

Conversazione with Manuel Villafaña

On November 20, 1997

At the Minnesota History Center
St. Paul, Minnesota

James Fogerty: Today is November 20, 1997. Today we are holding a *conversazione* cosponsored by the Bakken Museum and Library and the Minnesota Historical Society. The speaker is Manuel A. Villafaña.

Thomas E. Holloran: ... nostalgia, and Manny does that for me. It was almost thirty years ago when Medtronic, then a company with revenues of just a little over \$10 million, decided that it should go more direct in its distribution in Europe. It decided that it would sign up a number of distributors who had been selling its products, but for a company called Picker, International, which was part of Picker X-ray. We didn't know at all what the credit worthiness was of these companies that we were going to be selling to, so our clever move was to look at Picker and decide that we would hire the accounts receivable clerk at Picker and persuade him to come to Minneapolis. That was Manny.

So, we hired Manny. Manny came to Minneapolis. He was marvelous in the way he helped Medtronic to get started in Europe. Within several years after that, Medtronic decided that it would try to open a South American market and, in addition, that it would try to start manufacturing in Argentina and Brazil. When we looked around at who in the company spoke Spanish, we had two choices: a Catholic sister and Manny. So with great brilliance, we picked Manny. Manny did go to South America. He claimed that we almost tried to kill him because we didn't realize how far it was from Buenos Aires to Caracas. He said as far as from Minneapolis to London, all of which was part of his territory.

I've told you the brilliance of our hiring Manny and sending him to South America, where he did just wonderful things for the company. I haven't told you of my greatest mistake, or one of the greatest of my time at Medtronic, and that is that I let him get away.

Manny, it's really good to have you do this. Thank you for coming.

Villafaña: Well, let's have a conversation. *Vamos charlar*. That's the extent of my Spanish. But it's good to see this group. I'm a little bit intimidated by the group because a lot of these people here I have had the enjoyment of working with. I can't tell you anything that isn't true, because they know the truth. But it's good to be with everyone here.

When asked to make this presentation, to have this conversation, one is always wondering when they say, well, “the historical society,” “the pioneers,” and things like that, one really begins to get a little bit concerned about age. But we’ll see later on as we go along that that doesn’t bother me too much. I thought that today I wanted to discuss, the title was “The Way Things Were,” “The Way We Were,” and I was going to play a little bit of Barbra Streisand, but I couldn’t find a record of that. I wanted to tell you that in all the pioneering efforts that were done by some of the distinguished pioneers of our community, including Walt Lillehei, who’s with us, that in all of us there was an entrepreneurial spirit. I want to first start off by talking about the entrepreneur and what he or she might have to endeavor, to begin this conversation, and then maybe go into some of the historical things that I’ve been involved with and some of the work that the group that we have put together to do these things has encountered.

So if we can have the first slide. Basically, an entrepreneur always has a dream. He has a dream of reaching the moon and doing great things. However, the entrepreneur does have to always encounter the skeptic. No matter what he or she might be doing, the skeptic will say, “What are you talking about? Everything that’s been invented has been invented,” and, believe me, this was said by Charles Duell, who was the head of the patent office back in 1899. Think about that. Can you imagine saying that back then? There are a lot of skeptics like that.

How about this one? I love this one. You know the four-minute mile. Forget it. The mile record is four minutes, 12.75 seconds. This record will never be broken. And yet, in 1954, Roger Bannister went and did it, went and did, in fact, less than four minutes. These are some of the skeptics.

The entrepreneur has to believe that, within himself, he or she is a super person, has got to have a little bit more than his colleague might be. He must believe within himself that he is better, she is better, and can do some of the things that have to be accomplished, because if you don’t have that spirit within you, there’s just too many roadblocks, just too many things that won’t allow you to get things done. You just have to feel that you’re a little bit better at the things you do. If you feel you’re the average Joe, the average Jane, it’s not going to happen.

But one of the things that drives the entrepreneur is this one. I feel this is probably one of the things that drives most entrepreneurs, and that is that one of the greatest pleasures in life is doing things that people say cannot be done. I think you will see, as we go along, some of the things that were accomplished by the entrepreneurs of Minnesota, that they got great pleasure in doing things.

Typically this is the story of the entrepreneur: “I’m thinking of quitting my job and becoming an entrepreneur. I want to experience life on the edge, full of risk and

challenges and adventure.” But then reality sets in: “Oh, really? The company stops paying you if you quit.”

“Oh, okay. Well, then, never mind.”

And it’s always interesting that as you begin to develop your ideas and your projects—and, of course, you can’t do these things alone, and you try to call your friend. “Hey, Charlie.”

“Yeah. What’s up, Manny?”

“I want you to quit your job. Come on. We’re going to do this project.”

“Oh, really?”

“Well, you know, I can’t pay you vacation pay, and I don’t know if I can even pay your salary, and, of course, I don’t know about benefits, and I don’t know this, and I don’t know about profit-sharing and all those things.”

And you really start to think. When you start thinking of these things, it’s hard to put the initial teams together. And, of course, the entrepreneur has to be prepared, together with his spouse, to work all the time. It always happens. I mean, the long hours, the long travel. And then the first big challenge comes, and you know what this is?

Unidentified Speaker: Raising capital.

Villafaña: Raising capital. Of course. Okay?

By the way, I’ve got to tell you a side bit. I went to a restaurant the other night called the Capitol Grill. They misspelled “capital.”

Anyway, whenever I’m talking to the young entrepreneurs, I tell them, “Look, if you’re going to raise capital, the key thing is honesty. And I don’t mean that you’re a dishonest person, but to be honest in the things and the requirements and the beliefs of what can be accomplished in your project. Be honest in telling how long it’s going to be, how much money it’s going to take. I mean, it’s easy to say, “Well, I really need \$5 million, but I’ll tell them I only need \$2 million, and that way I can raise my \$2 million.” In fact, if you need \$5 million, be honest about it and do that.

Always have the best technical knowledge. You, as the entrepreneur, must be the most knowledgeable person in order to do a project. You have to know the product well, you have to understand it, etc. A financial plan, the cash flow, understand how much money you’re going to need. The marketing plan, of course, without that, you’ll never know,

really, which way you're going to be going, and, finally, the key personnel. You can't do the thing by yourself. If you feel that you can do it by yourself, you probably don't have the right project.

Be ready, as our friend Harvey [Mackay] always says, to "swim with the sharks," particularly when you're raising money. I'm working with a project right now in which a friend of mine is starting a company, and he is right out swimming with the sharks. The venture capitalists come in and they want to do it a little bit different and run the company a little bit different, but, again, the entrepreneur, the pioneers of the Minnesota medical technology area, have had to do all these things. But I tell them, "Don't be afraid in raising capital. Don't be afraid to ask." My mother always used to say, "Ask. Don't be afraid to ask." Sometimes you'll get flak, but as the old saying goes, sometimes you'll get kissed.

Another thing with doing these things, I tell the young entrepreneur, be prepared to give away a lot of the pie. So often the young entrepreneur wants to start a company, he's going to own 51 percent of the business, he's going to have all the control, and the truth of the matter is, when you start to develop the project, you have to keep giving away pieces of the pie for the money, for the team that you're putting together, for a variety of reasons. But as long as you end up with a piece of the pie that's meaningful, you'll get the project done.

Be prepared to have distractions towards the goal, the ultimate goal that you want. I find this one is very true, and a lot of young entrepreneurs who are struggling, you know, they get a phone call from their old boss, who says, "Hey, Charlie. Come on. You've been working on that project long enough. Why don't you give it up and come on back. We've got a good job for you," or "a nice secure job," or maybe some other opportunities, or maybe, you know, "Let's go skiing today." It's hard to keep focused, but you have to keep focused when you're doing these projects.

Finally, I tell the entrepreneur, it's better to have tried and failed than not to have tried at all. I really encourage the young people that if they want to try a project, to study it, develop your marketing plan, business plan, get some good help, but go for it.

Part of the things I tell them, and part of the success that we've had in Minnesota is that we've been able to put teams together, not only internal teams, you know, the engineering staff, the variety of disciplines that you need within the company, but also we've been able to attract support. An example. Here we have several distinguished people who have helped us in doing projects. You know Walt [Lillehei,] of course, who has always been on hand to help us whenever we needed help in any of our projects.

This is Dr. H. David Friedberg, a cardiologist, Bill Greatbatch, a pioneer in pacemaking, people who've been able to help us whenever we wanted some scientific help.

And, of course, to do a project, they say in Minnesota you've got to find a garage. I'm sure we've seen this picture before. This is the garage where Earl Bakken and Palmer Hermundslie began the development of Medtronic, the birthplace of Medtronic.

Speaking of birthplace, let me, if I may, go to the birthplace of the Villafaña family. For many of you who have gone to New York City, you have visited Manhattan, and this is an island that continues to go down here, but just north and slightly east of Manhattan is an area called the Bronx. In a very small section of the Bronx, the Mount Haven section of the Bronx, the south Bronx, which is considered by many to be probably the worst place in New York, I was born and raised in the South Bronx.

I don't know how this picture got in here, because I was born on August 30th, and I can't believe that they found some snow, so this must have been a few months early, probably an early snowfall in New York, and it probably told me that I should move to Minnesota where I could have even more snow.

I had a little bit of an excursion to Connecticut for a couple of years while my father worked in a wartime plant up in Bridgeport, Connecticut. But then I came back to New York and joined the Kip's Bay Boys Club, an organization that really took me under their wing, as my father died when I was nine years old. They gave me my first job, and they really took good care of me.

A very important woman in my life, my mom, a Puerto Rican, raised four boys. She was always proud. She said, "I kept you out of jail." And that was true. She did keep us all out of jail. That was a challenge.

The other woman in my life, Elizabeth, I decided one day to take her up to see where I was raised up in the Bronx, and as you can see, she was scared. She was holding on to me for dear life.

Well, I didn't find a garage. I found the other thing, and that's a basement, and, of course, when developing some of these products, you've got to have the latest in scientific equipment to do this. So the latest in equipment in helping us make decisions is this instrument over here. Okay? The latest in oscilloscopes is this little thing over here, which, by the way, is very advanced because on this oscilloscope, you can also get the baseball game. And then, if somebody asks, "Who is this gentleman in the background?" I said, well, that was our vice president of trouble [refers to his young son.] This gentleman here, Jim Grabek, is a friend of mine who helped develop one of the companies that we were involved with.

Minnesota. The greatest asset, of course, that we've had has been the University of Minnesota, a source, a tremendous source of talent, skills, of all the disciplines that we

needed to help develop some of these products. As I said before, we were blessed in having teams and leaders like Walt Lillehei, who, back in the early fifties began doing a lot of work in open-heart surgery and developed the skills and sciences that we began to use. We developed a relationship with medicine and industry. Medicine told us what we needed. Industry gave the doctors what they needed.

It probably all started with this bathtub that came out of Montgomery Ward, which Walt and his team were using to cool down patients so that they could work with a beating heart that was going as slow as possible so they can keep the patient without circulation for a longer period of time. But it was very sophisticated. They had to go and buy this at Montgomery Ward, and it was for sheep, I believe? Walt? Right?

C. Walton Lillehei: Cattle.

Villafaña: Cattle? Okay. And this is one of the early pictures showing some of the early open-heart surgery that was done at the University of Minnesota.

He [Dr. Lillehei] went on to be a pioneer in a variety of things, but in particular, taking and developing the cross-circulation, in which the patient was connected to the mother. If it was a young child needing some corrective surgery in the heart, the patient was connected to the mother. He was highly criticized, often told that we'd developed a new technique that had a potential for a two hundred percent mortality [rate].

From those early works, we went on to bubbler oxygenators, then on to membrane oxygenators, which allowed us to continue to do open-heart surgery without the need of a donor like the mother. Other people that came out of there were Dr. [Norman E.] Shumway, who studied under Walt Lillehei, pioneers who went on to become the leaders of surgery throughout the world.

Some of the people that studied under Walt, that left the University of Minnesota, came back to help us. Here we have Dr. Christian Barnard, who did the first heart transplant, Dr. Zuhdi from Oklahoma, Sigwart from Switzerland. Of course, here's Walt working with us again. So it was a two-way street. The doctors came here and learned and then went to their countries, but they came back whenever we needed them.

Now, the electrical part of the business, that is to say the pacemaking side of the business that was developed here, started with this gentleman here, with Bill Greatbatch, although the external pacemaker was developed by Earl Bakken working with Walt Lillehei. The first implantable device, the first successful implantable device was started by Bill Greatbatch, with a very crude circuit, a timing circuit that was used—what do they call it? A metronome type of circuit that was used for a piano. He [Greatbatch] had inadvertently picked up a resistor of a wrong value, and he only shows this, and that allowed him to develop this circuit that eventually went on to become the pacemaker.

With that circuit, we were able to develop what became the first successful implantable pacemakers by Medtronic, and really was the event that kicked off Medtronic and the pacemaker industry in this community. These units were quite big, large, had about ten batteries in them. Some were five, six, seven batteries, ten batteries, had a limited life of about anywhere from one to three years, and were surgically implanted. I was discussing this recently with someone and said, “You know, the big thing about the pacemaker was that it had no side effects.” And before, we used to treat patients with drugs to try to maintain a heart rate that was suitable for the patient but always with a side effect. The beauty part about a pacemaker was that you implanted it, and then there were no side effects. The patient didn’t feel it, the heart rate was controlled, and it was really amazing. It had a very fast successful [rate] and developed into an industry like this.

This is Medtronic a couple of years ago, this picture, but Medtronic with a variety of devices, the pacemaker, defibrillators, heart valves, and the early—that brought Medtronic into [the industry as] a world leader today in medical devices.

Then I ran into another gentlemen, Richard Lillehei. Richard and his wife, B.J. We became friends, and I remember very clearly that I approached him with an idea of developing a pacemaker that would last a little bit longer, maybe three years, and that would be a little bit smaller, maybe 160 grams. I still remember, Walt, that I walked into his office, showed him what we wanted to do. He got from behind his desk, walked around, closed the door to his office, and he came up to me and almost like in a whisper, he said, “Do you really think we can do this?”

I said, “Yes, I really think we can do this.”

He said, “Great. I would like to give Walt a run for his money.”

At that time Walt was related to Medtronic, and he [Richard] wanted to be in the pacemaker business himself somehow, and I said, “Yes, I think we can do it.”

So, with his help, we started a company called CPI [Cardiac Pacemakers, Inc.]. This picture was taken in July—no, no. It was taken in February. [Laughter] We started CPI in this part of town on the St. Paul side of the river, and we had, again, a bunch of mavericks, a bunch of young entrepreneurs who wanted to start their own businesses, and we selected young men and women that were willing to start their own little companies to sell the products. These were what we call independent representatives. The little guy over here sticking his head out is yours truly. Many of these gentlemen went on to be very successful in starting their own companies and selling the products throughout the United States.

The pacemaker we developed was the first pacemaker that would incorporate a new type

of power source, a lithium-iodine power source. It would be the first type of pacemaker that would incorporate a totally hybrid circuit technology made in-house; although Medtronic was doing some hybrid circuitry outside of their facility, we were doing it inside, and it was the first pacemaker that was totally hermetically sealed. Those three technologies: the lithium [battery], the hybrid circuitry, and the hermetic sealing, allowed us to make a pacemaker that was a little bit small and hopefully was going to last three years. Well, it turns out that with the circuitry and the energy that we're able to save, plus the large capacity of the battery, we now have pacemakers that are still running over twenty years. I have some pacemakers at home that are actually twenty-five years old and that are still running on the original power source.

We had a tremendous growth. I was really surprised, myself, how fast we grew. In 1976, when I left CPI, we had the company already up to \$21 million in sales, a very fast growth, and I've got to tell you, the profit margins were beautiful in those days. I remember my accountant, Don Dietz, coming in and he was shaking, and he was actually sweating, and I said, "What's wrong, Don?"

He said, "Manny, I just did the numbers," the numbers we were going to report for the quarter.

I said, "Yes, what's wrong?"

He says, "We're bringing down forty-eight percent to the bottom line."

I said, "Forty-eight percent, you could go to jail for that." I said, "Can't you do anything about it?"

He said, "Manny, I've already given every employee two years' vacation. We took out two years' vacation already, and we still end up with forty-eight percent." That was before the DRG [NASDAQ Pharmaceutical Index], okay?

Then a whole new industry was beginning almost simultaneously. Back in 1954, Dr. Hofnagel at Georgetown [University] in Washington [D.C.] had implanted in the descending aorta of a patient a heart valve, a device that would allow the patient's blood not to regurgitate back into the heart. And instead of putting the valve inside the heart as we do it today, he was gutsy enough to put a valve in the patient in the descending aorta, a very crude, plastic-type model. Believe it or not, that patient lived for over twenty-five years with that original valve. And that was the beginning.

Simultaneously, a few years later, again, Walt Lillehei was working on this valve. This went on to become the Lillehei-Kaster valve, a device, a tilting-disc device incorporating some of the latest technology, such as pyrolytic carbon, to make a tilting-disc valve that went on to have thousands and thousands of implants throughout the world, and, truly, at

that time, one of the leading devices in this field. But again, all from Minnesota.

In 1976, a young surgeon at the University of Minnesota approached me, Dr. Demetre Nicoloff, with an idea of developing this valve. This was the first crude prototype of the valve that was bileaflet configuration they approached us with, to try and develop, which went on to form [the basis for] a company called St. Jude Medical. If the building looks familiar, it was the exact same building where we started CPI [Cardiac Pacemakers, Inc.]. We just went up, got a tall ladder, tore down the letters, and put "St. Jude." It was the exact same thing, except that this time we were a little bit more careful. We took this picture in July instead of February. We used the exact same building, exact same address, and everything when we started the company there.

After a lot of work, the configuration of the valve changed, and it became the St. Jude heart valve as we know it today. There were people helping us doing this, including this lady here, also a pioneer from the Iron Range here in Minnesota, Helen Heikkinen, who was the first patient, at the age of sixty-seven, to receive the first successful bileaflet valve. She lived over eleven years with that valve and died of other causes not valve-related. She was a gutsy lady. She was really a spunky lady and very, very happy to have helped us.

The company, of course, went on to develop a series of valves. Today it's the most commonly used valve in the world, with over 750,000 implants throughout the world. It is considered the gold standard, and it became a very successful financing as well. With the help of Tom Holloran, who is here with us today, we did an underwriting back in February of 1977. I'm one of those guys that does the financing before we even get the first product out the door, but we started out financing in February of 1977. Mind you, the first implant wasn't done until October of '77, and I don't want to tell you how much \$10,000 invested on this piece of paper would be worth today. You would get really ill. It was a lot of money. Tom was our attorney, and he, like my mother, kept me out of jail. We also had a nice growth with St. Jude during the years that I was there, and they've done even greater things since I've left, but also it turned out to be a very good financial success.

It should be noted that the bileaflet design was tried by Walt in one of this residents, Dr. Kalke, back in 1967 in a design, but, unfortunately, the materials, the pivot design just wasn't there so that it could be further developed. So that design was abandoned, it was dormant until we came in 1976 with the St. Jude valve.

Another industry that developed in the Twin Cities was the development of angioplasty balloons, catheters and balloons, to try to open up clogged vessels. Companies like SCIMED [Life Systems, Inc.], Angiomedics, and a variety of different companies like that again began in the Twin Cities. And again, with the help of physicians, we put a team together to develop a company called GV Medical. Again, Walt was there to help

us, Dr. Friedberg, Bill Greatbatch, Dr. [Richard J.] Gray, who is now the head of cardiology for the University of Minnesota and also Fairview, and Jim Grabek, and we developed a company called GV Medical.

That company developed the Lastac System, which, with a very unique type of catheter system, including a balloon and some fiberoptics, we were able to combine four different technologies simultaneously. We were able to combine catheter technology, balloon technology, laser technology, and fiberoptics all in one system to bring laser energy into the heart to try to open up clogged vessels. Unfortunately, the rate of restenosis was still too high, and the project was not as successful as we had hoped it would be. There's still continued work on this project under the name of Spectrascience today, and that company still is in existence.

Then I began a different endeavor called Helix Biocore. Here, with a group of engineers, what we tried to do was to try to mimic the human body and grow mammalian cells on a very large scale, to try to use secreted proteins to try to make new kinds of drugs. It was a real strong venture, very heavily capital-intensive, but unfortunately it failed because we needed the support of drug companies to give us their cell lines to work with. They were hesitant on relinquishing their cell lines so that we could grow those cells and make protein on a large scale.

Just about that time, around 1990, these gentlemen approached me. They called me up, and said, "Manny, could you come over to Europe? We want to talk to you."

I said, "What about?"

He says, "Well, we want you to develop a new heart valve."

I said, "Excuse me. I've done that before. I've been there, and I don't think it can be done."

At that time, St. Jude had elected to go direct. These were some of their independent sales reps, again, very successful business people, a lot of smarts, a lot of capital, and they said, "I think you should take a look at that." And when we started to look at it, we found out that with heart valves, there was still a significant rate of thromboembolism, that is to say, clots that would go to your brain and cause strokes. And the rate, as shown in this study done in the U.K., was about four to six percent of the patients would receive a clot during the first year, although that rate would decline with a period of time.

It was felt that one of the major contributors of the clots was the way the pivot mechanism was designed, and that is that the leaflet would go inside of a socket, inside of a cavity, where clots could begin to form. You could end up with situations like this, where right in the pivot area clots would form that would either thrombose the valve, or,

if they fell off, they would go to the brain.

So we began our work in November of 1990 to develop ATS Medical. The name is not coincidental, by any means. We strategically picked the name of Advancing The Standard—that's what ATS stands for—because we felt that many members of the team that we had put together to do ATS had, in fact, developed a standard, which is the St. Jude valve. So we felt, "Let's tell the world what we're going to do," and that is to advance the standard. The basic principle of our valve was that instead of having a cavity design, we would take the design and reverse the pivot mechanism so that the ball—we would replace the cavity with a ball, and that would be in the bloodstream where we have constant washing of that area to try to reduce the formation of any clots.

Again, Nicoloff came to our rescue and helped in the design of the valve, helped in the implantation. He was present both at the first implant in Europe, as well as the first implant here in the United States. Of course, he always asked me to come in and show him how to do it, but that's okay. We asked a lot of physicians from throughout the world to give us a helping hand, and they came to our rescue, they really did. I mean, people who said, "Manny, if you feel you can reduce thromboembolism, let us give you a helping hand." Physicians from Belgium, from Germany, another physician from Belgium, from Australia, from a variety of different places throughout the world. People that we have known over the years stepped forward and said, "We helped you with the St. Jude [valve.] If you can show us that you can do it better, we'll help you again," and they have stepped forward and given us a helping hand.

Finally, we did a study for what we call the FDA [Food and Drug Administration] of Europe, which is the TÜV, and we had to do a six-center study. We were able to demonstrate that we did accomplish what we wanted to do, and that was to reduce thromboembolism. Although we can't make any claims here in the United States until we complete our FDA work, overseas, where we are in full marketing, we can make claims based on the data that was received from that study and that show that our rate of thromboembolism was four or five times less than what you see with other valves. We were able to do it with very low bleeding rates, so that the doctors can take a look at this data and start their own studies.

A lot of people say, "Well, how are you doing, Manny?" Well, if you take a look at the first five years that we did St. Jude, and compare it to our first five years, I don't think we're doing too bad. Now, in the United States, because of the FDA, you know, we have done zero. They've only just this year allowed us to begin our work. So if you compare the international, I think we're growing about seventy percent faster than we grew St. Jude, in spite of the fact that even in international areas, we've had regulatory hurdles to overcome, things that we did not have when we started St. Jude. So I think we're doing okay.

We find today that our valve is being used extensively in all positions. Here is a triple-valve implant showing the valve in the aortic mitral and tricuspid position. I love this slide. It's really a true surgical slide, and it really shows the intensity of what's involved with a triple-valve implant.

So where do we go from here? I think that we will continue to see the growth of new products as we take into replacing different parts, different organs in the body, and, of course, the ultimate is a totally implantable artificial heart with a patient that's truly mobile. This is with an electrical battery pack. This is thing that we are seeing.

I wish I could see the next slide. We're going to have to see it together. I think I know what it is. I was wrong. [Laughter]

I'm proud to be part of Medical Alley. The work that we have done has allowed us to develop a variety of companies that have been offspring from our company, just as we were an offspring of Medtronic. As Tom said, one of the mistakes that he said was not holding onto me. It was interesting, another little quirk. I remember when we started CPI, when we wanted to do it, I went into Tom's office. I said, "Tom, I want to do this," and almost in a way asking for their help to see if this type of pacemaker could be developed. He escorted me out the door. But no, all kidding aside. [Laughter]

And the same thing happened again when we were doing St. Jude. I went to CPI, and I said, "Can we do the valve together?" They decided, no, they didn't want to do a valve. So I said, "Okay. I'll start it myself," and we did St. Jude. And then when we started ATS, I sat down with Walt [Lillehei] and with the president of St. Jude, I went to their offices, and I said, "Can we do a new valve?" and again, they said, "No." So again we had to do it by ourselves. So it isn't that we haven't tried to do it as a team. Sometimes you've just got to do these things on your own. It's amazing, as we look at this picture, and it's a pretty old picture, how many medical companies we have been able to develop.

Now, as I said at the beginning of my conversation with you, I'm always concerned when you're asked to talk about historical things and pioneers, you start getting to feel a little bit old, but I just want to tell you guys I'm not finished yet. All right? Any of you guys want challenges?

Elizabeth blessed me with a set of twin girls last year in 1996, Lisa Beverly, named after grandmom, my mother and Elizabeth's mom, and this little character here, Manuela, "little Manny" as we call her, was the reason why we had these two. Elizabeth once said to me, "I'm really concerned that if something happens to you, there won't be a Manny around the house anymore." So when the girls were born, I was going to name the other girl a name like Sarah or Jennifer or something, and I said, "Well, we're going to have to name her Sarah Jennifer."

And she said, “No, no, no. We’re going to name her Manny.”

I says, “Honey, we did not have a boy.”

She says, “I don’t care.”

So the poor kid got stuck with Manny. But, really, all kidding aside, they’ve been beautiful. They are a challenge. And I just want to say that we’re still doing our thing.

I want to thank you for allowing me to spend some time with you, having a conversation with you about the medical industry from my point of view, from the things that have happened with me. This continues to be a lot of fun. At ATS, we have developed a valve that we feel is the next step, and we’ll continue to develop other things. So, as these kids grow up, we’ll still be growing up.

Thank you very much for spending the afternoon with me.

David Rhees: We certainly have time for questions, so the floor’s open.

Question: I like very much what you said. You’ve got a wonderful history. The question that I have is, hindsight is always great. Looking back into the situation, did it turn out as well as you would have liked? What would you have done differently in those situations?

Villafaña: The easiest answer is I wouldn’t have started them, but I think that you learn from these things. Whenever you’re starting a project, you do your very best to study as much of it as you possibly can. I found that I failed in projects that I didn’t know that much about. I mean, what the hell did I know about mammalian cells? I couldn’t even spell it, okay? I remember, in trying to teach investors about mammalian cells and the project we were working on, I had to revert to talking about peaches and bananas. I had to talk about how you feed the cells and how you—well, you know, we eat peaches a certain way and we get bananas, and I had to use terms like that because there was no way that I could really talk in an extremely scientific way, although, in all these projects, you learn and you study. And as I said before, you’ve got to be technically knowledgeable if you’re going to do a project.

When I started heart valves, when Dr. Nicoloff approached us in doing a heart valve, again, I’ve got to be honest with you, I did not know the four valves in your heart. I couldn’t name them. But, by the same token, I remember him giving me a book. He says, “Where do we start?” He gave me this thick, thick book. “Read it.” We then went to the library and got a couple more copies, and all of our people all had to read—

[Tape interruption]

—things with it. We took little pieces of copper, and we'd cut little holes in them and put them in the bathtub, and we'd be sitting there in the bathtub, moving it back and forth to try to get flow characteristics, an idea of the flow. Fortunately, we had some good engineers that came up with the design as we know it today, and it went on.

Later on, Walt [Lillehei] came in to help us, keep us out of trouble, and he, too, like my mother and my accountant before, tried to keep me out of jail, kept us out of trouble, and the rest is history. But no matter what you do, you try to learn as much as you can, and sometimes you get sucked into doing projects that you don't know that much about, but you can learn, and the valve was a good example. Today our people are extremely knowledgeable about it. We can stand bellybutton to bellybutton with any doctor in talking about valves.

Tom Garrett: I'm going to suggest to you that perhaps the answer to that question relates to where you came from, that you know cardiology, that your marketing drive essentially channeled these companies that were successful. You didn't have a valve. Nicoloff did not give you the valve that we wound up with, but you and your team created what the market needed, and I think that's your particular brilliance. You recognized a market, and you formed a team that created the product that addressed the problem, and you were successful.

Villafaña: Thank you. Plus he keeps me out of jail.

Tom Holloran: Manny, I went to a conference in New York a number of years ago where you were the prime presenter, and the reason you were at this conference of entrepreneurs is that you were described as the best entrepreneur in the country at raising money, and you had raised it for at least three ventures, I think, at that time. You really had no problems, you were able to get people to believe in the project that you're bringing forward. What characteristics do you think you have that allow people to follow in that way?

Villafaña: Well, I used to use a slide that I can't use anymore. People say, "Well, how can you finance these things?" One of the slides that I used to have was a picture of the state of Minnesota, and it used to have a person throwing dice, but it was a line going through the dice, and I would say, "Well, in Minnesota we don't have gambling." As I said, I can't use that slide anymore. I said that in Minnesota, we always have a little bit of gambling spirit, and the reason I've been able to raise money is not because of me, but because of Medtronic and the success that Medtronic had in making a lot of people wealthy and because they were medical, they were electronic, they were pacemakers. So when we came along with a new pacemaker, it wasn't that easy, believe me, to raise money. Believe it or not, we had to raise \$50,000 to start CPI, and the money had to come in in checks of \$2,000. Okay?

Tom, I'm glad you're here, because I've got to tell this story. We had to raise \$50,000 by a certain date. It had to be by the end of February. Fortunately, in February of 1972, there were twenty-nine days. I had that extra day. The investment banker, Craig-Hallum, said, "Well, if you raise \$50,000 on your own, we will help you go public with a big offering of \$450,000." Okay? That was it.

I said, "Okay. We'll do it."

"But you've got to have it by February 29th."

"Okay."

So we got checks in the mail from friends and anybody we could find on the street and steal it from them or whatever. But finally, on the last day, the 29th, the last check came, and it was delivered by the postman. We were waiting by the postman there, and sure enough, it came. It was like about one o'clock in the afternoon. The check had to be in the bank, deposited in our account, by two o'clock, because, as you know, after two o'clock it goes into the next day. So the check came, and one of the other guys with me, Tony [Adducci,] we jumped in my car to run to the bank, to go to the bank. You won't believe it, but it's God's honest truth. We jump in the car, and I ran out of gas right down the street. And we're on the street.

How long does this *conversazione* go? This is a long story.

We were on the street, and there's a gas station, you know, about, I don't know, a hundred yards away, a couple hundred yards away. I said, "Tony, stay with the car. I'll go and get it."

So I go over there, and I grab a can, and I fill it up. You know, first of all I ask the guy for a can and he says, "Here's the can." I fill it up. He says, "That's six dollars." I only put a dollar of gas in the can.

He says, "That's six dollars."

I said, "What's with six dollars?"

"Five-dollar deposit for the can."

I looked, and I don't have it. I had a dollar, and I did not have six dollars. He says, "You can't have the can."

I said, "What do you mean? My car's right over there." He would not give it to me. I left my wallet, "Here. Take everything," and I ran. [Laughter] So, we finally got to the bank,

and everything was fine.

But then that story doesn't end there. The rest of this story goes to Tom Garrett. In May—this was February, and in May we did the public offering. In those days—and correct me if I'm wrong, Tom—in those days we were working with another attorney called Tom King, also very well known because he's helped a lot of medical companies in town. Tom King was representing CPI. Tom Garrett was representing the underwriter, Craig-Hallum. So Tom had to take the last document on May 26, 1972, to Chicago or Washington, I forget, to get some final stamp from somebody. Okay? And so he calls back at 9 a.m., and he says, "Okay. I got it. I got the stamp and everything. We can go public."

Tom is in the room, and Tom says, "No. I want to wait until I see it."

I turn around to Tom. I said, "Are you kidding me? This is a fellow attorney, you know."

He said, "Okay. Okay. Okay. Okay. I'll let it go."

So finally we went public. Well, Tom King, who was in Chicago or Washington—what was it, Chicago? Chicago. Gets on a plane to come back. He lost his briefcase with that stamp. [Laughter]

So, those were some of the trials and tribulations of being an entrepreneur and raising money. Those are some of the stories. But it went on to become a very successful offering. We opened at \$4.50, was the opening. We started trading at \$9.00, and we closed the first day at \$11.00. You don't see those anymore. Right, Mark? We don't see those anymore.

Dr. Walt Lillehei: There's a story that was given at St. Jude's medical meeting last year. It was one dollar in 1977, invested. That's for the stock offering. It's now worth \$51,000.

Villafaña: Yes. That's the St. Jude one, but the CPI one was even better than that one. Harold? [Addressing a member of the audience.] This is Dr. Katkov.

Harold Katkov: I'm a retired pediatric cardiologist, and first I think Walt [Lillehei] and I should give Manny an M.D., because he talks like one. I was a student and got involved with Dr. Lillehei by going up and asking if I could work with him, because I was fascinated by a lecture he gave in the junior year. I think Dr. Lillehei had a scientific entrepreneurship that is without equal. He just loved this idea of fixing hearts. If I remember right, Dr. Wangenstein had a Ph.D. and the Ph.D. was not in physiology of the heart. Correct me, Walt. I think it had something to do with something to do with the stomach. [Wangenstein's Ph.D. was in surgery.]

The next morning, he started operating on dogs. I think the blessing of Dr. Wangenstein is that he knew he had a genius on his hands, was very vigorous, and he let him know it. Those of us who were around in the early years listened to ideas that just kept flowing. I was a student here. But he talked about heart transplants, lung transplants, the [shocked suit.] I have notes from 1952 about three people in a G suit [anti-gravity suit]. Well, of course, that's standard now. He talked about heart-lung transplant, and he did one. He did the first heart-lung transplant in the world when he was at Cornell [University].

I think he was a little annoyed with me that I didn't go on in cardiac surgery, but I think it's because I like to talk a lot, and when you're in the operating room all day, you can't talk, so I became a pediatric cardiologist. I think he was pretty satisfied with that. But he helped me get my residency in surgery.

But I think the things you mentioned about being willing to help are absolutely true, and the people that were around in the early fifties went on to carry this concept of inventiveness, concern for patients and their future all over the world. So, here we are now. I'm seventy, and I still sit at the feet of this great guy, and I know all of you do, too. Thank you. [Applause]

David Rhees: I'd like to throw out a question, and the question is, I keep coming back to this: Why Minnesota, and why do we have one of the leading medical-device industry concentrations in the world right here in the middle of a frozen tundra? You offered a few ideas, but I was wondering if you could reflect on that?

Villafaña: Well, that one I have talked about before. We have several factors here. First and foremost is the University of Minnesota and the leaders like Walt and Wangenstein, who developed the first heart surgery and the things around the heart. Secondly, of course, we have the Mayo Clinic that, at about the same time, was developing the open-heart surgery and the equipment, and we have some great doctors of the world that came out of there. That was the medical side.

On the industrial side, we had the Control Datas, the Honeywells, the 3Ms, the industry side of things. On the third side of the picture, we had a financial community that was very willing and able to look at new ventures and develop new ventures, again having made a lot of money and being successful with things like 3M and the Honeywells and the Control Datas, so there was a flush of money available and this gambling-type spirit. Because let's face it, to throw money in some of these crazy ideas, you know, "Putting a what into the body to do what?" you know, "Are you crazy?" Take a roll of the dice. And some of it is. Some of it's a roll of the dice.

Then, finally, we had some great teachers, you know, Walt, on the medical side. We had Earl Bakken. One thing that I've always learned from Earl was that he says, "Always tell your engineers to go to the library, because oftentimes they'll find that the idea that

they're working on was tried ten years ago or fifteen years ago or twenty years ago." And that is so true. Recently, a pacemaker manufacturer had a problem, a lot of problems, because of some wire left in a catheter. And I remember years and years ago, back in 1965 that we learned that if you leave a wire inside of the catheter, it's going to break. So we took them out. I remember some of the original catheters that we put at Medtronic, we learned you've got to take the wire out or else the wire will break inside.

Well, here's a recent manufacturer, one of the engineers said, "Well, we can solve that problem. We'll stick a wire in there." Obviously he didn't go to the library, because if he'd gone to the library, he would have found papers written on that subject.

So, we've had the great teachers, we've had the medical entities, we've had the industry entities, and then, of course, we've got the cold. What else are you going to do during the cold?

David Rhees: Can I just follow up on that and ask you to look into your crystal ball and make a prediction? Twenty years from now, do you think this industry will be in the same position or are there lots of other rivals in this country or abroad? How do you see the long-term picture of the industry?

Villafaña: We are faced with some real challenges today, particularly on the regulatory side of things, you know, where we cannot breathe, we cannot do things as quickly as we have to do things. I think Medtronic has answered that by saying we're moving much, if not all, of our R&D [research and development] overseas and taking it away from Minnesota. And these are the best-paying jobs. These are not, you know, hamburger-flipping jobs, these are the best-paying jobs, and they're going overseas, again, because for us to remain competitive in the industry with our competitors overseas, we have to develop products in a very timely fashion. Unfortunately, particularly for your Class Three devices and the heart valve, it takes a hell of a long time, too long. And there's got to be a change there, or else we are going to lose our leadership. And will we lose our leadership to another state? I don't know. I don't think so. To other countries, yes. Yes.

The gentleman behind me.

Question: I have a question about what's—now looking at the future which is in all likelihood [unclear] the present than the past. What do you see as the major threat to the medical device industry? Say something about gene therapy or other challenges. What do you see as the real threat to the device industry in the short term and the long term?

Villafaña: I can't see an end to the device industry. I can't. For some reason or another I go home and I always have ideas of new products. I could form three new companies right now if I wanted to, you know, if I was crazy or if my wife kicked me out of the house or something like that. But there's always new ideas for new products, but I've got

to tell you that I'm always hesitant because the regulatory cycle makes it so long that it makes it so costly, so prohibitive, that I'm scared to try a new product. I think that ATS, for me, might be the last Class Three product, although I've got to tell you I've got in my back pocket things that are itching for me to do. I love doing them, but I get scared when I think of the regulatory cycles that are now involved.

For example, I'll give you a good example. Within ATS, we feel that our next step of development is to develop our own carbon. The valve is made out of pyrolytic carbon, which we have to buy, and because we have to buy it, we don't have a competitive edge. Rather, we are behind the eight-ball a little bit because we can't compete on prices. We can only compete on technology. But to develop carbon is not a difficult task. It'll take you two or three years to do it, but to go through the regulatory cycles, then you're up to the seven- to ten-year frame. And you say, "Excuse me? I've got to do this for another ten years?" It burns a lot of people. And that's the challenge. If anything, forget about putting money into the device industry and doing this and that. Solve our regulatory. That's what's hurting us.

David Rhees: Thank you very much for a good conversation.

Villafaña: Thank you.

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