challenge. I said, "Well, why are you doing this? Why are you demanding that? It's unnecessary."

"Well, Peter, they can do it."

I said, "But you're paying for it. You're paying a price. And what about that manufacturer out there who can produce a superior flow meter that's cheaper to produce, more reliable, less maintenance, that can meet your requirements, but it can't meet plus-or-minus 3 percent, but it can meet the 10 percent that you really need?"

He goes, "You know, we never thought about it that way."

And these guys, these were professors. These guys were department heads. They'd worked, you know, the guys who wrote the book. And I'm going like, they just don't think like an engineer.

RJC: But that's pretty common that a physician is trying to push the standards to a tighter level.

PBC: Better than they need, though, Bob. And it's like, there's no free lunch.

RJC: No.

Well, we've given you some material.

SJ: I'm trying to think if I have any more questions.

RJC: Well, you can always ring back.

END OF INTERVIEW