

Oral History with Tom Umbel, June 9, 2020
Interview by Benjamin Spohn for Hagley Museum and Library
Hologic oral histories project

Q: We are about to be recording on Zoom. There we go. So today is June 9th. I'm sitting down with Tom Umbel. We're talking about the oral history of the medical business and the Direct Radiography Company. Or would it be Corporation, not Company?

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A: Well, it was a variety of things over the years. But yeah. I think Corporation was the formal name.

Q: Okay. So to start us off, can you just give us a quick, brief overview of your career, some of the highlights, maybe a little bit of your professional background?

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A: Sure. I'm a chemical engineer by degree. So DuPont was a good fit for me when I came out of college. I was one of the lucky ones who kind of hit the timing right when I graduated in [19]'76. The world was in desperate need of engineers. And so I had more job offers than I knew what to do with, even though I was just a slightly above-average student at best.

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So DuPont was where I ended up. I ended up in textual fibers, oddly enough, in the Orlon plant down in Camden, South Carolina, and went through a variety of position with DuPont, both in textile fibers, and then when they acquired Berg Electronics, which was Quentin Berg's privately held company up in the Harrisburg area, then transferred up there. Worked for them for about seven years, I guess, in manufacturing, engineering, capacity planning, business analysis kind of positions.

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Then I ended up down in Corporate Market Research in Wilmington. That's when I meet Jim Culley. Jim was the [Associate] Dean of the Business School at University of Delaware at the time. And we convinced him to join us in the Corporate Market Research Group. And then, then from there, I went into the medical x-ray film business. And that was my first venture into med., back in gosh, 1981, I guess it was. And I was in the medical x-ray film business for about 16 years. And then, went into staff positions at the med. business level. And that was what I was talking about before, when I was the strategic planning manager in the medical products businesses, and manager of national and corporate accounts across the medical products businesses back then.

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Agfa bought the—I guess it was before Agfa bought it. It was Sterling came in, a private equity firm, and bought medical x-ray film business, and moved the headquarters down to Greenville, South Carolina. I was a single father at the time with two kids in school. And didn't want to follow suit with that. So I was fortunate, and they gave me the job to create integrated radiography systems using the new digital x-ray detector that they were developing in the direct radiography piece of the Sterling diagnostic imaging piece. So I got to stay in Glasgow [Delaware] as a result of that.

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They came in later, as the Sterling management team kind of felt they were going in the wrong direction, and felt the things that I had been kind of speaking out loudly about, was more the right direction to take the company. And that was to stopping a digital detector company and to be an integrated system provider. And so I then became the VP/general manager of the Direct Radiography Business Unit. Then Agfa came in and bought Sterling, the private equity entity, Sterling Diagnostic Imaging. They didn't want the Direct Radiography piece. So we were thrown out on our own to go find funding, and find a home, to try to sell the company.

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And, about six months later, we were fortunate enough to convince Hologic up in Boston to buy it. I then went on to Hologic and integrated Direct Radiography into that company. As we came to the market with the first mammography integrated system, incorporating that digital technology, they asked me to take over and restructure the sales org in Hologic in general, across the board. So I became the Senior VP of Sales up there. Got that job done. And they decided to start to grow the company.

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There was a group of us that kind of got together and decided the best way to do that was to acquire companies. And, since I was the only one in the company that had ever been acquired, they felt I was the one to do that. So I became the Senior VP of Business Development. And, for the next 15 years, that's what I did up there, from—I guess it was 13 years, in 2001, until 2014, when I left Hologic. So I did all the M&A activity that grew Hologic from an \$80 million dollar company to a \$2.4 billion dollar company, including still managing the marketing for the company as a sideline for me in that process.

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Then the new CEO came in, in 2014, and fired all of us. So the whole senior management team went out on our ear at that point in time. I then became the Chief Operating Officer of a molecular diagnostics company out in Santa Clara, California. And we did not manage to get the funding that we needed to take it into the next level. So I then became the head of business development for an orthobiologics company in North Carolina called Bioventus, and did that for not quite a year, when I got offered the CEO job down here in San Antonio, back in—let's see, 2016, I guess then, January of 2016. So I've been down here since then, running Seno Medical now.

Q: So you started off as an engineer, and eventually became sort of a business guy? Or were you always working on some sort of engineering project, too?

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A: You know, it's funny that you bring that up, because in college, I think toward the end of my junior year, I started to realize I was less technically oriented than a lot of the other engineers around me, who were bits and bites and all the things that the techies like to talk about. And then I was having a lot more fun doing the business things. And so my senior year, all my electives were in business. And I found that I really enjoyed that side of things. So when I got out of school and was primarily in manufacturing engineering, my desire was to get out of that.

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And I can remember still, when I was the plating technology supervisor at Berg Electronics, in charge of the development of electroplating of electronic terminals, that my boss was talking to me. And he was going through the annual performance review. And he said, "What do you want to do next?" And I said, "To be honest with you, I want to get out of here." And he said, "What are you talking about? You've got this great career in engineering. You're going to be able to do all these things." I said, "What's the craziest thing that I could ask you, that I wanted to do next?" He says, "I don't know." He says, "You're going to be an engineering manager and stuff like that." And I said, "No. I don't think so." I said, "What's the craziest thing I could ask for?" And he says, "Be a business analyst. I don't know. Why are you asking that?" I said, "That's what I want to be. I want to be a business analyst. I want to go as far away from where everybody wanted me to go, and I want to get on the business side."

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So, believe it or not, I got assigned to being a business analyst 60 days later. And from then on in, I was in business in all the business elements of it. And it was kind of interesting, because from that business analysis group that I was in at Berg Electronics, I learned all the business from all the different angles, and all the analytical things. I didn't know a booking from a billing when I got in there. And my job was to computerize business analysis. That was before all the desktop computers came out. And I literally went in there with a process control computer, and computerized everything they were doing, and interfaced it to the mainframes and created the first desktop kind of technology at Berg Electronics at that point in time. And it was just fascinating to me. And so primarily was in the business side of things, from that point on.

Q: So you talked about bits and bites. And I guess in general, things going digital. And that seems to have been a really big theme with your involvement with the imaging business.

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A: Yeah, it sure was. Imaging, you know, it was really interesting. Because when you watched the amateur side go first, from the film-based technology to the digital cameras and things of that nature, x-ray had a few barriers that the optical information that was being captured digitally didn't have to go after. So there were some hurdles, so it lagged the amateur film business going digital. And everything went digital through a variety of different ways. There were kind of semi-automated technologies. There was one called PSL, photo stimulated luminescence, that came out of Fuji, where they converted the x-ray beam to light first, and then exposed film with that light, just like they did with a screen.

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And, at the same time, then they had a digital detector that captured that light as well. So it exposed both a sheet of film, and a captured digitally in a digital format. They then got rid of the film and just went to the digital format with that. And general radiography was kind of the place that would first using that kind of technology. So the digital detector technologies, there was three of them that were coming out, I guess, at the same time. Ours was ideally suited for mammography. And that's why Hologic went after us, because they wanted to get into the mammography side of the world.

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And the other ones were more suitable for general radiography purposes. So it kind of got split that way, from that point on. But initially, we were targeting general radiography. I used to joke that it was so foreign for DuPont to have that in their development, in that we used to joke that, if it didn't go in a boxcar or a tank car, they didn't know what to do with it. And that was kind of the idea that came along with this. You know, there was great research people at DuPont. And we had two of them in particular at Direct Radiography that were phenomenal.

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And I think Jim [Culley] was trying to get one of them to talk to you, Lothar Jeromin, or Denny Lee, were just brilliant scientists, that really knew how to take this technology that came out of Xerox, and really brought information and understanding around digital imaging, that transformed what we were doing there.

Q: So it seems like the—oh, I don't know how to put it—the importance, or maybe a different way to put it, the potential impact of doing digital imaging wasn't immediately understood.

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A: No, I think that's fair. There was a variety of things that they were doing. I know within the research facility, for instance, they were working on what later got to be known as CAD, computer-aided diagnosis. But it was Neural Networks that were trying to simulate what the radiologist did, to be able to look at an image and find a malignancy in the image, due to the anatomical characteristics that are present in a malignancy.

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And so they had a variety of things that were kind of playing in that area. The digital radiography one was one of those. And it was just a ton???. And it sounds funny now, you know, when you're talking. But the TFT, the thin film transistor technology that you and I are looking at right now on our laptop computers here, that was the biggest sheet of glass you could get, was about the size of my pad, iPad that I'm looking at right now, you know. So we had to tile it. We had to take four of those sheets of glass, grind the edges of them, match them up ideally, and not damage any of the electronics that were right adjacent to it, and put it together in one big sheet of glass, at that point in time, to be able to make a 14" x 17" digital detector that is equivalent of a 14" x 17" sheet of film that was used for chest imaging. And so just knowing some little things like that, that we had to overcome, in terms of creating that technology. And the guys like Denny Lee and Lothar were just hugely instrumental in that.

Q: So you guys had to do a lot of custom machining, it sounds like.

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A: Oh yeah, yeah. We may have had the only devices in the world, that we did that tiling equipment on, to polish those edges, and under very, very high magnification scopes, maneuver the four sheets of glass together, to create that uniform set of electronics that captured the image then. Particularly right at that point where all four sheets met together, you can imagine the complexity of that, in trying to keep that perfectly aligned. The pixels were 80 microns, about the thickness of your hair. And so we were working in dimensions that were less than that 80 microns, because that was the edge of the glass that we had to avoid the electronics on one side, and then on the other side, so that those two lines of electronics were 80 microns apart when we were done at those seams. And so that was just incredible technology.

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In fact, when we lost our TFT [thin film transistor] supplier in the US, and I can't recall the name of it now [JC- Optical Imaging Systems – a division of Guardian Industries], but it was a company that went under in the Detroit area while we were in our development process.¹ I convinced LG [JC – Lucky-Goldstar at the time. Later shortened to LG Corp.], in Korea, to begin to develop our TFT technology for us, in return for showing them how to polish and make larger sheets of glass before they were able to make ones that become all the thin film transistor TV monitors now that we have today. And so that was our bargain. I showed them how to do that, if they would begin to manufacture our glass, so that we were left high and dry.

Q: Wow. All of that sounds like it made for a very high-pressure work environment.

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¹ Here are links to two articles on OIS ... one in their involvement in making liquid crystal displays for the military and one on their shut down and its impact on Hologic.

<https://www.militaryaerospace.com/home/article/16707602/ois-throws-in-the-towel>

<https://www.diagnosticimaging.com/view/digital-radiography-resolves-supplier-and-backlog-problems>

A: That's an understatement, yeah. I mean the toughest part was when we got the word that Agfa bought Sterling Diagnostic Imaging, but didn't want our piece. So I was on my way to the RSNA [Radiology Society of North America Annual Meeting] in the fall of 1998, November. And got the phone call from the CEO of our business unit, and let me know that, you know, they were going to give me – I forget if it was 30 or 60 days to find alternative funding, to keep the company alive. And that they would help me with an I banker from Bear Stearns that they assigned to me.

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And so we left the RSNA that year, and headed back to the office, not knowing whether we were going to be alive in 60 days or not. And we were trying to do all this development stuff at the same time. And we were really pleasantly surprised by the number of companies that came to kick the tires. Ultimately, in the end, Hologic was the buyer. And we didn't know much about Hologic going over there. It was just, I didn't know anything about bone densitometry. And that was the single product that they had in being less than \$100 million in revenue, they weren't exactly so big that everybody knew them.

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The other players that were looking at us were Kodak and GE and Phillips and Picker at the time. But none of them ultimately made an offer. Hologic was the only one that made the offer. They had hired a consultant to interface with us by the name of Jack Cumming. And Jack and I became close friends during the whole process of the sale of the company. And ultimately, I think the deal that we ended up with, and Jack had to go through a lot of players because DuPont had their toe in the pie still, and a variety of other players, in terms of who actually owned the assets of Direct Radiography.

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And he and I kind of had some conversations late at night, a couple of them in person, and a couple of them on the phone, that I think ultimately ended up with the terms that were accepted. And ultimately, then Jack, through a variety of things that happened later, Dave Ellenbogen, the

CEO died shortly after they acquired Direct Radiography. And Jack became the CEO of Hologic then, then became my boss up there.

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And so that relationship carried on, still carries on to this day. Jack and I stay in touch. Jack's long since retired, and lives on his ranch out in Colorado now. But we email and text and stay in touch to this day. And it all started back in 1999, when they acquired us.

Q: Do you know why Agfa wasn't interested? Do you know why Agfa wasn't interested in buying your part of the company?

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A: Yeah. It's funny, because I, you know, remain close with the people at Agfa over the years. And they would just die to think that they made that decision. But fundamentally, just like that technology that I talked about, that Fuji developed, Agfa was the second one to develop that technology. And they felt that the Direct Radiography technology conflicted with that. And that that was their area of expertise, and they wanted to stay with that, and to not do anything more. It was absolutely unbelievable, you know, to us, from the Hologic side. But it was a blessing, in that I think Hologic ended up being the ideal partner with the right people, you know.

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Once we got to Hologic, there was four or five of us that kind of drove this whole idea that being a growth engine company, and that they were going to build the company on the Direct Radiography platform. And then raise revenue internally, on our own, by doing that. And so when we launched Direct Radiography in the digital mammography arena, that just took off. And all the money that we made from that, we just funded all our acquisitions from that point on, and create the Women's Health Company that is Hologic today.

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And we just—It was just like a dream. I mean it was, to have four or five of us that would sit in a room, and make a decision, none of us fought. None of us would climb over anybody's back. Each of us had our role and what needed to be done. And there was so much work that needed to be done, we didn't worry about your next job. Just get this one done right. And we just had a blast.

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And it got so big, that it started to feel like DuPont again, with all the process and everything in it, at that point in time. It kind of lost that entrepreneurial thing. And I always tell everybody, it was my own damn fault, because we added too many companies and grew so big within Hologic. But from '99 until probably 2010, that was just a dream job.

Q: Wow. So how did the work environment at Hologic compare to some of the other places that you'd worked at?

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A: Yeah. There was somebody I worked with at DuPont that had an expression - forgive me, I'm going to butcher it. But he said, "You know, at DuPont, we have meetings to decide the possibility of the eventuality of the risks that are taken to consider who's going to be in the next meeting." [laughter] And it was very, very process-driven. And we have a company the size of DuPont, you know, there's a lot of rules. I can still remember my first job as a manufacturing supervisor at DuPont. It was a rotating shift job, God-awful job, where you worked daylight for seven days, had two days off, worked afternoons seven days, had two days off, worked graveyard seven days, and had five days off.

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And, when you came into the office, they had a Rolodex. And you would go to Monday, and you would look at Monday, and it would have all the different cards in there of things that you had to get done on Monday during your shift, in order to get, you know, the production out, and keep harmony in the ranks, and be safe, and all those things, you know. And when we sat down at

Hologic, there was none of that I mean it was, what's working? What's not? How are we going to fix it? Let's get it done.

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And I can remember when I lost the supplier for the TFTs, we were at Hologic at the time when that happened And I went into the CEO of the company, and the CFO was there. And I told him what I wanted to do. I want to go over to LG in Korea, and I wanted to negotiate with them. They had a research line that I thought they'd be willing to build a very low volume of detectors on it for us. And they said, "Well, what do you need from us?" And I said, "I think I'm going to need some NRE expenses to give them some money upfront, to do the development in support of us." And they said, "How much do you need?" And I said, "Probably about \$100,000 dollars." The CFO walked out of the room, went next door, wrote a \$100,000 dollar check out, came back, and handed it to me. He says, "Just fill in the company name or the entity when you get over there."

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And that was the difference. [laughter] And that would have taken me six months to have gotten that check at DuPont. And it happened in six minutes at Hologic. And we maintained that kind of work environment, even until we were—we were probably a billion-dollar company, and we're still run that way, with four or five of us, just sitting down in a room, and deciding what were we going to do next. And just uniquely talented, uniquely fit group of people. And it was fun.

Q: Sounds it. What do you think—Why do you think that company seemed to have lended itself to that management so well? Is it because it was small, because it was newer? Or something else entirely?

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A: I think being small and desiring to get bigger, the desire to become a bigger entity and being successful was just common to everybody that was there in that senior management team. But that alone, I don't think, would have done it. I think the unique personalities that were running

that company were really something. And I can remember later, when the Board mandated that three of us be a part of the sales effort going on with the digital mammography systems, where we were in the market, because they knew that our success rate went way up when the three of us were involved.

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So the CEO, Jack Cumming, the COO, Rob Cascella, and myself, were mandated by the Board to spend 15 to 20 percent of our time in the field, in support of the salespeople around the country selling these units. And so Jack and Rob and I just literally had a competition. We were betting on every single thing that happened, anywhere, anytime, as to who could outsell the other. Who was going to get more this quarter? Or what was going to happen, you know. What reps were calling us versus—I understand Umbel is batting a thousand. So I'm going to call him rather than Rob or Jack, you know. Or vice-versa, you know, in terms of the things that were going on. And we just had a blast doing it. It became successful, obviously. And that kind of continued to foster that kind of entrepreneurial attitude on it. But the three of us had carte blanche, you know. We went out there, we could negotiate anything on the spot that made sense, and we did. And it just worked tremendously well.

Q: So it sounded like you guys were tremendously driven.

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A: Yeah, yeah, no question about it.

Q: So if I could ask you a follow-up question about your changing TFT manufacturers, why LG in particular?

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A: We knew of about four or five different companies at the time. There was two in Taipei, and don't ask me to remember the names. They were names I could barely pronounce even then. One in Mainland China, and then LG in Korea. And when we went to visit each of the four, and I did

it with—I think actually, Denny Lee and Lothar went to one of them. And the first meeting at LG was with Bill Carew, who was the head of operations. And they came back and said LG had this research line that they thought might work. So when they're developing TFTs or manufacturing TFTs, they were running about, I don't know, 10,000 to a million times more in a year than we would ever consume. So we were truly a drop in the bucket to them.

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And so, to interrupt their main TFT lines was impossible. And this was the beginning of the laptop work at about that point in time. And that's where all the TFT technology was focused. We were very fortunate, because our particular electronics were similar to what was being done on the laptops. But, instead of energy being applied, and light coming out, we went the other way, you know, with x-ray energy going in and current coming out the backside. We ran it backwards. But the same basic layers. We had more layers and more complex electronics in those TFTs, but the same way.

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Whereas, everybody else, in all the other technologies in the digital market, had to build their own foundries to do this. So we were pretty lucky to do that. And every time they made improvements for the laptop market, we got the benefit of that. So we were really kind of riding their wave. But it really boiled down to that research line, that when we got together and made that decision and started the negotiation, LG was willing to [run] our whole year demand, on a research line, took about a week for them to run all the TFTs we needed, hundreds of TFTs, to be able to meet our needs in the early days. So yeah, we were very fortunate that they bought onto that and followed suit with that. And they were very supportive in those early days.

Q: Sounds it. Forgive me for asking a little bit of an off-the-wall question about technology. I just kind of got my own wheels turning when you talked about doing the trade with LG, about the manufacturing with the different glass plates, and putting them together to make one screen. And we're starting to see, right now, some of the very earliest consumer releases of cell phones

that have folding screens. Do you know if that technology is in any way related to the technique that you showed them all those years ago?

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A: I doubt it. But it is—What they've got to do is to be able to get those electronics, so that in the x-ray detector—and I think it's true in the cell phone screens, and I haven't seen it, but you have an active area that, in the case of the display, is there. And then, on the periphery of that, in the x-ray world, we had all of our electronic connections that we initially wire bonded, but later wave bonded, along the diameter of the screen. And so all of the communication in and out of that screen was from the edges through those lines of current that were photo-deposited into the layers of the TFT.

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So I think with the tiling, what we had to do was figure out how could we do that without being on all four sides, that we could run current from just two sides of a quarter of that, and be able to manage that as well? So I suspect that might be some of the pieces of it. Because obviously, if you're folding it, you can't have any electronic connections on that seam side of the screen. So that they may have done some of the electronic stuff, but I doubt it was the tiling stuff that we had to do back then.

Q: So yet another follow-up question, semi-related to the change in TFT manufacturer. When you had said that there were only four other companies that provided what you were looking for, if you needed to switch up supplier, that seems like you had very, very few choices. Is that the normal, if you have to switch up anything like that?

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A: No. when you're in that development phase, it's not uncommon to have sole source suppliers on key elements. So you just have to be incredibly diligent in choosing those manufacturers and so forth. As to why my predecessors chose the TFT supplier that was in Detroit, I really couldn't

be certain as to what drove their choice, other than it was in the US. They were the only TFT manufacturer in the US at that point in time. And unfortunately, went under.

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And for Seno Medical, for me right now, we have two key elements of our product right now that are sole source supplied. As soon as we get approval from the FDA for this next generation product that we're building right now, the second generation, we will begin to look for alternative suppliers, to fill those needs. But to get these people to work with you in the development phase, you have to make commitments to them, too, to stay with them for a period of time. So they kind of feel like they got a return for the gamble that they took on us, you know, to work with us, and do those things.

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You also have to, you know, kind of pay in advance with these people very often. So with our one ultrasound supplier, we were absolutely paying upfront for the time and effort that they're putting into provide us with the unique ultrasound capability

Q: It sounds to me like that that could lead to having some really, really intense business-to-business, and like interpersonal relationships with whoever your counterpart is that you're dealing with in a sole provider situation.

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A: Yeah, there's no question about that. With LG, they had a specific scientist over there that was incredibly interested in what we were doing. He ultimately left LG and created his own digital detector company. [laughter] You know, there was some debate whether we educated him, you know, and that he could copy what we were doing. But ultimately, I don't think that was the case. Unlike the Chinese situation that everybody worries about these days. But Dr. Young [?] you know, started his own company. And I think it got to be successful. I don't know what happened to it in that space, because it's been a while since I've been involved over there.

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But he was the real driver on that side, that really helped us there. And today, in Seno Medical, the company that we chose to supply us our ultrasound equipment, I've known them for 20 years. So I had that relationship going in. With LG, we didn't have that advantage. We had to develop those relationships during the negotiation. And fortunately, Dr. Young really was very, very interested in what we were doing. And therefore, you know, helped us through those early days to get us the product we needed, and the improvements that we asked for, before the numbers started kicking in. I mean we were still using LG when I left. I don't know if that's still the case today or not.

Q: So since you were working on this new technology at a time during the transition from film to digital, was there ever any sort of like “aha” moment, where you really might have come to realize, “Oh, whoa. Like this stuff that we're working on IS the way of the future”? Or not so much?

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A: Yeah. So one of the things we had our technology, I think I briefly mentioned it earlier, was ideally suited to mammography. And the fit was because, unlike general radiography, where you have very significant density differences between flesh and bone, for instance, or between air in the esophagus or that might be trapped in a colon, and the tissue that's around it, it really enables visualization of what you're looking for, pretty easily.

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In a breast, the difference between a duct, a lesion, a malignancy, a benign fibroadenoma, and normal tissue, is just incredibly subtle. So you're working at very, very low energy levels. And our technology, the selenium technology that we had, was just ideally suited to work in that range of energy. And so once we discovered that, and realized that we could really work in the digital realm with algorithms, display algorithms that helped sharpen the image, helped detect those subtle differences in tissue densities better than x-ray film, I think that was the time where we really said, “Man, we might have something here. This is really good.”

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And it was amazing marketing being done against us. You do not want to be—I described to the *Wall Street Journal*, when they interviewed me back then, we were the mouse dancing between the feet of elephants. GE Imaging was a \$10 billion-dollar business unit within GE. And we were a \$100 million-dollar company in medical imaging, and just breaking into that space. They had a marketing engine that could roll over us, and not even know they hit us. And they would turn those marketing engines loose as to why our technology was going to fail, and all the things that were going on.

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But fortunately, radiologists are people of evidence-based medicine. And so they trusted their eyes more than what everybody was telling them. And ultimately, we got that chance to demonstrate to them that we could do that. We acquired Lorad, another breast imaging company, that had the film-based equipment. It was actually part of Trex Medical. And it was the only division that we ultimately kept in the four divisions of Trex Medical. And to have the rest of the mammography equipment that was needed, and then integrated our detector into that, and I forget what the revenue was at that time, but it was \$20 or \$30 million dollar's worth of revenue, I think, in the film-based side of the equipment.

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And just the equipment side, today, of Hologic, has got to be close to a billion dollars of mammography equipment that they sell each year now. That's as a result of building into that. We went from virtually zero percent of the digital business when we first came into the market, and Hologic has about a 70 percent market share worldwide now in the mammography world. They are breast imaging to the world these days. And it was because of that ideally suited technology that we had as a foothold to start with, and then a lot of other smart things that we did along the way.

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And one big lucky thing, we were the only detector that made a big enough detector that they didn't have to do multiple images on a woman to cover a large breasted woman. We could do it all on a single detector. And that was just dumb luck on our part there.

Q: So what was it like convincing folks to go digital?

[00:43:10]

A: The x-ray world had gone digital everywhere except digital mammography. They just couldn't find a digital imaging technology that would get them there, with the quality that that demands. It's a very high-quality imaging area within the x-ray business. So the world just wanted to get rid of film completely, get everything still with digital. They called them PAC systems in radiology, picture archival and communications systems, PACS.

[00:43:45]

And so they were looking at all their imaging on monitors at that point in time, with these cockpits that radiologists would have, with four or five monitors around them, one with a patient information on it from the radiology information management systems, and then the others with imaging. So they could look at priors, and different angles of imaging, and so forth, all at the same time on the monitors.

[00:44:16]

And they grew very accustomed to that, and didn't want to have to get up from that cockpit they had, and go over to a normal light box, and look at mammography images when those came in. So there was a real driving force to get digital mammography to come in. but it wasn't going to happen until we were able to demonstrate that we could do it as well, or better, than x-ray film. And so we were convincing a lot of people that digital did better than x-ray. But there was a lot of resistance, still.

[00:44:54]

And then radiology had their own study that they did, it was called the ACRIN [American College of Radiology Imaging Network] Study, ACRIN, that they did comparing digital to film-based mammography. And in one key area, women over 50, with normal tissue, we outperformed film. In all other areas we were equivalent. But that one key area, we outperformed film, and you couldn't stop the transition at that point in time. It just took off. And so we went from selling 100, 150 systems a year, to selling seven, eight, 900 systems a year, as a result of that.

Q: Can you tell me about some of the biggest challenges that you have had to face throughout your career?

[00:45:52]

A: Oh boy. Inevitably, the hardest one, for me, is when you reach crunch points, where funding is not sufficient. And you end up doing some downsizing going on. That's the toughest thing in the whole world for me to do. But I've had to do it, you know, six, seven, eight, times, probably, in my career, with different companies. And it's always the single toughest thing. The other thing that is frequently difficult, when you're in these companies where you're developing something, you seek the smartest people you can find to be on your staff. The guy who runs the company is only as smart as the people that work for him.

[00:46:49]

And I tell everybody that my strength is, I know a little bit about everything, and not much about anything. You can take your finger and poke it through my depth of knowledge, in just about any area that you want to go after. But I know how to pull it together, and pull all the pieces and parts. Because I've been in engineering, I've been in manufacturing, I've been in marketing, I've been in sales, I've been in business planning, I've been in financial areas.

[00:47:16]

And so I understand and can be empathetic to the situations that are there. And I also understand what they need to do, to work together in what's happening. And so I think the biggest challenge

is taking those very smart people, who inevitably are going to be toe-to-toe, nose-to-nose, screaming at each other, somewhere along the line telling each other that they're stupid, you know. To get them to sit down long enough and hear out the whole thing, and find either the compromise, or the common thread that's between what they're looking at, and get them all going in the same direction.

[00:47:52]

And so at Seno Medical, when I've got 60-some people standing there looking at me, not knowing which way we're going to go, I think that's the biggest thing, is how do you get them all facing in the same direction? They're going a million miles an hour, as fast as they can, in that direction.

Q: Are there any other moments in your career that stand out as being particularly noteworthy?

[00:48:35]

A: I think probably the other area that, you know, when we first got to Hologic, the Board of Directors there were—I call them friends and family. I don't think any were actually related to anybody there. But they were all friends of Jay Stein's and Dave Ellenbogen's, that they had known forever. So it was a simple Board. And you just kind of went in and said, “Here's what we're going to do,” and everybody kind of nod and said, “Sounds good,” and we went on the way.

[00:49:11]

As we became a bigger company, though, and sought out professional Board people to be on there, and people who came in who were just as smart as we were, if you will, in terms of what's going on, the challenges that that brought, you know. So when I would—We bought Cytoc in, gosh, somewhere around 2004-2007, something like that. I forget. 2007, I think it was. And we went to the Board and asked for \$6 billion dollars to buy them. And it was C-Y-T-Y-C if you're looking it up there.

[00:50:04]

And that was a whole new era for me, to go in and start to deal with boards, with that kind of leverage and so forth that had to be sought out. You know, we had to go out and borrow money to be able to make that deal. Cytac was actually slightly bigger than we were. And so that was a real challenge to learn to deal with a Board in that kind of situation. And I think once I got past that, that became a part of my norm, from that point on, in dealing with Boards, both at Hologic, and then with my own company since then.

Q: Do you know why Hologic made the decision to pivot from being a bone density company to a women's health company?

[00:51:08]

A: Initially, with Jack Cumming, the consultant that they hired, who ultimately became the CEO there, what he was challenged with, was to go out and find a growth engine, find us something that is growing fast. Bone densitometry had this phase that it went through, that was just growing incredibly well. And Hologic was one of two companies—and I can't remember the name of the other company out of Madison, Wisconsin—Lunar, that GE ultimately bought.

[00:51:39]

And so they had this great growth phase. And then all of a sudden, it just dried up. It just became a very plateaued company. In fact, it fell back. I think they peaked out at revenue like at \$130 million, and then fell back to like \$90 million by the time I had gotten there. And so his charge was to go find a technology like bone densitometry had been, and just let's add it to the company. They had had one or two smaller things that they had bought prior to that, that they kind of thought they had that technology. But they never panned out. One was a mini C arm that's used in orthopedics, and they still sell that product. And I forget one of the other ones.

[00:52:28]

But so Direct Radiography really looked like that one that they thought could be something. And they got, you know, acquired us at a pretty reasonable price, I think. And so I think they were

pretty happy with that. Jack will tell you that, you know, I just brought the company to their knees, though, in integrating it into Hologic, and fixing all the things that were still wrong with the product, before we finally got it right. Because boy, it was a lot more money they had to put into the company than I think they felt they were going to have to at the time they acquired us. But a funny thing was, Kodak came back twice, after they decided not to buy us, and tried to buy us from Hologic. [laughter] That was—We called it Groundhog Day. It's back again. [laughter]

Q: Do you know why they had a change of heart?

[00:53:30]

A: I'm not real sure. I can recall the VP/GM of their Medical Imaging Group, I'm trying to remember his name now, he became the CEO of the spinout that was of the Kodak Medical Imaging business of the new company. I can't remember the name right now. But Ken Hitchner [?] something like that. I think he wanted to make the deal, and couldn't get the corporate Kodak people. You know, they were so focused on losing the amateur film market, that they couldn't see the forest for the trees, I guess, is the way he kind of implied.

[00:54:22]

So once somebody must have changed, or the attitudes changed up there, they came back twice and tried to buy, first, Direct Radiography back from Hologic, and then second, to try to buy all of Hologic.

Q: Oh wow. When you say amateur film market, do you mean like hobbyists?

[00:54:51]

A: So just the photography market, yeah. So Kodak, I don't know what the percentage was, but they had over half the market share in the world for amateur photography film. And when that went digital, they were kind of on the forefront with the digital cameras. But they just failed miserably in staying at the forefront there. And just got blown away by everybody else who came in, and outperformed them in that space.

[00:55:21]

Rochester, I don't know if you've ever been up there, Rochester, New York, but it turned into a ghost town when Kodak started closing up all those things up there. That had to be devastating to the economy there. Probably similar to what it was like when I was a kid, and they shut down all the steel mills in Youngstown, Ohio. And we went from 20,000-some people that were employed by the steel mills to zero in about 10 years. And it's just, you know, they've still not recovered.

Q: Wow. Yeah. No, I'm familiar with that type of story. Because here where I am used to have a lot of steel mills. And they were closed for probably about 20 years before towns started—this town started to come back around again.

[00:56:13]

A: Yeah. Wasn't one of the independent steel companies still there in Phoenix, Phoenixville? I'm trying to remember what the name of it was. They kind of came out into the specialty steel products there for a while. And I think that they were located there for a while, and then somebody acquired them. But I can't recall the name of it. But yeah. I mean I can still remember my father, he was employed by the steel mills at that point in time. And he went out and interviewed at the Fairless [?] Works for US Steel in the Philadelphia area. And came back, and he says, "They've got one foot in the grave there too," he said. "There's no point going down there." So ultimately, he ended up his career down in Pittsburgh, at US Steel down there. But that was a tough time in Youngstown.

Q: So what happened, if you were working on something new, and it didn't pan out? Like whatever you were working on just didn't turn out to be what you wanted it to be?

[00:57:40]

A: I'm trying to remember if there was ever that case, to be honest with you. Certainly, in one case, with the [00:57:48] Diagnostics Company out in Santa Clara, we just ran out of money before we got everything finalized with it. But it holds the promise, still to this day, there are

some people still keeping, you know, that technology going. But to be honest with you, I don't think I ever was involved in a product that didn't make it. And I don't mean to take credit for that, but just God's blessings or something. But fortunate to have always been involved with something that came into fruition and was successful.

Q: Oh, that's amazing. A career with no dead ends. I mean did you ever have any moments where it seemed like you were maybe going to hit the wall? What was it like to pull back from that point, and be like, "Ah, yes. This is what it was meant to be."

[00:58:49]

A: Well, it's interesting, you know, because this company that I'm running right now, several times I've pulled it back from the edge of disaster here, you know. And sometimes it's just finding someone else to invest in the company. Sometimes it's getting past a hurdle, you know. Sometimes it's changing the path a little bit. I mean Direct Radiography, had they fought me and said, "Listen. We're only going to be a detector company. We're not"--Their design was, with that company, that was being built within DuPont, was, "We'll build detectors. And we'll sell it to the original equipment manufacturers in the radiology world. And they'll incorporate that detector into their systems."

[00:59:37]

Those companies were the biggest believers [in] not invented here that ever came into being. They were going to make their own. And they had no desire to acquire a company like that, or to acquire somebody else's products and make those successful. And I said, "The only way you're going to convince them is go out and build your own system, and to stick it in their face that you can do it, and they can't, and start to hurt them in their marketplaces. And then you'll get their attention."

[01:00:06]

And so, you know, in many cases, it's a course change like that. And fortunately, for me, they believed that. And that's what became Hologic. And fortunately, for us, they didn't believe that

little company, that little mouse between the elephant's feet could pull it off. And we got so far out in front of everybody in that space, with the best integrated system, that they couldn't catch up.

Q: Was there anything else that Hologic did, that made their product so successful?

[01:00:42]

A: Yeah, there was—I always tell everybody there's three things. One, we had the selenium-based technology that inherently gave sharper, better image for mammography. The second thing that I mentioned to you earlier, that was kind of serendipitous, was the fact that we made our detector the same dimensions as the largest film that was used in the breast imaging space, from the very beginning; whereas everybody else made a smaller detector, because it was easier. And then they would have to take two exposures of a woman's breast in order to get the larger breasted women in it.

[01:01:21]

And women and radiation dose, you just don't mess with that. They're smart enough to know that they're getting more dose. They know that's [audio breakup] [01:01:32]. And so we were fortunate in that respect. Another thing we did, though, because everybody else was—all of radiology, GE provided every single thing that was used in radiology. Phillips did the same thing. Picker did the same thing. Siemens did the same thing. We were focused just on mammography.

So whereas their PACs [Picture Archiving Systems] systems and their PACS workstations had to cover everything, and then they tried to make a general radiography monitor, and a general radiography patient flow, and a general radiography paying protocol for images work for mammography, we didn't do that. We built the system to work just for mammography, just for breast imaging, so that everything a breast radiologist wanted, if it was different than general radiography, we had it in our system. So it was ideally suited for them.

[01:02:25]

So they could make it work their way, as opposed to the way the big company was saying, “Hey, listen. You're going to have to compromise here, because that's the way it works with all the other images, from CT and mammography, and other parts of general radiography.” And we could customize it to just mammography. So we went after those centers, that that was all they did, was just mammography. And they were the biggest and the smartest and the best. And then everybody wanted what they had.

Q: So the key to success is specialization.

[01:02:59]

A: In that case, it was. I'll call it focused. We were deadly focused on breast images and their need.

Q: Did that generate any challenges of its own, too? Like was there a concern that that might also lead to a plateau?

[01:03:16]

A: Yeah. The biggest concern there was, we didn't make the big PAC systems. We didn't make the archiving systems. And the archiving, early on, was really a challenge in digital. So a terabyte drive, back in the '80s, was as big as a CT, okay. I can still remember seeing the first one at UCLA back in the early '90s, actually. It was '93, '94, something like that. It was literally six feet tall, a disc, and probably three to four feet deep. And stood on edge like a big donut sitting on the side of the room over there. And that was one terabyte. [laughter] Yeah. And now you can get that on a stick and run around with it.

[01:04:15]

And that was something like \$160,000 dollars for a terabyte of storage. So if you're coming in with digital mammography exam, telling them, “Hey listen. Each one of these is 30 megabytes,” they look at you and go, “Go away.”

Q: Wow.

[01:04:32]

A: Yeah. And so, you know, data compression, the storage [audio breakup] [01:04:39] kind of came along with it, all of those things, we didn't have that. And the biggest fear we had was that the big guys, like GE, would say, "Hey listen. You're not putting their images on our archive. We can't guarantee it anymore, because you don't know what they did to their images. You don't know what's going to happen when you transfer their images into our archive and back out." So we were afraid that they would take that. And in some cases, they did.

[01:05:05]

And so we literally had to get the radiologists so—And this was the greatest part about mammography. It is the single-most passionate part of radiology or medicine, I think even, that you'll ever run into. The radiologists and the technologists, and the managers involved with breast imaging, are so passionate about what they did. And so, when you serve them and serve them well, and give them something that they really like and become accustomed to, they're going to fight for you. They would literally call us and tell us when competition was doing something, to try to unravel us in the marketplace.

[01:05:42]

And so when the Siemens and the GEs would go to the IT people at the hospitals and say, "Listen, you don't want that Hologic mammography system on your network. You can't be certain what's going to happen," things like that all the time. And so we were really afraid, you know, that they were going to be able to block us out. And, in some accounts, they would come in, and sign up all of radiology. "We'll provide you everything you're going to need in radiology. Just give us \$5 million dollars a year, and you need a new CT, we'll get it. You need a new MRI, we'll get it. Just give us \$5 million a year for the next 10 years, and we'll take care of it all." And I can't compete with that, okay.

[01:06:25]

But fortunately, for us, there was most of the marketplace saw that we matched up with what they needed, and just said, “You've got to figure that out.” Even to the point with national accounts, with multi hospital groups, like Humana and HCA and things of that nature, they would get an uprising of the breast imagers in their networks. And they'd come out and say, “I don't care if you sign an agreement with GE or not. We're not buying a GE mammography system. We're buying a Hologic.”

Q: What do you think it is about that sub-field that engenders such passion?

[01:07:00]

A: I think one, that it was women. And I think that that was the thing we saw early on with that group of us, that we could become a women's health company. Nobody had ever focused on women's needs in medicine before. And we could really show the empathy. I mean everybody's got a mother. Everybody's got a spouse or a daughter or whatever, you know, that they can relate to in that situation. And so we really incorporated that whole mentality into a marketing, on every single thing that we did, on the breast side.

[01:07:41]

And so, when we bought Cytoc, that was looking at cervical cancer, minimally invasive of OB/GYN, surgical procedures. And that ideally matched with our women's health piece of it. So we were, you know, very quickly, about a billion and a half women's health company. Then I added another diagnostic company to that – Gen-Probe [Corporation] - later, and a number of other smaller technology companies that we added. And so when we were \$2 ½ billion dollars just focused at women's health, I mean that was something the market hadn't seen before. So that just carried tremendous marketing power in the course of what was going on there.

Q: So when you touched on the idea of archiving the images, and the way some of your competition reacted to that, was that just pure competition? They were saying whatever they had

to, to get their sale over yours? Or was there genuine concern about like different file formats or anything like that?

[01:08:58]

A: There was always a nugget of truth in what they did. But they would—So, for instance, selenium that's used in our detectors, the unique thing about selenium is it's photo-conductive. So we could take x-ray energy and convert it to electronic signal in one step. Whereas all the other technologies went through a phosphor-based technology that converted the x-ray into light. And then it converted the light into electronic signal. So it was two steps.

[01:09:36]

So there was a diffusion that went into that process. And so they were constantly working on that. And so we outsold them, because we were the direct conversion company that was part of Culley's, you know, marketing spin that we had, was direct conversion. And we had a little insignia for Direct Radiography. That's what it's talking about, is the signal that you get as perfect, you know, match across that pixel of conversion of that energy.

[01:10:03]

And so when we would fight them with that, they would come back and say, “Well gee. Do you know that when selenium gets below 10 degrees Fahrenheit, that it sloughs off. It separates from the detector and falls off. And your detector is crap.” And they're right. That would absolutely happen. But how often do you get 10 degrees Fahrenheit in a hospital? Well, there are places in the world, and there are shipping containers around the world, and so forth, that that can happen. So we just had to protect against getting to that point. But they would build that into a huge thing, “Oh my gosh, this is just terrible.”

[01:10:49]

And then, on the other end of the temperature spectrum, the selenium is an amorphous structure. So as soft as a metal can be, which isn't very soft, it was softer than most, because of its atomic structure. The selenium would crystallize, harden, when you got to the high temperature range.

And that wasn't so far out of whack. It was—I forget. It was under 100 degrees Fahrenheit that that could start to happen. And so we had to put it into an environment that protected it from reaching those temperatures. And then, once it's in the healthcare facility, then it was fine.

[01:11:35]

So they would blow those things out of proportion, and just talk about how terrible. “You're going to be replacing detectors like toilet paper around here. Come on.” And it literally came out, and sent these papers out—I can still remember. Kodak actually listed all the things that they said would be bad about our technology on a sheet of paper. And when I'd go out to talk to customers, I'd say, “Okay, everybody get your Kodak papers out.” And everybody would kind of look at me like, “How does we know we got Kodak papers?” I said, “Come on, everybody's got them. Pull them out. Pull them out.” And they'd all pull them out of their own folders, and, “Okay, let's go down through those. Number one.” And I would just walk down through. And they'd just laugh, like, “Oh, get out,” you know.

[01:12:18]

And, when it was all over and done with, half the people were going to buy a Hologic, just because of what Kodak tried to do in their position, or GE, I think—I guess it was GE, actually. And so it didn't matter what our technology was in half of them. And the other half of them, you know, they started to understand what we were doing, and that we were there to tell them the truth.

Q: Wow. So this was a case for your competition, where going negative seems to have really blown up in their faces.

[01:12:49]

A: Yeah, going negative is—you have to be very, very, very careful. Yeah, there's a barrel pointing in both directions whenever you go negative. And you want to make sure the bullet goes out the other end. Yeah. [laughter]

Q: Can you say anything about what it's like to sell a new detector or any other new product? How do you convince folks to sign on?

[01:13:10]

A: Well, that's an interesting one, because when we first got to Hologic, we were very concerned about the credibility in the marketplace being the mouse between the elephant's feet. Everybody knew the elephants, but they didn't know the mouse. And so one of the ideas we had was to go out and talk to some of the other manufacturers in the marketplace, and convince them to incorporate our detector into their system. And just having another major company endorse our technology would take it out of oblivion and bring it out where everybody--"Whoa, whoa, whoa. You know, so and so is going to buy that detector now too."

[01:13:56]

And so, as I went around to other companies, and had that conversation with them, they were all interested in hearing it. But I think they were just hoping to learn something that would give them an advantage, or help them decide what to do. But ultimately, I did convince Siemens to endorse our technology and buy our detectors going forward. And once they started using our detector in the marketplace, there was nobody that could say, "That's just some small company that's doing that," because, you know, Siemens was a big huge dog in the medical imaging, or still is. And if they were going to buy Hologic's detector, then this was a good detector. And it made a big, huge difference at that point in time.

[01:14:45]

So we had to do some creative things along the way. Fortunately for us, for Siemens people saw how successful we were being, and they weren't quite as successful as we were in the marketplace. So some of their people went negative. And they said, "Listen. Hologic is only giving us their bad detectors. And so that's why we're having problems, and they're not." And so stuff like that started coming out. And they shot themselves in the foot.

Q: So what were some of the creative things you had to do?

[01:15:17]

A: Well, one of them obviously was that endorsement situation. The other was to stay focused on it. We had that conversation, I'll bet you, every month, where we would start to stray off, you know. "What if we built this? What if we did that?" Staying so laser-focused all the time really saved us on that. The monitors and the equipment that other people were using to display their images were not a good enough grade monitor or—I forget what the drivers were called that they used in the monitors that we were using. But none of those were quite up to par to handle the data that we had.

[01:16:11]

We captured images that could not be displayed. They were that sharp. Monitors hadn't caught up to that point. And so we were constantly working with monitor development and the drivers that they used to display those things on their—I can't remember the statistics exactly. But I think we captured at 12 bits of greyscale, so 12 factorial [01:16:40]. And the human eye can detect up to 10. So we were actually beyond what the eye could see. But the monitors could only display eight bits.

[01:16:52]

And so we were compromising to put our images up on those monitors. So getting monitors up to the 10 bit, at least that made the human eye could see, and see those shades of gray. And getting ours so that it could be that displayed was even that much more. And we could do technology measurements to show that and prove that to the customers at that point in time. And so it was that kind of stuff that we did, that just staying laser-focused on what we were doing.

[01:17:24]

Other parts of radiology didn't need 10 bit. They didn't want to spend that money on monitors, and have them all sitting there, you know, costing twice as much as what they needed to, just because they might put a mammography image up on there. So by focusing on the laser or the

mammography business only, we were delivering a higher quality for specifically that application.

Q: Did you have to work with any monitor manufacturers to get a piece of equipment up to snuff for that?

[01:17:58]

A: Yes. And I'm desperately trying to remember the name of the company. It was like Planar or something like that. They became the standard in mammography for everybody after that. But yes, we did work with them specifically all along the way. And that kind of thing made the difference. Our workstations became more expensive, though, than anybody else's. I can remember having the discussion with Rob Cascella, the COO. He says, "How long do you think we're going to be building our own workstations before everybody has the same technology in that space?" And I said, "I can't imagine it's more than two or three years, and everybody will catch up and realize why we're beating them in the marketplace." And he says, "I don't think so. I think we're going to be doing it a lot longer than that." And, to the best of my knowledge, they're still making all their own workstations. I was way, way off the work on it.

[01:19:06]

They absolutely love the Hologic workstations, in addition to—You know, we sold a lot of mammography equipment into other people's workstations. But the heavy users still love that Hologic workstation.

Q: Why do you think that is?

[01:19:27]

A: Again, just because of the image quality, the workflow, the speed, you know, everything is matched to mammography and breast imaging applications. There was just a lot of time, a lot of effort spent on those workstations, because we were so afraid that we were going to get blocked out, to do it right. And it ended up being one heck of a good move And I'm not sure I would have

spent as much money on that piece of it, and fortunately somebody else made that decision. And that was the right one.

Q: So when it came time to design a next generation piece of equipment, whether that's the whole workstation or any one component of it, how did you do that? Would you take user feedback into account?

[01:20:31]

A: Yeah. So again, both Jim [Culley] and I came out of market research. So we were big, big proponents of it. And so we had a medical advisory board that we called it, that were the leading radiologists. I think we had four of them around the country, there were about six to eight of them in each of those areas, that we met with quarterly. So we were with these people a lot. Then the whole time we were with them, we were showing what we were working on, getting their input on a regular basis through the whole situation.

[01:21:10]

Whenever we built a system, then, we brought the technologists who would operate the system. It's kind of an interesting thing. In the US for instance, a technologist runs all the equipment in radiology. And then the images are just ported over to a workstation where a radiologist sits and interprets them. In Europe, there's probably 25-30 percent of the procedures that the radiologist does. So you have to always accommodate things, because the radiologist, in some cases, particularly in Germany and in Sweden, they like to get their hands dirty, and get involved in the imaging itself. So you always have to think of it with those things in mind, whatever your design.

[01:22:03]

But most of this was very US-focused in the development process. So we would bring 15 technologists in, and show them what we developed, mock-up workstations, let them put their hands on it, tell us what worked, what didn't work. Go back and revise it, and bring them back in again. And did we get it right? Did we hear you right? How is that working? Until we had them all sitting there saying, "I want that." And then, that's when we would build.

Q: And what's it been like working with the government?

[01:22:44]

A: I'm in a huge FDA [Food and Drug Administration] fight where I am right now. And that's one of the toughest things, is getting everything through the FDA. During the digital mammography piece of it, there was actually a very famous problem that they had at the FDA, a gentleman by the name of Robert Smith, who refused to approve anything. He said, "All these new technologies are bunk. And they cost too much. We're crazy." So he wouldn't let anything even go through. And digital mammography was one of those things that he picked a fight on. So all of the development of digital mammography was hindered, in terms of getting into the marketplace fast enough, until the FDA finally was able to get Robert Smith out of there.

[01:23:36]

He went into one of those early whistle blower modes in the government, where they had to treat him very carefully and get him out of there. But I think there's pendulum swings with the FDA. So something comes through the FDA, and you know, God forbid, kills somebody in the marketplace because shouldn't have ever been approved. And then, all of a sudden, everybody clamps down, and things we're asked to do are crazy, to be honest with you.

[01:24:10]

This technology I'm developing, we've had approved in Europe for four years already. I can't get it through the US approval process. And then, you know, other times, they seem to be more reasonable with it. The FDA, I think, is one of those places where, you know, the best of the world don't necessarily want to be—There are some great people there. But a lot of cases, it's, you know, something that was not their first choice. And so you get a lot of people in there that are disgruntled, that are power-seekers, want to be able to make the rest of the world squirm or whatever, you know. So you encounter some very strange personalities at the FDA. And I just think they're tough.

[01:25:05]

And right now, we're dealing with some of the requirements statistically, and from a clinical design perspective, that just don't seem reasonable to me, don't hold logic to me. And it's very difficult to deal with those within the FDA. And the PMA [Pre-Market Approval] that we had— And there's degrees of FDA approval. 510K is the lowest level of it, that basically says, there's another product that does the same thing out in the work place, a predicate. And I'm going to show you that I'm every bit as good, or better than that, okay.

[01:25:49]

The PMA says, there is no predicate. I'm doing something new, something novel. And the bar gets raised quite a bit higher. Clinical studies get very big. Dollars get very big, that you have to spend. I've spent over \$40 million dollars on the FDA with the current product that I'm on right now. The PMA for the first general radiography system we did at Direct Radiography, was \$10-plus million dollars. We spent another \$10-plus million to get mammography through a PMA. So it's big dollars whenever there's no predicate device out there. And so it's very tough, very tough.

Q: And how does that compare with working with governments in Europe?

[01:26:47]

A: From a medical technology perspective, Europe does one thing, show me it's safe, okay. And we can do that much more simply than we can to—In the US you worry about claims and marketing. Are you—What are you saying about your product? You're telling me, this is better. Prove it, okay. We can't say it's better until you prove it. In Europe, you just go in and you say, “Our product is safe. We think it's better. And here's the papers that support that. You make up your mind, and you just go.”

[01:27:31]

Now that doesn't give you the protection, though, that the PMA does in the United States. So if I get a PMA, anybody who follows me has to get a PMA too, until there's so many people in the marketplace that it's kind of standard way of doing things. And then they might reduce it down to

a 5-10K. So digital mammography is at the 5-10K level now, in the United States. I don't believe tomosynthesis, the 3D imaging, is as yet. It might be. So getting that PMA gives you two or three years headstart on anybody else. It has to go down through that approval process behind you.

Q: So were you—have you worked with government in any other parts of the world, like Asia, Africa, South America, Australia?

[01:28:28]

A: Yeah, not so much me directly, though, but yeah. China, mainly the governmental work I did over there was with acquisitions. But the regulatory stuff, somebody else handled all that stuff. The regulatory stuff, you tend to, as a CEO, get a lot more involved in the ones in the US and in Europe. So you're kind of on top of that stuff.

Q: Were you involved with the development of the tomosynthesis?

[01:29:01]

A: Sure, absolutely, yeah. Yeah. So I was—I can still remember the day that Jay Stein, the Chief Technology Officer at Hologic. And he's still there, to the best of my knowledge, not on an everyday basis, but still going in and out, and Chairman Emeritus, I think on the Board. Jay, one of the smartest technology guys, and an amazingly good guy with the regulatory affairs, with the government, too. But I can still remember when Jay walked in my office and said, “You know, we can do 3D imaging on our system faster than anybody else.” And I said, “What makes you think that?” He says, “Because the orientation of our x-ray tube rotation that we built into it is focused at the detector. So nobody else can do that. Their point of turn has the detector turning separately from the arm. And ours all goes in one motion.”

[01:30:07]

And I said, “Oh my goodness.” And literally, a couple of weeks later, he came into my office with the first 3D images. So Jay and I then presented that to the rest of the company and the Board, then, in terms of how that was going to change breast imaging. And that was just—I

mean literally, that was a summer, in August-September kind of timeframe that he came in with that news to me. And that November, we had the first images on display at the RSNA, the very first tomosynthesis that anybody had ever seen.

[01:30:49]

And we were years behind the others, who were developing it. And we knew they were working on it. But we were able to actually accomplish it and put it up on a light box for people to look at that quickly. And got approval probably a couple years later on that one.

Q: Wow. So from inception to approval, for a thing, how long does that usually take?

[01:31:18]

A: Well, you're usually looking at five years.

Q: Five years.

[01:31:20]

A: So that was just remarkable, in terms of what they accomplished there. Yeah.

Q: Wow.

[01:31:27]

A: It might have been three years, but it was way under the norm. it was fast.

Q: Wow. So I think we're starting to wind down a little bit. Could you maybe compare and contrast some of the differences between what a good day at work at Hologic, or if you have a favorite part of your career there, versus a bad day at work?

[01:31:57]

A: The good days were just the successes. I mean our win rate in the market was remarkable. It really was. And because I never lived in Boston, I remained down in the Southeastern Pennsylvania area, and commuted for, gosh, 13 years I guess to Boston. When I was in Boston, there was a group of us that were commuting in and out. Rob Cascella did it, I did it, some of my guys in BD [Business Development] did it, that you just had a group of us that would work all day long, and then go out and have dinner together, and then get up and do it again the next day, you know. So three-four days of the week, we were together in a way that you just don't get in a working environment. And fortunately, we did get along. And you know, just had a great time there. But it was remarkable, the closeness that we had there. And so, when we were successful, those were really good days.

[01:33:38]

The bad days were, I don't know, probably when we had tough times with the Board, fighting on stuff that we wanted monies or got approval to go do some things. We were a very aggressive acquirer of companies and technologies, a lot more than probably anybody else in the business. And I know that scared everybody. In the end, we bought Gen-Probe not too long before I left. I forget what that one was, \$3.2 billion or something like that.

[01:34:21]

We literally went out and got funding for, I don't know, \$2-\$2 ½ billion of that. But no more than 30 percent down out of cash. And that kind of leverage just scared the Board sometimes. But we were, we were generating \$500 million in cash a year, at that point in time. And just a very highly profitable company. We could pay it down so quickly. The new CEO that came in and fired all of us, Steve MacMillan, was talking about, you know, how crazy all that was, what we did. But he's kept it all. And, you know, we talked about spinning all kind of things off and everything, he hasn't done a thing to do that.

[01:35:08]

And it was just because of just how much cash we could generate with what we put together up there, it was very profitable thing. But the Board wasn't real sensitive to that. And, you know, it

got them very concerned about being leveraged. And we just did it so successfully. I mean we were getting-- convert financing for two percent and less rates even back then, just simply because the banks had that much belief in what we were doing, that it was almost free money, we called it. And so getting the Board to get comfortable with that, those were kind of the tough ones, where we had literally long, long nights, just meeting someone on forever, trying to rationalize that for them.

Q: And it seems that I accidentally skipped over a sub-question related to dealing with the government and regulations there. Did you ever have to deal with insurance companies?

[01:36:10]

A: So we did in the payment side of it. So whenever you come out with a new technology, particularly a PMA product, there's no coding for it. And so the insurance company's way of dealing with anything like that is just deny payment. And so you have to constantly be working with the government to get the CPT codes [a five-digit numeric code] in place, and then be going back out to the payers to show them that it's a cost-effective thing to reimburse for those procedures. And whether it's a strategy on their part just to say no for a long, long time, so that they can save money by not having to pay for those things, or whether they are seriously looking at what saves money or not, I don't know, to be honest with you. It kind of felt like it was a strategy on their part, you know, to start with.

[01:37:11]

But the reimbursement process in the United States is abysmal, absolutely ridiculous. So if my new technology got FDA approval today, it would be 2024 before a code would be given for reimbursement of that technology, four years. And you go through—there's this series of steps that just, that it drives you nuts, because the technology we developed then at Hologic, the technology we're developing now, saves lives. And it prevents women from going through the angst of thinking they have cancer when they don't, and prevents huge costs in the medical imaging world, where they're going to do other procedures to desperately try to find an

anatomical feature that tells them that something is malignant or not. And we've got the technology that can do that.

[01:38:19]

And they just wouldn't reimburse for it. So reimbursement drives behavior in the United States. If they get more money to do one procedure versus another, they're going to be inclined to do that other procedure, whether it's better or not. And it really, really makes the doctors step to it. So there was that CAD [Computer-Aided Diagnosis] technology I was talking about early on, with the artificial intelligence. We bought a CAD company, R2. And they were getting, I forget, something like 17 or 18 dollars reimbursement to apply the CAD to the imaging. So you had a second read from the computer in addition to your own interpretation as to whether something was malignant or not. Up until we got that code, not a lot of people used it. As soon as we got that code, everybody used it. It went from zero market share, and it was honestly 10 or 20 percent, probably, to 70 or 80 percent in two years. Because reimbursement drove that behavior.

[01:39:24]

And I don't think there's any reimbursement for it any longer. It's, you know, just part of the system anymore. But that's how much reimbursement Tomo got given, I forget, it was a \$25 or a \$35 dollar reimbursement increase above just digital mammography. And so the 3D, as soon as we got that code, everybody had to have a machine at that point in time.

Q: Wow.

[01:40:02]

A: Yeah. It's not the benevolence society that you want to think it is sometimes. But you know, the good news is, a lot of good people, and doctors and technologists and so forth, that are in this thing for the right reason. And they want to use it, but that reimbursement makes it that much greater. I mean I've got a guy who's on one of my medical advisory boards right now. And he's a good friend of mine, and I've known him for 20 years, a radiologist down in Arkansas. And he said, "Tom, you need to understand this technology you're developing is going to cost me

money.” And I said, “I know that. I know that,” I said. “But it's also delivering better care, Steve,” I said. “And I think you'd want to have the conscience to deliver that better care, and also have control of your own destiny, in terms of, you know, being able to make the changes that are the right changes to make for a woman's health, and have the best technology that you could possibly have, while other people may be fighting it, and struggling to hang onto what they used to have.” And he said, “You're right,” he said. “But you need to understand that not everybody's going to feel that way.” And so it's a reality.

Q: So this is kind of a compound question. What parts of your career would you say that you're most proud of? And is there anything you would do differently, if given the chance?

[01:41:45]

A: Wow. I guess there's, fortunately for me, I'm blessed to have a lot of situations that I've been proud of all along, my career. It'd be hard for me to point to one, one thing, or even a couple things. It's just been a lot of good people, a lot of—it's one of the blessings of being in healthcare, period, particularly with the technology development associated with healthcare, that you can't, at the end of the day, look back, and if you've made things better in healthcare or not, feel good about it. And I think that's one of the blessings of being in this area, is we're making lives better for people.

[01:42:44]

As far as things that I would do differently, I would have gotten a lot more business-oriented earlier in my career than I did. I think had I done that—it's funny. Because, you know, to run a company, you have to have a very broad background to do it, and do it well, I think. And there's also a confidence issue that comes with that. And maybe it took me longer to get to that point than I would have, if I'd gone through a different career path.

[01:43:39]

When I sit down with engineers and manufacturing people, and I can talk their language, I really appreciate that time that I spent in those areas like that. But the business side, I think, if I'd been

exposed to more of that sooner, it might have given me some different opportunities, you know, in my life. I'm 65 right now. And you know, whether this will be my last company that I run, or whether there will be more—I hope there's more. I'm still having fun. I love to learn, and I love to do, I love to build. Whether it's a house, piece of furniture, a company, I love to build. And so it's something that I'll just keep on doing until I'm not having fun.

Q: So over the time that we've been speaking today, is there anything that I haven't asked you about, that you really wish I had asked you about?

[01:44:48]

A: Oh goodness. no. I don't think so.

Q: Okay. So while we're still on the record, then, is there anything else you'd like to share?

[01:44:59]

A: No, I think I'm good.

Q: Okay. I'll stop our recordings, and then we can talk about the filling out the release form.

[01:45:09]

A: Oh, okay. I forgot all about that. I did print it off. I think it's on my printer in there. I will go sign it, and maybe it's here. I will go sign that.

END OF INTERVIEW