Oral History with Jeff Yorker, January 16, 2020
Interview by Benjamin Spohn for Hagley Museum and Library
Hologic oral histories project

Q: Today is January 16th, 2020. I'm sitting down with Jeff Yorker, formerly of Hologic, to talk about his career in the medical imaging business. So to start off, tell us a little bit about your early life and education? What got you to Hologic, sort of speak, plus DuPont?

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A: There's a lot of history before Hologic. But I was born and raised in Denver, Colorado, or suburbs of Denver, Colorado. I attended public schools throughout my education. I was always pretty good student and I gravitated really early toward math and physics. Well, not physics. I mean, we didn't study physics in elementary school, but we did have math and arithmetic. And as soon as it was available, I got into a fast-track in mathematics programs and took all the advanced placement in placement programs and enjoyed that quite a bit. I also was a hobbyist at home. I enjoyed putting together electronic experiments, Heathkit things. You know, fiddling with electronic things. So it was always a hobby of mine.

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I was also heavily involved in music in and out of school. I played in, my favorite was the jazz band in high school. But I also played in the symphonic band, and I was in a jazz combo outside of school. And actually played a couple of successful jobs in the Denver area. I wasn't completely a geek though. I also was a skier. Growing up in Colorado, I started skiing when I was about six years old. And continued skiing, and eventually taught my kids how to ski. So it was something I did. It was a lifelong passion of mine. And I ran track and field when I was at school and continued running for quite a while.

Q: So a fellow band kid? What did you play?

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A: I played saxophone. I still do. Just recently, I was in a band. It was actually since before 2000, we had a band at Kennett Square called Rocket Science. It was all Ph.D. chemists and scientists. We played in the Kennett Square area. And that just broke up a couple, about a year

ago, because the driving force behind the group moved to South Carolina, which is unfortunate. We're trying to get something back together again.

Q: All ex-DuPonters?

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A: Except for the singer, was a woman who's not from DuPont, but everyone else was an ex-DuPonter.

Q: That's great.

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A: Yeah, it was crazy. We had a good time. We didn't give up our day jobs. We weren't that good, but we had a few jobs. When I finally got to high school, there was a teacher, a physics teacher who was really influential on me. He was a great teacher. He was a youngish guy, and he was a really good teacher. He was a good mentor to me during high school. He lived close to me, and we used to ride our bikes together to school pretty much every day. And he encouraged me to continue in science and technology when I went to college. And I did. It was good advice. After high school, I attended Cornell University in Ithaca, New York, where I double-majored in math and physics.

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After a couple of math courses, I did complete the major in math, but after a couple of courses, I realized that that was probably above my head. And physics became a place where I could practice mathematics but didn't really have to get into the abstract stuff, which was difficult to understand. And that was '72 to '76, that I was at Cornell. After that, I went to grad school at M.I.T. for a Ph.D. in physics. And I was there from '76 to '82.

Q: So did that graduate research have any direct relationship with the sort of things that you worked on, once you got to DuPont.

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A: Yes, very much so. I think it was both in style and substance. The work I did in grad school had a lot of bearing on my industrial work. The guy that I worked for at M.I.T., my research

advisor, was a very hands-on, do-it-yourself kind of guy. He believed that graduate students or students in experimental physics should be able to build their own scientific apparatus. And the group had a really nice machine shop and eventually used all the equipment in the machine shop. I already knew some of it, but we had milling machines, lathes, stuff like that.

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And I got pretty good at fabricating things in the machine shop. I also learned quite a bit about electronics, how to design and build electronic circuits. And how to build prototypes. If there was something that we wanted to prove out, just to see as a concept, to see if it had any merit, we got pretty good at putting together a prototype to prove out a concept. So that was kind of the style. It was very good for somebody who was going into instrumentation, electronic heavy industry. On the substance side, the project that was working on was called molecule microscopy. And the idea was to use molecules to create images of biological surfaces.

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And it was a very difficult project because we were looking for studying the interaction of small molecules like waters and alcohols with biological surfaces. And of course, those are abundant in the environment. And so, we were looking for very small amounts of molecules that were emitted by biological surfaces in the background of lots of water or alcohol. And so we had to use every trick in the book, in order to pull the signal out of the background. We don't have quite the same problem in radiology but optimizing signal-to-noise ratios is very, very important in that business, as well.

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I also learned how to take electronic signals, in this case we were counting individual molecules, and translate that into something you could display as an image, which is what radiography is all about. So then after M.I.T., I went into industry, and just as an overview, I worked in industry for 33 years from 1982 to 2015. Most of my work was in medical imaging, medical imaging equipment development. And I worked basically for three companies, DuPont, AGFA, and Hologic.

Q: So how did you get your first job at DuPont?

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A: I have to back up a little bit. I met my future wife while I was in college at Cornell. And she's a chemist, and she was studying chemistry at Cornell. And she also wanted to go to graduate school to get a Ph.D. So we had to work very hard to try to find a place where we could go to school close together, maybe at the same school. But at least in the same city. And we ended up in Cambridge, Mass. She went to Harvard and I went to M.I.T. And then after graduate school after we both got our Ph.D.'s we had the same problem of trying to find a job co-located in the same city. And we looked all over the country, and ended, as it turned out, DuPont gave us both jobs working at the experimental station, which was a blessing.

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She was working in agricultural products at the time, and I was interviewed with the engineering physics lab, which is a group of physicists and electrical engineers. It's a corporate resource that makes equipment or develops equipment that is not commercially available. And the interview that I had with DuPont went really well. They thought it really clicked. They thought that my background was ideal for working in this lab. And they hired me fairly quickly as a research physicist. That was my first position.

Q: So to clarify and back up a tiny little bit. Did the two of you find DuPont, or did DuPont find the two of you?

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A: I think I met a recruiter at a job fair. And my wife was interested in either pharmaceuticals or agricultural products. We did not recruit together. We recruited independently, but we tried to apply to the same companies or companies that we knew we could commute to. I would say we found DuPont, but it was mutually beneficial.

Q: Certainly. So your first position was as a research physicist. What was it like climbing and moving up through the ranks, or about where was someone with the title of research physicist be within the organization?

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A: It was an entry-level position for a Ph.D. That's kind of where all Ph.D.'s started, either as a research chemist, research physicist, or research, I don't know, engineer whatever. But it was an

entry-level position for a Ph.D. It was very interesting, and educational, and competitive being at DuPont at that time. But I think EPL, Engineering Physics Lab was a good springboard for a career at DuPont. And being a corporate resource, people in EPL and central research got to see different businesses around the company. So we were working with fibers and skull photo products at the same time and polymers.

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So we got to see quite a bit of the company from that one place. I was encouraged by my management in the mid-eighties, the late eighties, to move into management, to take a management position myself. Which is a way of sort of progressing faster than just being at the bench. And also, move into a business unit, to get some business experience, which is one of the best things that ever happened to me. So in 1988, I accepted a position to be a supervisor of a group that was making process analyzers. These are, this is custom equipment that is used to measure the physical and chemical properties of materials moving through pipes in a DuPont plant, for example.

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That was a very interesting job. We developed a couple of pieces of specialty equipment. Some of it was in process, so it was actually placed in DuPont plants. Some of it was portable equipment that could be taken out in the field. But it was all custom stuff that could not be bought off the shelf. So it was kind of a niche for us. I was with that group for four years, and then I accepted a job in medical products, the diagnostic imaging business, in 1993, to work on a product that was called the LP400. That was a medical printer. It took electronic images off of a network and formatted them and put them onto film.

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And this was a me-too product. All the film companies had something like this. AGFA, Kodak, Fuji, all had hard copy devices that they used to take medical images and put them onto film so that the doctor could look at them on a lightbox. That was a good product. It was already in progress, and I took over for a guy who was retiring. And that was an interesting experience. In 1995, 1996 DuPont divested medical products and broke them up, and sold them to different companies. And I ended up being hired by AGFA at that point.

Q: What did you do for AGFA?

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A: It started out, the medical products business was bought by a holding company whose job was to take undervalued businesses and break them up and sell them to other businesses. So the diagnostic imaging business in DuPont consisted, or the medical products business in DuPont consisted of three or four major businesses. There was diagnostic imaging, where I was. There was diagnostics, which is like blood serum analyzers. And there was the digital radiography product, which they decided it was still under development. They decided to break that out as a separate entity.

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It was about six months to a year, while they figured out what to do. And the different businesses were bought by different companies. So there was a lot of uncertainty for a lot of people during that time. People didn't know where they were going to end up, or if they were going to have a job in the long run. But for the most part, I think people did pretty well. The diagnostics business went to a company called Dade, which still is working at the Glasgow plant. It's now, Dade Behring, which was later bought by Siemens and it's still at the Glasgow site.

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The digital radiography group went to Hologic, and Hologic did really great things with that. Diagnostic imaging was sold to AGFA, who basically shut down the business. They closed our film plants. I think we had four or five film plants that were all closed. And the work that I was doing, that our group was doing on electronic imaging was shut down. I was retained and there were basically two managers, myself and another guy who's still with AGFA. But the first job I had to do was to reduce the size of my group by 40 percent, which was very unpleasant. I stayed with AGFA for about two years. And the writing was on the wall. They really didn't want to have a satellite research group working in Delaware. And so after doing the job that I was asked to do, I ended up moving to Hologic, which I'll go into later.

Q: So to continue talking a little bit about DuPont, since we're interested in capturing that part of your story, too. How did DuPont change over the course of the time that you were with them?

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A: I was with DuPont for about seven years, I think, or maybe, no, maybe 13 years in two different businesses. And it changed quite a bit. I think the number of employees decreased dramatically from, I think, 120,000 if I remember correctly when I first started with DuPont, to about 80,000 when I left. And I was one of the 40,000 who was not there anymore. DuPont was trying to figure out-- there was an exercise called core businesses or core technologies. And I think DuPont was looking at businesses or technologies that they had to have in order to support heir their long-range plans. And there were businesses that were best done by other people.

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I think the medical products is a good example of that. I don't think that DuPont really knew how to manage medical products. It just did not fit into the model that they had for the products that they liked, that they were successful making and then selling. So this definition of core technologies was a big exercise, and it was what kind of drove the decisions on which businesses were vested, kept inside the company, and which businesses were divested outside the company. How did the organization change over time? I think there was a definite, deliberate change in demographics that I saw over time. There was a push to hire and promote under-represented groups of women and minorities, primarily, which is something where I think we've made a lot of progress, but there's still a lot of progress to be made.

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There's still a lot of issues around pay equity. And continuing to support under-represented groups. There were sort of slow and steady progress progressions that happened while I was in DuPont and other companies. There were kind of, I call them management experiments. What will have happened if we did this? I think the main trend was to move from hierarchical organizations where you had levels of people to more flat organizations, where people were more on equal footing, and kind of collaborated more with each other. There was something we called 360-degree reviews, which was a useful thing, where instead of having your supervisor or management be completely responsible for writing your review and evaluating your performance, you get Peters to input and collect.

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The supervisor would collect information from peer reviews and so on in order to create a performance review for a person. And that was interesting. I think it was eye-opening for a lot of people. There were experiments with open offices. We'd go from everybody had an office with a closed door, to everybody was in a big bullpen or cubicles where it was noisy. And that went back and forth a couple of times. And some of it was just a question of how much real estate you had available. The biggest change that I saw was within Hologic. Hologic was fairly conventional, but a little bit more agile than DuPont when I joined them. But they had basically, a hostile takeover in about 2013 or so.

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There was an activist investor who's pretty infamous, who acquired enough stock, Hologic stock, that he could have a big influence on the board. And he put all of his own people, or he would stack the board with his own people. And I think he had in his mind that he wanted to break up Hologic into different businesses that he would then sell off at a profit. And so, they replaced about, well everybody from two levels up from me was replaced all at once. It was really a sudden change in management. One of the reasons I retired when I did.

Q: Yeah, it sounds very difficult to weather. So what would you say were the most important jobs that you held over the course of your entire career? And that can be with any company.

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A: I thought about this for a while. I think, in order to-- when I say, most important, I had to think about what that meant. And I think, first of all, in order to be important it had to be something that was technically successful. It had to be commercially successful. That is, make money for the business. And being in medical products, you'd like to have some benefit to mankind as a result of your product. Most projects that I worked on never got off the ground technically. And that's just the way that I think product development is. Somebody has an idea and people say, "Well, that's a great idea. Why don't we turn that into a product?" But you just can't make it happen technically.

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There's just too many hurdles or it's too expensive or something like that. So most projects I worked on never got off the ground. A few of the projects I worked on were technically feasible, but not financially feasible. That is, they would lose money for the company. There were a couple of those. The first product that I worked on that was technically feasible and financially feasible was that LP400 that I mentioned, the first thing that I worked on in medical products, diagnostic imaging. And it turned out to be the most profitable product in Diagnostic Imaging Equipment's history. I wouldn't say that benefitted humanity much. It was a me-too product, and the only purpose was to put medical images on film so doctors could read them. But it was still a good product.

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I think Selenia, which we'll talk about I guess later, was the product that I moved to Hologic to work on. It's a digital mammography system, and it turned out to be, technically, a very challenging product. But we did overcome the challenges, and it turned out to be a breakout product for Hologic. They went from being $300 million dollar company to over a billion dollars. So it was very, very financially successful for Hologic. And I think it really led the competition in terms of image quality, ease-of-use, diagnostic utility. And so, I think it really was good for humanity as well. That was a product that I was really proud of.

Q: How long did it take to develop that?

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A: It was very short. And it was because we were able to combine technologies that already existed. The basic technology came out of the digital radiography. And the first product that they started working on that in 1990. That was within DuPont, and that was the business that was bought by Hologic. The basic technology was a solid-state detector that was used for detecting X-rays. And it was detecting X-rays of informing images. And they had developed that into a general radiography system, which basically is a 14 inch by 17 inch to replace X-ray film. And

so that basic technology was there. Hologic also bought a company in Danbury, Connecticut called Lorad, which made film-based mammography systems.

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And so we had the detector, the basis of the detector from Hologic. We had a mammography X-ray machine from Lorad. And we had a workstation which all also came from Hologic. It was part of the digital radiography product. So those were the three components that went into Selenia. So we started working on that in 2000, summer of 2000. And we had the first prototypes in 2002, summer of 2002. And we were commercial and had FDA approval in 2003, sold our first product. So it was less than three years from concept to sale, which is remarkably fast. It was, like I said, put together from pieces. It was kind of a Frankenstein of a product, but it was very successful.

Q: As long as it works, right?

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A: As long as it works.

Q: What were some of the other things that you worked on?

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A: The theme of my show was replacing silver halide film with digital electronic imaging. That was kind of what I worked on. The first thing was the LP400. That was the laser printer that was within DuPont, that was shut down by AGFA. There was another interim product there. It was from Polaroid, which went out of business, and we picked up their laser printer product. It's called Helios, and it was a technical tour-de-force. It was a very, very complicated piece of equipment. And it produced very high-quality images, but it was not worth the expense. And so, we kind of worked on that for a year or so, and then retired it.

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When AGFA looking at DuPont, or the business, the electronic imaging DuPont. I think they wanted to see what we could do. They had their own laser printer. It was called the DAYSTAR.

And they said, “We would like you to take this DRYSTAR, and integrate it with your networking system. And basically put together, use the DRYSTAR as a replacement for the LP400 in your networking system.” And we called that product the Contact 400. We worked on that for maybe a year and it was successful. But obviously, once AGFA bought us, they didn’t want to continue with that product because they had their own DRYSTAR.

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Selenia is the direct replacement for a film-base mammography. So it's two-dimensional mammography. That was, like I said, an important product. Dimensions was an extension or an enhancement of Selenia. I said that Selenia was kind of a Frankenstein. Dimensions was starting with a clean sheet of paper and making a completely new mammography system, but adding on a new feature, a radically new feature, called tomosynthesis, which is a way of making 3D images of the breast. And in a static, two-dimensional X-ray, the X-ray tube stares down at the breast, which is on the detector, and just transmits X-rays through the breast which are projected onto the detector.

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So you get a 2D. All the structures get compressed into 2D. So things kind of get flattened out. And if you have an overlapping structure in the breast, you can obscure things. You might not see some lesion that's there, because it's behind some other structure in the breast. Dimensions took multiple images of the breast at different angles and then combined those, what we call projections, into a three-dimensional image of the breast, so that you could unsort those overlapping structures. And that was a groundbreaking product. It improved diagnostic and clinical efficacy. After we came out with the product, there were several academic studies done where it was shown that the ability to detect lesions was improved by 40 percent, which is remarkable.

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And that the false positives, that is the detecting something that's not actually there, was reduced by 40 percent. So the tomosynthesis product was bought a really revolutionary in mammography and it's become the gold standard in mammography.

Q: Is that used at all outside of mammography?

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A: It is. It's kind of a poor man's computed tomography, CT. With CT you can, you basically look at all 360-degrees around the object. So you go into a tunnel, basically, and you have X-rays and detectors that are going around the body, the object, the thing you're looking at, all 360-degrees. With tomosynthesis, you're only looking from a limited angle. I think we went plus and minus 15 degrees. And so you can't get nearly the volumetric information from that, that you can from a real CT. But you can get slices, basically. And so, instead of getting volumetric information, you get a slice. So you could just literally take a slice through the breast and see what's at that level, at that slice.

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I've seen it used. In fact, AGFA has a product, a tomography product that's for general-purpose. It's, like I said, a poor man's CT. It doesn't replace CT, but it's much less expensive than a CT machine. I think it's ideal for breast imaging because you've already got the tube head. All you have to do is make it move. If you're building the system, for tomosynthesis for general radiography, it's kind of difficult to either move the patient or move the X-ray source. It's not part of the usual procedure for body imaging.

Q: I just had to wonder if that had any impact on, you know, the idea of, I don't know if there's any good, more conscientious way to phrase this. But with the obesity epidemic, if people can't fit in the normal tube.

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A: Yes, and that may be what AGFA uses that product for. I don't know. I'm not sure. That's a good point.

Q: Sorry to get knocked off, but after that you listed the product called Trident?

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A: Yeah. We talked about this on the phone. It was a very, very quick development product. I think we did this within a year or so. It's called a specimen radiography system. And it is not for diagnosing, not for doing anything with live patients. It's for looking at tissue that's been excised from a patient. The was this is done, the way it has been done, is when a patient's been diagnosed with breast cancer. She goes in and she has a lumpectomy, where they try to excise as much of the lesion as they can. And to make sure that they've got the entire lesion with adequate margins, they would take the sample, a tissue sample, all the way over to radiology and X-ray it. So they could see that they had margins. And depending on what the workload is in radiology, that could take twenty minutes or longer.

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And so we developed this product. It looks like a microwave oven. It's an X-ray source, and a detector in a box. You put the tissue-- you roll it right into the operating room if you want. You put the tissue in there, take the image and look at the image of the biopsied material right there on the screen. So it's what we call a workflow enhancement product, rather than a diagnostic utility product. And it reduces the amount of time a person is on the operating table.

Q: By how much? Does it take the full 20 minutes?

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A: Oh, yeah. It's instant. You put it in there, and you can have a result in a minute or two. So it's significant. And that's important. You don't like to have somebody under anesthesia on the operating table for a long time.

Q: No, not at all.

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A: There's two other things that are kind of knock-off products. We call them Affirm Breast Biopsy Systems. And there's one where, it's an attachment to a dimensions system. And so, the woman would have this biopsy while she's standing up. And then there's a prone biopsy system, where the woman lies on the table. Same basic technology, well no. The product is, the upright one, is an attachment to dimensions, which contains a biopsy needle. And it takes images of the

breast to look, to locate where the lesion is. And then uses, lost the word here, triangulation to calculate exactly an X Y coordinates, where that lesion is.

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And then it moves, by a robotic device, a needle to that location and takes a biopsy. So it takes two images, triangulates, and then sticks the needle in based on that triangulation. That's best done-- the upright biopsy is kind of dramatic for the patient because it's right there in your face. And you're watching a needle going, hopefully not watching but knowing what's going on. And there are a lot of cases where women just faint during the procedure, which is not very pleasant. So the prone biopsy, the patient lies on the table. The breast is pulled down through a hole in a table, and then the biopsy device is underneath the table and the needle is inserted out of sight.

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Q: [00:38:12] an ice pick.

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A: I think the upright biopsy is-- any big hospital is going to have a prone biopsy. I think that the upright biopsy is to give small hospitals in rural areas access to biopsies if they can't afford or don't have the space for a prone table. Prone tables take up a lot of space. And that's expensive in the radiology department.

Q: So then on the other side of that coin, do you like large inner-city hospitals where real estate to expand might be unfathomably expensive, also use the stand-up systems?

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A: Yeah, I think so.

Q: Since you were there at the time when, during the time of the switch over from film to digital, can you tell me a little bit about some of the benefits? Why is one better than the other or is it just a sort of a change?

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A: I think digital is much better than film. There are pluses and minuses, but on the whole I think the digital has pretty much replaced film. I can only think of one product that still uses film, and that's when I broke my foot. I had to have an X-ray of my foot, and they didn't use a digital projector for that. They just used a little tiny piece of film. And I think they still use film in dental, but most dentists now have electronic devices for looking at dental X-rays. If you think about what's gone on from the 1990 to 2015, or so, there's been a revolution in digital photography, or in photography. I mean, in 1990, everything was based on film. And you take your pictures of your kids and you'd send it into CVS to have it processed. And that's all been replaced, I think. Nobody uses film anymore. Or not very many people use film anymore. I think he can still buy it from Fuji and AGFA.

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But Kodak and 3M and Polaroid are all out of business. So I think we've moved from a realm where everything was film back in 1990 in amateur photography and in medical, to where everything is digital. Both in photography and in medical. I think there were cultural barriers in the beginning to eliminating film. Radiologists like to take a piece of film and pop it up on the lightbox and look at. And they had what they called hanging protocols, where they would put an image-- for breast imaging, you typically take an image of the right breast, an image of the left breast. And each breast has two angles. One is straight up and down and one's angular.

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So you've got four images from each examination, four pieces of film. The doctor would want to compare those with the previous examination, which was probably taken a year ago. And so, he would have an array of white boxes, and he'd pop up images and put them so that the chest wall was adjacent on the film. And be able to go back and forth and compare them very quickly. And without a magnifying glass, if you saw something that he was suspicious of. So there was a lot of information as being presented by film back in 1990, that just couldn't be done digitally. I don't think that the technology was there.

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Well, certainly not in 1980, it was not there, to be able to get that amount of data on to a monitor, so that you can look at it, a display. And the quality of monitors has increased dramatically. Back

in the middle ‘80’s or even 1990, everything was still a CRT. LCDs were just kind of coming out, and they were not very high quality. And so, you could not get a simultaneous high-resolution dynamic range on a CRT monitor, or an electronic monitor that you get on a piece of film. But I think there was something almost visceral about that act of flipping a piece of film up onto a white box.

Q: Absolutely.

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A: We used to have a joke that if you took an airplane and filled it full of X-ray film, mammograms, and sent it from New York to Los Angeles, the data rate would be so high that you couldn't possibly do that electronically. And there's some truth in that. I mean, the information density on a piece of film is tremendous. But I think that we have moved into a realm where electronics are much faster. Monitors are much higher quality, much higher-resolution. Networks are much faster. And so, it is possible to do pretty much the same thing with electronic system that used to be able to do with film systems.

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So you can put up lots of images. Now if you look in the radiology reading suite, it's just a bunch of high-resolution monitors. And the doctors have the same thing. Instead of a lightbox, it’s an expensive monitor, very high resolution. So that's one thing. An important thing that is true with medical imaging, is that you're able to put a lot of additional information, couple that with the image, and there's a whole other realm called DICOT, which is Digital Imaging and Communications in Medicine. Which is how you represent-- it’s like, you probably know about JPEG images. DICOT is like a JPEG image, except it’s medical. And it’s a standard now.

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You can associate patient information with the medical information. So if you have a DICOT image, an electronic image, you bring it up on the screen. The patient information, the exposure information, everything that there is to know about that exposure is right there with the image. It used to be that you put a piece of sticky tape on the film and write the patient's name and stuff like that. So now, all that information, all that metadata is right there with the image. It's the same with film. If you look at your JPEG images, it's got a bunch of metadata attached to it that tells you what the exposure was, and what the F-stop was and all that stuff. It’s the same thing.

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My biggest thing is that digital imaging, the advantage of digital over analog, is that digital imaging uncouples the image capture process from the image display process. And with film, the image capture medium is the same as the image display medium. That piece of film that you are using to capture the X-rays, is the same as the thing that you're using to display them to the doctor. And so, it's not possible to optimize one piece of it, the detection piece, versus the display piece. So you end up with some serious compromises when you're trying to design a product based on film. With digital, the detectors typically are separate from the display. And it's almost always based on different technology. And so you can optimize the detector for capturing X-rays, and you can optimize the display for displaying X-rays. And the two can talk to each other, but they can be optimized independently. And that's a big deal.

[00:46:53]
The pluses of films, I think film systems are still cheaper. You can put together a film-based X-ray system very, very cheaply. But I think that the digital technology compensates for that, in terms of, it may be more expensive to deploy a system initially, but you make up for it in terms of workflow and speed and convenience. And a lot of studies have been done that show that digital is ultimately more economical than analog. One of the downsides of digital is, it can generate huge amounts of data. And this data all has to be run over hospital network. And you can really clog up a hospital network with all that data.

[00:47:44]
When we went from digital mammography to tomosynthesis, the amount of data increased by a factor of 15, or something like that. And then, there was another product that came out just as I was leaving Hologic, where we went from low-res tomography to high-res tomography, which increased it by another factor of four. And so, we were talking about 60 times the data from a conventional mammogram, to tomosynthesis. And I think the IT administrators in the hospital hate Hologic products for that reason because there's just so much data.

Q: How about the energy footprint? Did that go up, too?

[00:48:27]

A: The amount of energy it consumes?

Q: Yeah.

[00:48:27]

A: I think probably not. I think the biggest energy consumer in an X-ray machine is in the X-ray tube itself. That's a huge burst of energy that's coming out of the X-ray tube. And you've got to supply that energy from the wall outlet ultimately. And that's pretty much the same between tomosynthesis and 2D. Now, if you're talking about, just in terms of image capture, I think it's probably not that much different. If you talk about a room full of liquid crystal displays, that may be an energy sink. And the computer horsepower that's required to drive, that probably tips the balance. I've never done that study. That's a good question.

Q: So since you spent a significant amount of time at two different research-oriented companies, DuPont and Hologic, can you compare and contrast some of their approaches to research and development?

[00:49:40]

A: Yes. DuPont is primarily a materials company. It always has been. I'm not sure what it is now. It's kind of, changed quite a bit. My wife still keeps in touch, because she was there for 33 years with one company. Hologic is an equipment company. And so, that that affects the way you do research. It affects the kind of people you hire. DuPont hires and employs chemists, material scientists. And Hologic hires and employs electrical engineers and software engineers. There's a big difference in size between DuPont and Hologic. And I think that affects how research is done. I think DuPont can put a lot of resources on to development of a project or development product.

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Hologic has to be pretty lean, and it uses the same group of people for developing different products. It's a much smaller group of people to work with. I think DuPont had a very formal development process. It was a phase gate process, where you did discovery for a while. And then once you had an idea, you'd do a concept evaluation. And then, once that was done, you'd move

into prototyping. Everything has a phase, and you step through those phases. I think Hologic is more agile, and much more adaptable, much more informal. Hologic does have a development process, and you have to have a development process in order to meet FDA guidelines.

[00:51:33]
But I think that Hologic is a little more agile and adaptable to customizing it to the product that's being developed.

Q: Earlier, when you talked about DuPont and sort of moving up within that company about how you were encouraged to sort of switch and take on a business managerial role as you moved up through the company. Was that sort of the same approach at Hologic?

[00:52:08]
A: I think that Hologic had much more flexibility in what managers can do. I think at DuPont, there was a fairly firm line between what was on the technical staff, and what was on the management staff. And you didn't cross, you didn't mix the two. With Hologic, as a manager, I was in the lab every day. And I was not as productive or as creative as some of the people who were still doing research. But I never felt that I was prohibited from doing research. So that was one of the nice things about Hologic.

Q: So when compared, DuPont was much more structured and rationalized, as a larger organization. How did you approach to the whole research and developing change over time? New technology and all that?

[00:53:11]
A: I think when I first started working in equipment development, computers and software were there, but they were kind of in their infancy. There were big mainframe computers, and there were a little PDP-8's and PDP-11's, but they were not the little microcontrollers that we have now. Products were based on, primarily, mechanical engineering and electrical engineering. And software engineering was maybe thrown in, if you needed to do some data analysis or something like that. But it was very much mechanical and electrical ruled. And now, I think we use almost--you try to make everything in the software, because the software is cheap and it's flexible.

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And you try to make the hardware, I don't know if generic is the right word, but you just want to make the mechanical stuff and the electrical stuff once. And then do everything else in software. So there's a shift from hardware-oriented things to software oriented things that have happened over the last 30 years.

Q: So essentially, you're doing as much modeling within your computer as possible before you hit the machine shop?

[00:54:34]
A: Yeah, and that's a good point, is that the tools, the tools for doing mechanical design and development are really powerful. Back when I started, there was a room full of draftsman who would make drawings that sent to machine shop. Now, there's AutoCAD or whatever tools they use. You can put together a mechanical design, make sure there's no interferences, look at it in all three dimensions. And send it electronically down to the machine shop and have it actually electronically produced. And now, we've got 3D printing. That's really radical. We just got a 3D printer as I was leaving Hologic. I would love to play with that.

[00:55:34]
So that was increasing use of software. Use of distributed intelligence in the system. Micro computers have become very powerful and very cheap, and it used to be, you just had one computer that was controlling the experiment or the equipment. Now we've got distributed what little microprocessor that controls this, little microprocessor the controls this. And they're all talking to each other. So you try to have lots of little computers that are distributed throughout the system that are controlled by some master controller. But that's something that didn't exist back then.

[00:56:17]
Another thing that's changed I think is the leveraging of mass produced electronics in medical. Products that come from Telecom and entertainment. You think about how many cellphones there are in the world. There's probably five billion cell phones in the world. And so anything that goes into a cell phone is going to be very inexpensive. And so we try to look at stuff that's in

a cellphone, like accelerometers, magnetic sensors, displays, GPS. We try to use that as much as possible in developing stuff, just because it's very low cost.

[00:57:01]
We also look at their industry standards. There's something called a CAN bus.. I have that. It stands for Controller Area Network. It comes from the automotive industry. And so, again every car that exists today has a CAN bus. in it. And every car that exists has microcontrollers all around it that are talking to each other over this CAN bus.. And used that CAN bus. in our Dimensions tomosynthesis product. And it was really, really powerful, very successful. So that, borrowing ideas from the automotive industry, from the communication industry and so on, and putting them into medical.

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And I think that most medical equipment would not be affordable if we didn't do that. So that's been a big change. Another thing that's changed in my tenure, is automation. Now we have tools that automate the development process, tools that automate the design process, that automate design documents. You have tools that actually create software code, and tools that automate testing of equipment. And so, it used to be that you'd write a specification, give that to a software engineer. He or she would look at it and try to figure out how to turn it into code. There are tools now that you can actually write specifications, and the code will be generated to meet those specifications.

[00:58:40]
And test cases will be generated to test that, once you've got the product done. So the use of automation is really powerful.

Q: So what's sort of the research and development process for any given thing you've done? What happened then, when you invented and had to go through the process of patenting something new?

[00:59:18]

A: Yeah, this is, I put this in the general category of development process. And there are different ways to think about this. When you're in the lab just exploring, research notebooks are very important. You have to document what you've done. If you're trying out some sort of experiment or putting together a prototype, document it, have somebody look at it and say, and date it, so that you have proof that if it's a real invention, that you've got proof that it was something you came up with, with a name and a counter signature. From there, it goes to, we have a patent liaison, which is usually a technical person who is interested in patents and has moved into the legal department. We put together notice of invention, which is reviewed by the patent liaison or the patent attorney.

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And if it's really viewed to be a unique invention. They would go ahead and write a patent with the help of the technical person and submit that for approval by the patent office. So that's sort of the patent piece of things. Another important thing is the financial analysis. And DuPont was very formal about that. They actually had spreadsheets that you would put everything in, and it would tell you whether or not it was a plus or minus, positive or negative investment. I think Hologic is much more informal. I don't think that there was any financial analysis done. That's probably not true.

[01:01:11]
But I don't think there was nearly the amount of formal analysis done when we came out with a tomosynthesis product. Somebody just, "That's a really good idea. I think it's going to be a blockbuster. Let's do it. And we did it, and it's been very successful.

Q: So once that was done. Maybe I put the cart before the horse here. When you developed a new machine or a new method to doing things, how did you test its efficacy? And did that part come before or after you'd secured a patent for it?

[01:01:46]
A: The patent process is kind of independent. Before you go into development, you need to make sure you're not infringing on anybody else's patents. And that's important, because you don't want to get down to the end of the road and say, "Oh you can't do that. I've got a patent. Somebody else has patented it." But if you're applying for a patent, that can kind of go in

parallel with development. So you don't actually have to have the patent before you start development. But you want to make sure you're not infringing on somebody else's patent.

Q: That sounds like something it would almost take a whole department of its own.

[01:02:27]
A: Yeah, and we did have a patent department in DuPont. Hologic just has an outside contract organization that does patents for us. So the testing of the efficacy, that's something that comes-- you have to do that before you can get-- you don't have to do that before you get a patent, but you have to do that before you can get FDA approval to sell the product. And we have a test group that does just that. The process, the development process is, you start out by putting together a set of requirements. This is what the product has got to do. And then you put together, based on the requirements, you put together specifications.

[01:03:28]
And there's a lot of discussion about the definition of requirement versus specification. But I like to think of it as, requirement is, this is what the product has got to do and the specification is, how it's going to do that. How you implement the implementation of that requirement. And then, based on that, a test engineer would put together test cases that would test whether or not you met that specification. And whether you satisfied that requirement. And the test cases would go into a test plan or a test document, that would then be executed when they have prototypes available to test.

[01:04:11]
So that's how we do the testing. You want to show, first of all, that you've met the specification. But you've also satisfied all the requirements. The test cases are reviewed by the design engineers and cross-functional group, to make sure that they really are valid test cases. That you haven't missed some. And that's one of the potential pitfalls when you're doing testing, is that you either miss a requirement or you don't test a requirement correctly. So you've got to review those test cases very carefully to make sure that they really test what you think they're testing.

[01:04:55]

And there's a lot of horror stories about things that have gone wrong in the field because the test case was wrong or something like that. So that's very important. The test cases, the whole development process, the requirement development, the specification development and test case development is subject to audit. And we regularly have audits by internal quality control. We have quality control groups in both companies. And we typically have one every quarter, and they will choose a topic or a product that they want to look at. And dig down into the design documents and see if they hold together. Also, FDA inspectors will typically come by once a year. They can have surprise audits or they will, if you're coming out with a new product, they will typically come in and have an audit. And they will dig into your development process and look at your design and development documents. And look for problems.

Q: So do they have the power to show up unannounced?

[01:06:08]
A: Yes they do. Yes. And I think I've only been through one of those where person showed up unannounced. I think he gave us one day's notice. It turned out okay. But, yeah, they can come unannounced. And they can go, not only to a development site, they typically go to the manufacturing sites, because that's where most of the problems are found. That's not fair to say. But it does happen, yes.

Q: So if you're working on something and, like, how early in the process do you let the FDA now that you're working on something, and they need to be involved? Generally?

[01:06:57]
A: I don't think we get them involved until we put in a request for, there's two kinds of approvals that we get from the FDA. One is called 510K, and that is, so in order to-- you basically submit all the documentation that they ask for, for this kind of approval. And that doesn't come until you have done some level of testing in-house. They don't get involved during the design process. I think it's more during the testing. And so, you're pretty far along by the time you get the FDA involved.

Q: Like, how far out are you from being able to sell something, when you get the FDA involved?

[01:07:43]

A: That's a good point. It can take a year or more to get FDA approval, especially if something goes wrong. They may ask for more information. They may say, these clinical trials are not effective. You have to do them over. So the FDA approval can go, stretch into years. So you want to, don't want to do it too late. But you actually have to have some data to show them. So you have to have prototypes. You have to be able, in our case, to show them images, to show them some test data, to show them that kind of stuff. So sort of halfway through development is probably a good time to start thinking about that.

Q: So in addition to the FDA, who else did you have to convince to adopt something new? Individual doctors, hospitals, health organizations, insurance?

[01:08:38]

A: Yes, all of the above. That is not really something that R&D gets involved in too much. I was involved in a little bit, but not too much. I think getting the FDA clearance is the biggest hurdle. Once you get that, pretty much, everything falls into place. Once you get the FDA approval, probably the next thing to do is to, for a new procedure like tomosynthesis, is probably not covered by health insurance. Because it's too new, and they don't know how effective it is. And so we have a group, both in Hologic DuPont, that actually worked with the healthcare organizations, primarily Medicare, to convince them that this was a useful procedure and they should consider it for reimbursements.

[01:09:36]

And figure out what the level of reimbursement was, is, should be. And with tomosynthesis, that was a big deal. And I think the reimbursement for-- actually it was a big deal for digital, too. I think the reimbursement for a film X-ray was like $50 dollars or something like that, per exam. And I think they were able to negotiate a reimbursement of $75 dollars for a digital X-ray, I think. I may be misquoting that. But I know when tomosynthesis came out, I think they were able to negotiate $150 dollar reimbursement for examination. So that was a big deal.

[01:10:24]

And obviously, if you don't have that reimbursement, somebody's got to pay for the exam, and the patient's probably not willing to do that. So convincing Medicare and the other insurance agencies is a big deal. Besides FDA, there are other compliance organizations, safety compliance organizations, we have to satisfy. There's Underwriters Lab, UL. There's C.E. Mark, which is sort of the European UL. FCC, we have to show that our equipment doesn't interfere with other people's equipment because of radio waves. And there's a bunch of different certifications you have to get. There are independent labs that do that for you.

[01:11:18]

You send your equipment out to an independent lab and they make measurements on it, and say, "Yup, it passes." So there's a lot of customers. Early on, when I was working on different projects, I found that doctors were very interested in hearing what I was working on. And people like Jim Coley, we would, he would set up a meeting with a radiologist, and we'd go in and talk about what we were working on. And they were interested and very engaging. That doesn't happen so much anymore. Sometimes we get feedback, mostly negative feedback, on the equipment that we put out there. But they don't seem to be so interested in talking to R&D, as they used to be.

Q: I wonder why? Is that resistance to change? Or just a change in the industry as a whole?

[01:12:14]

A: I'm not sure. Maybe I've just fallen out of the loop. I'm not sure. The times when I have had the best interactions directly with the doctors was when we were doing clinical trials, and we spent a lot of time at the clinical trials. Sometimes it was just keeping the equipment working. But just to see how things were going, and make sure everything is working properly. And you get a chance to talk to the radiologist. Especially the radiological technologists, the person, the women who actually carried out the procedures. They were always really happy talk to you and give you feedback on what you can do to improve the workflow.

[01:13:00]

Or what they liked about little things, like the feel of the switches and stuff like that. They were very forthcoming. One more thing I wanted to mention was that we have had special interactions with, we have universities that we like to work with. And they're always anxious to get a hold of the latest equipment. And in return for that, they typically would use the equipment, and do

clinical studies to see if there was an improvement from one technology to another in the ethnicity of that procedure. And they get research papers out of that. We get lots of talking points for marketing material. And those relationships have been very productive. So that's another source of testing.

Q: So the next question I had was in my list. I think we talked, we covered pretty well earlier about management practices changing over time. But something that has sort of cropped up in my mind, as we've been speaking, in addition to change over time, there's also, DuPont and Hologic, a change in scale of the organization. I'm wondering like what sort of impact do you think that had, in addition to changes in management practice, too. Because Hologic sounds like it was a much, much smaller company.

[01:14:59]
A: It's possible to know everyone.

Q: Exactly, yes.

[01:15:04]
A: Totally impossible in DuPont. I think, develop some really, really good interactions. I think there was a lot more communication within Hologic between the different disciplines, mechanical engineering, electrical engineering, software engineering. And I think that there was more interaction between development organizations and, let's say, manufacturing organizations. And I think that the development group was very close with the manufacturing group in Hologic. It had to be, because we were developing, not just equipment, but processes for making that equipment. And that was done hand-in-hand with manufacturing.

[01:15:54]
So I think that there are very close relationships within Hologic between the different groups. There's another group that I haven't mentioned, it's the field service group. They're the people who have to go out and fix things when they break. And the field service group was very close to the R&D group in Hologic. They would come to us often with problems that they couldn't figure out. Or ways to fix this problem. And those interactions were good at getting feedback, back into the development process on how to do the next equipment. Or how to improve the equipment.

Q: So there'd be a note to that. Oh, this component tends to break a lot, like that type of thing?

[01:16:41]
A: Yeah, or I see lots of customers who, we have trouble with this piece of the product. Maybe that should be done, redone, somehow in the next iteration.

Q: The next question I think we talked about a lot, about how research and development practices changed over the course of your career?

[01:17:03]
A: Yeah, I think we've covered a lot of that. I've already mentioned, that there was a shift from hardware-based products, to software-based product. That's huge. There has been a move from a formal phase gate development process, to a more agile process. Where, if it gets to this extreme, I've actually seen, there's an agile development process in software, where you would have a test engineer and a software engineer sitting down together, doing the development and the testing at the same time or just, you know, concurrently. And that's not as applicable to hardware, where you have to build something in order to test it. But in software, the building is very quick, and so you can get feedback very quickly and whether or not it's working.

[01:18:01]
I think that we used to have isolated, specialized teams. And that's moved more into integrated, generalized teams.

Q: Is it like a more multidisciplinary approach?

[01:18:14]
A: Yes.

Q: Okay. Ever work with any historians?

[01:18:19]
A: No I haven't. I can't say that I have.

Q: But it would be like, instead of sort of being siloed off, you'd work with more people from different fields relevant to the company?

[01:18:35]
A: I would say that's especially true between development and manufacturing. I mean, within development, you'll always have to have the software engineers talking to the hardware engineers. But moving over into the manufacturing side, that's been interesting. I think that we've helped them to put-- manufacturing has to test every product that they make. And the development group has been, has helped quite a bit, putting together equipment that does the testing. So that's been real beneficial.

Q: So to pull back a little bit, not just to talk about a specific company, but the whole medical imaging, the business. How has that changed over time?

[01:19:30]
A: I'm sounding like a broken record, but the biggest change has been the move from film to digital. And that's had a huge influence. In the early '80's, all the images were viewed on film. And in 2015, there's essentially no film left. I think that high-speed electronics and networks, and high-res displays has enabled that move. As I said earlier, it used to be impossible with the electronics available at the time, to do the kind of things you could do with film. And now it's very possible. I think that the film companies that were not able to adapt no longer exists. The bankruptcy that killed Kodak was very public. Polaroid went bankrupt. DuPont is no longer in film. 3M is still a healthy business, but they no longer make film. They used to be a very strong in medical devices.

[01:20:33]
The two companies that seem to have been the most agile and adaptable were Fuji, who's doing really well, and AGFA who seems to be doing okay. Both of those companies, I looked it up last night, still make photographic film and X-ray film, which I'm surprised because they're both big in electronics as well. They have their own networking systems, and Fuji has a very competitive mammography system, that's similar in technology to ours. But they're doing well. Now medical is no longer a film-based thing. It's dominated by big electronic giants like Siemens and Phillips

and G.E. And when you think about electronic imaging now, it's not so much mammography, but it's CT scans, MRIs, things like that. And those are those are big moneymakers for them. But there's been noise. G.E. is having problems right now, and there's been noise about them divesting their medical business. I've seen that in the journals.

Q: I was not aware of that.

[01:21:49]
A: Yeah, and IT has become a big part of medical. In fact, that's what mostly medical is. Medical is moving lots of data around and displaying it and processing it. And it's become a big part of medical. And there's been some work done recently. I don't know if it's ready for prime time, but artificial intelligence, I read an article recently about artificial intelligence doing a better job of detecting breast cancer from radiographs then doctors, which is scary one on the one hand, but enticing on the other hand. I don't think it's quite ready, and I don't think I would trust the computer to look at my wife's X-ray, but I think it'll come. And there's a lot of smoke around A.I. right now. It's what everybody talks about.

Q: Sorry to keep harping on this transition from film to electronics, but I just had another thought, like with the infrastructure to support that, like storage. Keeping physical film images and digital storage, both have their pitfalls and benefits. What were some of the challenges dealing with that? I think that might kind of fall more broadly into the culture of the medical industry, trying to get people to be willing to go into new things.

[01:23:30]
Well, it was an issue. I think the requirement was that you had to keep X-ray films for seven years. And you can imagine a big hospital has a lot of space devoted to storage of films, and that the data, the digital data represented by rooms and rooms full of films, is huge. And I think making that transition was probably difficult, but it happened. And I think that's part of why IT is such a big part of medical right now, is that you've got to figure out how to get that information into a database so that it's accessible, readily accessible. It can be archived and so on. And that's still happening.

Q: I know outside of that, with sort of my peers who are still in the educational field to teach about things that happen primarily digitally, like on the internet is almost actually impossible. Because these things aren't actually meant to last. I mean, I know that's comparing apples to oranges, where you need the film and the images to last.

[01:25:03]
A: I didn't understand. So what doesn't last? The CD's or whatever?

Q: Just a lot of it. I wouldn't say all of it, in general, but people trying to teach what was the 2004 presidential election, like the online footprint from that, even though it was sort of like our first election that had wide use of the internet, is very difficult to track down now. Compared to something from, say, the election of 1980 where you were still dealing with everything on paper.

[01:25:38]
A: Okay, I understand. The internet's not very well organized. And I am sure that the medical departments and the IT staff that supports medical departments does a better job of organizing their archives. I mean they have to. So I think it's probably more centralized than what we're talking about. It's not all over the internet. It's centralized in some place, in a hospital, and maybe there's an archival storage that goes off-site. But it's got to be very well organized, and it's got to be possible to recall the information whenever you need it.

Q: This cultural aspect really, has kind of stood out as something that's fascinated me with our conversation today. In 1990, when you were starting to do this, it was entirely conceivable that you were trying to sell this to doctors who, at the extreme old end if they hadn't retired yet, could have been in practice since the latter half of the 1940's, at the most extreme side.

[01:26:42]
A: That's right, yeah. And there was a cultural resistance to phasing out film. And it was for that reason, partly a pleasure to work with younger doctors when we could.

Q: All of those changes. So anyway, to get back on track, if you could imagine a typical day from any part of your career, what would your schedule might have been like? What would you have usually done?

[01:27:18]

A: I chose to pick a day when I was working on Selenia, because that was probably the most exciting time of my career, sort of the height of development, which would have been in late 2001. By then, most of the subsystems were pretty well-defined and were pretty far along and had been built up into a breadboard at least, so we could piece things together and make some decent images. We had decent images coming out of the lab. Our TFT supplier, thinner film transistor array, which I haven't really talked about, that's really the heart of the detector. It's the thing that captures the charge and sends it out to the computer. It's very important component. We had to have a completely new TFT developed by our supplier.

[01:28:19]

And we had several lots and tested them and found that they were working okay. But they didn't fulfill all the specs. So we had to go a couple of iterations with them in order to get the TFT array where we wanted it. The selenium coating, selenium is the X-ray photoconductor that we put on the TFT did actually absorbs the X-rays and turns it in to charge. The coatings were in progress. The electronics was prototyped. And the software was just beginning. So I would spend a lot of time in the lab evaluating things that came in, either TFT's or selenium coatings. I'd spend literally hours in the cleanroom, evaluating these components. And developing processes for putting them together in manufacturing.

[01:29:15]

We had multiple, at least weekly, teleconferences with Korea to discuss issues with our TFT supplier to develop action plans for fixing those problems. And just to keep in touch. Korea is about 12 hours out of phase with us, so a lot of these phone calls involved staying at the office until 8:00 o'clock at night or getting in the office at 4:00 o'clock in the morning, so we could have these conversations at reasonable times in both time zones. So we were burning a lot of long hours in those days. We had regular group meetings to review the status of different components, issues, and develop plans to resolve the issues. We were just in the process of developing the specification between the X-ray generator, which I told you came from Lorad, and the detector.

[01:30:25]

So there was a lot of specification. There was office times putting those specifications together, just trying to keep everything documented. We had almost daily coordination meetings with internal groups. That's the software, electrical, mechanical engineers, talking with the manufacturing as they began to ramp up. And external groups, which are mostly suppliers. Management was very interested in our work. So we had management coming in all the time. We had to give them dog and pony shows and make them feel good about what we were doing. Give them demos, PowerPoint presentations, make them feel good about what was going on.

Q: I'm sorry to jump around a little bit here, but when you were working on this, were you working out of Delaware or up in Massachusetts?

[01:31:23]
A: Delaware. I've always been stationed in Delaware. Very little of this work went on in Massachusetts. It was all between Danbury, Connecticut and Delaware. So the detector was developed in Delaware, and this system was developed in Danbury. The system, being the X-ray generator, the workstation. And then, the detector was put into that. I spent a lot of time in Danbury, by the way, but very little in Massachusetts.

Q: Sorry to jump in there. I just realized that that wasn't clear. So what was the difference between a good day and a bad day?

[01:32:13]
A: I would typically come to work knowing what I wanted to accomplish. And on a good day,. I would go home feeling really good that I had accomplished everything that I wanted to accomplish. That things just went smoothly, and no conflict, no surprises, no problems. **A** bad day you go home and feel like you've moved backwards, that everything went wrong. Maybe you had some personnel problem you had to deal with, took you out of the lab. So I'm sure it's like a good day and a bad day in any profession. You just, you know, being frustrated at not getting done what you thought you wanted to get done.

Q: Did you work across with other companies? And how did you build those sort of cross-country relationships?

[01:33:08]

A: That was something that I actually spent quite a bit of my career at, and I ended up being pretty good at it. I was officially known as the ambassador to Korea. I think I spent, one year I went there six times. That's where the TFT supplier was. We fostered pretty good relationships with the suppliers. That's critical for good supply relationships. Most of our critical components were actually sourced from outside. The TFT was one, selenium was the other. That was sourced from a company first in Canada, and then in Germany. ASIC's, or application-specific IC's, we had a lot of custom ASIC in our product. And we had those developed and manufactured by a company in California. And X-ray tubes were developed by a company outside Hologic.

[01:34:27]

At some point, it was decided that selenium was too important, and we had a lot of trouble with selenium supply, it was too important to be contracted out. And so, Hologic actually bought the company that made the selenium and moved in-house. And so, the selenium coaters are here, or in Newark, Delaware. And that was a big project, to get that up and running. But it turned out to be a good idea. We did not buy the TFT supplier. Those plants cost a billion dollars. They're huge and have thousands of employees. And we decided that was okay. We didn't need to be in the TFT business.

Q: What was the name of the company in Korea you worked with?

[01:35:15]

A: I'm not sure if I can say that.

Q: Okay. I figured there was a reason, but I had to ask.

[01:35:22]

A: You would know them. They probably made your telephone.

Q: All right. Okay, so where were working through?

[01:35:40]

A: One of the problems with the TFT, let me back up. A TFT is a thin film transistor array. It's normally part of a liquid crystal display. It's the thing that defines the pixels in a liquid crystal display. And when they make a liquid crystal display, they take a TFT, which is millions of little transistors. They coat it with liquid crystal. And then, they excite the transistor, which causes a phase change in the liquid crystal, and you get some visible thing happening on the screen. So every LCD has a TFT array in it. So TFTs existed, but we wanted to use them sort of upside down. Instead of using him to display images as an output device, we wanted to use them to capture images as an input device.

[01:36:39]

And so, we would use the transistors, not to flip the liquid crystal, but to collect the charge that was coming from the X-ray and then read that out. So we were basically using it the reverse of how it was used in the liquid crystal. And so we couldn't just take a TFT that was made for LCD display and use it. We had to have a custom design. And so we had to put together a set of requirements and specifications for how that design would work. And that was a big deal. And the design turned out to be a little tricky. There were some special requirements for our application that are not there in the liquid crystal, LCD application. And so that was a challenging design for the company.

[01:37:37]

And the statement of that specification, and the clarity and precision of that specification was very important in communicating with them. Because they were working on something that they were not used to. But it worked out. And that's something that you need to be aware of. The quality and how the specifications are being met, is something you have to monitor continuously and re-evaluate over time. And hopefully improve and look for process upsets, that cause the TFT rate not to meet specifications. And another issue that we had, well, I'll get to that. There were other relations I had with, actually, competitors. The medical community is very small. And I keep seeing the same people over and over again.

[01:38:41]

And we would meet each other at trade shows, at technical conferences. And you get to talking with people. I got, actually, fairly friendly with people. There are no problems calling people up, saying, "How are you doing?" Or, "I have a problem I'm working on. Is there something you can do for me?" And I think those kinds of relationships were very valuable.

Q: So we've talked about the FDA. Did you have any other interactions with government?

[01:39:23]

A: Not so much. There was one. The Delaware government, that was primarily who I worked with. The interactions I had with the federal government was the FDA. The Delaware government took a lot of interest in our business. It's a fairly small business, but there's a Delaware business development, this group that is interested in fostering small businesses within the state. And when upgraded our clean rooms, I think is when we brought the selenium coaters in from Germany, we received a business development grant from the state of Delaware. And I'm not sure it was, it's not a huge grant but it was significant. And so they wanted to get involved and see how we used that money, just to get to know us a little better. So that was a nice interaction, and it was a nice little perk for the manufacturing group, to get that development grant.

[01:40:39]

I've had a lot of visitors, dignitaries, I guess. I know Tom Carper came through the lab once. And there was another guy who was very interested in our work and would ask for demonstrations and just a status once, just come by and see how we were doing, which is kind of nice. I think he was a governor at the time. Or was he the senator? I don't remember. Anyway, he was one of the two.

Q: Joe Biden ever come through?

[01:41:13]

A: No, I've never seen Joe Biden. I have seen Joe Biden at the country club, at a golf club, but I've never seen him in the lab.

Q: So did you ever have to convince insurance companies to cover new procedures? Or did they kind of follow suit, once FDA and Medicare were on board?

[01:41:36]

A: Yeah, we actually had a group that did that. And once we had FDA approval, then that group would get into gear and they would work with Medicare and the insurance companies to negotiate a reimbursement rate. I never got involved in that process, that I know. It was always a big deal when we got approval for reimbursements. That makes it much easier to sell your equipment.

Q: And were you ever a partner in a trade organization? Were they an important part of your day-to-day job?

[01:42:13]
A: I have participated in professional organizations, the American Physical Society is one, SPIE, which is Society of Photo-Optical Instrumentation Engineers. And that's a very good society. They have a conference on medical imaging every year. It's always in Laguna Beach, California, or something like that. And they devote three days just to medical imaging. And that's a very good place to present papers. I think I've done several papers there. And RSNA is Radiological Society of North America. That's a big professional organization. And they have a trade show every year, which is the biggest trade show. Not the biggest trade show, but the biggest medical trade show in the business, in the world.

[01:43:11]
It's every year, starts the Sunday after Thanksgiving. So it always ruins your Thanksgiving. We would always show equipment at RSNA. It's a full three or four days where people come by, Radiologists, technologists, students, everybody and look at the different booths that are there. All the big companies are there, Hologic, Siemens G.E., and it's a big trade show, quite a big deal.

Q: How about any, I always trip over myself here, how about any philanthropic organizations?

[01:43:57]
I was involved with something called Delaware Breast Cancer Coalition, which was a support group. And I met a woman who was in their management. And she was very interested in Hologic. And we invited them to our building, or to our labs, and gave them a presentation just to show them what we were doing. And kept in touch with her after that. I didn't really have a lot

of involvement. I have been in touch with the American Cancer Society. They ask us every once awhile to bring people in. We've had a group of students. We've had group of doctors. We've had a group of technologists. And we give them demonstrations of our equipment. And then, we have tried to host students, mostly from the University of Delaware.

[01:44:58]
But we've had other students from Del Teach, I think, people who are actually studying radiological technology. And we invited them in to give talks and show them what we were doing.
Q: I need to start watching my time before we close. Let me combine these next two questions on my list. So what are you the most proud of? Or what was your favorite part of your job? And what was your least favorite, or something that you would do differently?

[01:45:37]
I've been really fortunate, lucky in my career. I think I've worked hard and I've developed good relationships, but there's an aspect of luck that's involved in being successful. And it's good to be lucky. I did want to tell you the story about my wife, if that's okay. In 2006, there were not any Selenia systems placed in Delaware. We had several systems that had been placed outside the Delaware. There was one at Johns Hopkins, Mass General, the big hospitals. But not Delaware. The Selenium system was placed, actually down in Glasgow, Glasgow Medical Center in 2006. And my wife was due for a mammogram at that time. And I said, "Well, why don't you go down to the medical center in Glasgow and get an exam on my new machine."

[01:46:36]
She said, "Sure." And so, she went in, had the exam. They called her back. It turned out that she had a lesion on her breast, and the doctor, the surgeon in comparing the prior exam from the year before which was made on a film system with the current exam, which was made on our system, said, "You know, this was a really small lesion and I might not have caught it if it had been on a film system." So my wife was diagnosed with breast cancer on the system that I developed. So I don't know if that's divine providence or the ultimate irony, but she's a breast cancer survivor. She's been, she went through the complete treatment. So we know more than we'd like to know about breast cancer treatment. And she's doing well after 15 years, 14 years.

[01:47:40]
So the favorite part of my job is seeing your effort come together into a successful product. And that has little steps and big steps. The biggest thrill I had was when we saw the first Selenia image. And especially, we have little things, we call them phantoms, in the lab. They're things that are shaped like breasts and have things embedded in them that you use to take X-rays in the lab. And you get kind of tired of looking at the same thing. The first clinical image was made at Johns Hopkins. And that was the first time I'd seen a breast image, an actual human breast imaged in our system. And it was spectacular.

[01:48:28]
The image was just fantastic, and that was really exciting to see an actual human image come out of your machine. The first tomo image was really exciting, as well. That was because nobody had ever seen one before. Well, that's not true. They did it in a lab, but on a commercial product, that was a really new thing. So that was very exciting. The least exciting, or least favorite part of the job, is disciplining people and firing people. I think I mentioned, the first job I had in AGFA was getting rid of 40 percent of my group, and that was no fun at all. And I still don't like it, but I don't have to do it anymore.

Q: I guess that's a plus side of being retired.

[01:49:12]
A: Yes it is.

Q: So what was the largest change you've seen in your field? The smallest? And what stayed the same?

[01:49:24]
A: The shift from film to digital was the biggest change that I've seen. And it's happened in all aspects of medical imaging. Another big thing is the increase in all aspects of computer and electronics performance, which is enabled, and the reduction in price, of computers and software. That's really what's enabled a lot of medical products to be successful and to exist. So those are the big changes.

Q: Can you say something quickly about the orders of magnitude by which they've gotten more inexpensive?

[01:50:07]
A: I don't have a number on the top of my head. And our product is still very expensive. I think the tomosynthesis system is pushing half a million dollars, so that's not cheap. But I don't think it would be even touchable. It would be more than a CT machine if we didn't have the improvements in electronics.

Q: It would still be half a million dollars, but in 1990 money. Thirty years of inflation we can't capture.

[01:50:36]
A: There's another question in there. What was the thing where I expected to change, but there wasn't one. And I would say, that the interaction of the doctors and the technologists with the patients has not changed at all, since I can remember. The equipment has changed, and I would have thought with the advent of tomosynthesis, that there would be a change in the way that the doctors and technologists interact. But it's still the same. They still use the same positioning. The technologist comes in, places the patient, takes the X-ray, sends it to radiologists. The radiologist sits in a darkroom, looks at it, and make the diagnosis. And that hasn't changed in 30 years. And I don't know how it would change. I mean, it seems to be a pretty effective process. But it just seems that there could be improvements there. I'm not sure what they are, but that's not my field.

Q: So do you have any other thoughts which you'd like to share, or get down on recording?

[01:51:47]
A: I would like to say that this whole process has compelled me to go back and look and dredge up some of the stuff that I had forgotten about. And it was kind of enjoyable to remember how things have changed. So I really enjoyed it. I got a lot out of it.

Q: Great. Well, thank you for agreeing to speak with me.

[01:52:10]

A: My pleasure.

END OF INTERVIEW