

**Manuel Villafaña
Narrator**

**David Rhees
Interviewer**

January 21 and May 20, 1998

**ATS Medical, Inc.
Plymouth, Minnesota**

DR: This is David Rhees. I'm here with Manuel Villafaña at his office at ATS Medical. It's January 21, 1998.

I very much appreciate your taking time to be interviewed. If you don't mind, I'd just like to structure this chronologically, and it may be that we don't cover everything today, and perhaps we could schedule another time to get together. But if you wouldn't mind just starting off with a little bit of your personal history, when you were born, and all that kind of basic stuff.

MV: I was born in the South Bronx of New York on August 30th, 1940. Parents, my mother's name was Elisa Maldonado Villafaña. My dad's name was Joaquin Villafaña, Puerto Rican parents. I came to the mainland, to New York, in the 1950s. I was one of four boys. I was the last, of course. My mother was forty-eight when I was born, my father was fifty-nine, so I was really a late arrival, so to speak. Attended school in the Bronx, starting with St. Luke's Catholic School on East 139th Street, and then going to Cardinal Hayes High School on Grand Concourse in the South Bronx.

DR: Could you say a little bit more about your experiences in high school? I remember reading that you got a good background in math and science there.

MV: I did not have the fortune of going to college, but feel very fortunate that Cardinal Hayes High School contributed enormously to my education. This was a Catholic high school run by secular priests, as well as religious priests and brothers from a variety of religious orders. It was a school that had four thousand boys, no girls. It was, at that time, an excellent high school, and still, in many circles, is considered probably one of the finest high schools in New York.

DR: That was Manhattan?

MV: No, it's in the South Bronx. It's amazing, I've seen news stories on television discussing how it is that in the South Bronx, where historically you have very high rates

of high school dropouts and virtually no one going to college after that, that this school has a rate of about ninety-three percent of their graduates go on to college. They are a high degree of National Merit Scholar winners, and a variety of scholarships, etc., coming out of a high school in the South Bronx today, but even back when I was attending, it was a school that was highly disciplined, highly motivated. Religious education was a very predominant part of your education, and I must say that I feel that I've received an excellent formal education in the sciences and English and all the arts, as well as some crafts, as well, drafting, typewriting, things like that that were very useful as you go into your business life.

DR: Any particular teachers that—

MV: Oh, there were lots, lots of teachers.

DR: In science or math or technology?

MV: There are lots of teachers that I still remember. In fact, my wife and I continue to support that school through our family foundation and just our own contribution to some of the things they continue to do, because they depend a lot on private contributions since the dioceses of New York have very little support now for these types of schools. It comes strictly from tuition and private support.

In addition to Cardinal Hayes, I was very active in my formative years from nine years old to twenty years old, I was a very active member of Kip's Bay Boys Club. Again, since my father died when I was ten years old, I was fortunate to find a club which took me off the streets, particularly the South Bronx streets, that allowed me to have people who really cared for me, etc. It is there that I met a lot of young men who cared for us and went on to be like my surrogate fathers, caring for me and putting me under their wing and keeping me off the streets and out of trouble.

Again, both my wife Elizabeth and I are trustees of that organization, board members, and contribute both in time and money to the continuation of the work that they do at Kip's Bay. In the club, I was able to get my first job, basically a full-time job, because, at nine years old, I was working for them quite a few hours after school, and we needed that money at home. It was just my mom and I; my other brothers had already left home. Like I said, I was very late in arriving. So the little paycheck that I got, which was many times like twenty or thirty dollars a month, went home, and we needed that kind of money. So that's my early years of life.

DR: Is there anything in your early life that sort of triggered an interest in science or technology? Did you ever dream you would be involved in high tech?

MV: I've always had a tinkering kind of mind. I always used to like to take things apart

and see how they worked, and I remember finding old watches and taking old watches apart, radios apart, and all that kind of tinkering kind of scientific [play]. The Boys Club had science clubs within the club, and I was a member of the Science Club or the Physics Club, things like that. Always did well in math and science and English, English because I had to learn English.

DR: You grew up speaking Spanish?

MV: My mother spoke a lot of Spanish. I didn't have my brothers around so much to learn the English, so English was the second language, and so I had to learn it. The science was always with me, it was always in me, but, unfortunately, we didn't have the funds to go to college. So I had to go to work really full time, and my first full-time job was at Radio Engineering Laboratories, where I became initially an assistant in the printing shop where I would read and read and constantly read, proofreading things and collating things, so that's how I picked up a lot of my technical stuff. Then I moved into the engineering department as an engineering aide, as a technician helping to do some testing of various types of electronic equipment.

DR: What did the company actually produce?

MV: Radio Engineering Laboratories was one of the most preeminent manufacturers of early warning systems, troposcatter communication type of equipment that was used during the Cold War for the BMEW system, that is the Ballistic Missile Early Warning systems that were located in Alaska and northern Canada.

DR: DEW line.

MV: The DEW line kind of things, and so it was very highly sophisticated electronics. I would just read and learn and talk to the technicians, and so, again, that's where I got some exposure to electronics. I would take some night classes after I got that job at RCA Institutes, and learned some of the basic electronics and things like that. So that when I finally did get into the medical side of things, I had a basic technical background, not that I would consider myself an engineer, but, by the same token, not to be afraid of engineering and able to challenge and learn quickly the electronics or the mechanical aspects of medical devices.

From there, I went into a career working as a business assistant to a business manager at a gasoline testing laboratory called the Ethyl Corporation, whereby I got some of the business aspects of running a small testing laboratory. It was shortly thereafter that—

DR: Excuse me. That was in New York City?

MV: That was in Yonkers, New York, which is a suburb of New York City, a northern

suburb of New York City.

DR: And the earlier company, Radio Engineering Laboratories?

MV: Radio Engineering Laboratories was in New York City, on Long Island in New York City. Chronologically, if we can put some dates on these things, going back, I joined the Boys Club in 1949; Cardinal Hayes, I was there from 1954 through 1958; working at Radio Engineering Labs around 1960; working at Ethyl Corporation around 1963.

Then, after that, I joined the Picker International Corporation, which at that time was an export agent for medical products, including the medical products produced by Medtronic, Inc. They used to handle the export. I was assigned to handle those products, which included at that time the old, old pacemakers. Medtronic at that time probably had total worldwide sales of about anywhere from one to five million dollars, very early, early stages. I started working with Medtronic as their export agent when Medtronic had maybe seventy-five employees. Soon thereafter, Medtronic hired Charlie Cuddihy to take over sales and marketing and work with Picker as the international agent. Charlie and I got to know each other, and soon he realized that maybe Medtronic would be ready to do their own exporting, so he hired me from Picker, brought me out to Minneapolis, and—

DR: Can I interrupt just a moment. Sorry. Go back to Picker just a moment. Could you talk a little bit more about what you did there and what your experiences were?

MV: Picker, of course, had two main businesses. Number one, Picker was, I think at that time, probably the second or third largest manufacturer of X-ray equipment and nuclear resonance equipment and nuclear imaging type of equipment for the hospitals. It set up the Picker International to export those products and at the same time do the exporting for small medical device companies that did not have the know-how how to go overseas, of which Medtronic was one of those companies. They hired me to be a customer service relation type of individual, someone that would be on the inside communicating with their representatives overseas, and at the same time communicating with the supplier, in this case, Medtronic, and being the middle man and handling all the transaction and handling the questions from the representatives and the international doctors, and trying to get the answers from the suppliers, in this case, Medtronic.

DR: So that was your first experience working directly with doctors?

MV: That's right.

DR: These were doctors in—

MV: All over the world, outside the U.S. That worked fine, and I got to learn the

international aspects of business, as well as learn the medical product itself, the pacemaker itself.

DR: Did you do any traveling to these companies, or are you pretty much based—

MV: I did very little traveling. I did some traveling for them. I made a trip to Latin America for them. But I did get a chance to visit with Medtronic several times, which allowed me to—

DR: You came out to Minnesota?

MV: I came out to Minnesota to learn more about the product, learn more about the company and develop a strong relationship between the companies, but it was at that time that I got to meet Charlie Cuddihy, Ron Hagenson, and several others that really got me to like Medtronic. Obviously, it was a mutual relationship, because, as I said, in January of 1967, Earl Bakken and Charlie Cuddihy came out to New York and offered me a job, to join Medtronic, and their goal was to eventually set up their own international [distribution network,] and use my skills to do that. So, in March of '67, I joined the company and I became the first international employee for Medtronic.

I then later was given all of Latin America, and so I began traveling to Latin America and became the manager of Latin America, and eventually, in 1969, I actually moved lock, stock, and barrel, I moved my family to Argentina, to live a couple years in Argentina for Medtronic.

DR: So you had gotten married sometime after leaving high school?

MV: Right. Got married in 1965, so when I moved to Argentina, had two children, had a son and a daughter. We all moved down to Argentina, lived two years working down there.

DR: That must have been an interesting experience, moving down there.

MV: That was an interesting experience. We lived in an era when there were coups, political coups, in Argentina, and actually at one point got very closely involved when a couple of soldiers said, "You cannot go down that street."

And I said, "That's where I live."

They said, "Do you understand? You cannot go down that street," with their guns in their hands.

And I says, "Okay." You know, I got involved actually with two coups there in the time I

was there.

DR: That must have been interesting. Was it difficult working with the Argentine government?

MV: No, it was a wonderful time. I really learned a lot about sales and marketing working with these doctors and reps, and it was just a wonderful experience.

DR: You say that Earl Bakken and Charles Cuddihy came to you with the notion of starting their own international distribution. I wouldn't have thought that at that period South America would have been the biggest market, but maybe I'm wrong, that they would have been looking at Europe and other areas. I just want to get the context at Medtronic. Are they also moving into Europe?

MV: When they hired me, simultaneously they were grooming Ron Hagenson to go to Europe and set up a technical center, for lack of a better word, a support center in Europe, in Holland. Shortly after I was on board, where I was supporting Ron, in other words, he was there and I was his support man, I said, "What about Latin America?"

They said, "Okay. Go and study it." And I did, and it was a big market, it was an important market for Medtronic. So they said, "Okay. Then you go to South America, Ron will go to Europe, and now we're going to hire another person that will support both of you guys," and they hired a guy named Harold Gonier, great guy, great supporter. So that was the beginning of our international activities in the world.

DR: That must have been an interesting sort of point in Medtronic's history. When you came there, you said there were about seventy-five employees.

MV: Yes, when I started working at Picker, it was about seventy-five employees. When I joined Medtronic, I believe I was employee number 141, or something like that.

DR: What was the atmosphere at Medtronic like in those days?

MV: With Charlie coming onboard, it really changed the company from a little mom and pop type of operation to a company that was going to develop into an international company, high-growth type, and also a totally new view on profitability. I remember clearly that Earl Bakken had put the ten points of, like a corporate—

DR: Mission statement.

MV: Mission statement, exactly, and nowhere in those mission statements did it have the word "profitability." Charlie came in and said, "We're going to do all these things profitably," and that was a major, major step. There was also a thing that everyone was

satisfied with making five or six percent of the bottom line, or, I think, even ten percent. Charlie said, “What is so sacred about ten percent? Why can’t we do better than that?” Charlie brought in a real, I think, more business-type, aggressive business-type view, which was needed to get the company really starting to roll. I love the guy, I mean, he’s my mentor. In fact, we still work together today. He’s on my board of directors, and we have a very close relationship.

DR: Maybe we should interview him, too.

MV: Oh, yes, definitely. He went out to be the number-two guy at Medtronic. For years he was executive vice president. I remember clearly the day that they announced that he was going to move from being director of sales and marketing to being vice president of international. So all of a sudden, he was one of the most important officers in charge of international, and that’s what we needed. My forte was international.

DR: I’m just curious about the markets here. The U.S. has always been the largest market for pacemakers, but, I guess, fairly early on it became clear that success also lay with globalization.

MV: Yes. Like most companies, none of my companies, but most companies, they always start out looking at the U.S. and then eventually get around to outside the U.S. The fact is that in pacing and in other products, the world market is bigger outside than in the U.S. There are probably more pacemakers sold overseas, but that doesn’t mean that Medtronic’s—fifty percent of their business is overseas. No, I’m not saying that. The market is bigger, but there are a lot of competitors over there, as well, and we recognized quite early, after Charlie and I really started looking at international, we realized quite early that, hey, this is a market that potentially has the same potential, if not greater, than the domestic market.

DR: So you really started tapping into that market personally, in terms of selling, first at Picker and then with Medtronic. So these were your first early years working with doctors, and it’s been said by so many people that you’re a brilliant salesman. I’m just wondering if you could talk a little bit about the relationships you formed with these doctors and how you worked with them.

MV: Early on, you learn that doctors put on their pants the same way as you and I. It was always, particularly in the early years at Medtronic and early years of the medical device industry, there was this feeling that every doctor was a god, and if he said, “Tomorrow the sun is not going to rise,” they would say, “Okay, tomorrow the sun is not going to rise,” but you know that’s not true. You learn immediately that they’re human, that they put on their pants the same way, that they have their likes and dislikes like you and I.

So, I befriended many doctors in Latin America. I had the advantage that I knew the

language. I was Latin, I was Puerto Rican, one hundred percent Puerto Rican. I was very good technically, I knew my product well, and, remember, they were in South America. Who would visit them in South America? So I would come, and I would not only treat them as friends, but I would educate them. I would teach them about pacing. I would teach them the proper ways of putting in a pacer. I would be in the operating room.

DR: You were in the operating room?

MV: Oh, yes, always, the operating room, gloves on and everything, and there have been many cases where I was pounding on the chest of a patient, because the patient went into total block, and the pacemaker still hadn't been implanted, and keeping them alive. There were cases when I would say to the doctor, "Move over, I'll show you how to do it," and put the lead in, myself, into the heart.

There were times when we actually had to go to extraordinary means to get pacemakers into a country, because there were so many patients dying. We had to use creative marketing, having pacers stored in a bank to protect the value of the pacer while we'd lend money to the patients to get the pacers. And the doctors realized this, that we were really trying to get their patients a pacemaker when the government or the medical system didn't allow for that, and these patients were very poor. So you became their hero. At times, it went to the extreme. At times, I would come back from a trip and my secretary, Norma Glaiman, great gal, very, very well educated, real professional, lots of talents, I would come back from a trip, and Norma would say to me, "Oh, Manny, are we glad you're back, because they got three operations waiting for you."

I said, "What do you mean, three operations waiting for me?" They said, "Well, the doctors won't do the pacers without you." I mean, it got to the point, finally I had to sit down with the doctors, "Look, you know how to do it. I've been here enough times. You can do it by yourself without me."

They would say, "But, Manny, when you're here, our morbidity and mortalities are much lower."

I said, "Well, come on, you got to learn to do it yourself. I can't be here all the time."

We lived through some very difficult times when we had product malfunctions and battery malfunctions and things like that, and we had patients that were really on the brink of dying, because their pacers would stop. Yet we never lost any customers, because we educated them on what was happening, we supported them, we were there.

In fact, I remember one time we had pacers failing, and to get a new pacer through customs would take you two or three weeks, and we didn't have two or three weeks, and there was nothing we could do. So we actually took two doctors, a nurse, my secretary,

and we actually flew to Miami, had a bunch of pacemakers waiting for us there. We took the pacers out of the boxes, because we couldn't carry the boxes, and we actually just took the pacers themselves, and we slipped them into our pockets. I had a coat with sixteen pockets, a special coat, and we literally smuggled the pacers into Argentina, not that there were any duties. We weren't denying any duties, but we were just trying to eliminate the need for waiting, because there were patients waiting were in complete block and having Stokes-Adams attacks, as we went to Miami, which is a very long flight, took a shower, turned around and got on the plane coming right back. We filled our pockets with pacers. I remember my secretary putting pacers in her bra. This is an interview, right? Her bra, her girdle, I remember that. I had pockets, into our suitcases and everything, just to get the pacers back, and we ran to the hospital.

We went right in, and they were waiting for us. We took out the pacers, we still had them in their sterilized pouches, so we didn't have to sterilize them, but the little screws and tools and screwdrivers, they were not sterilized, and we had to very fast autoclave them and everything to get them in people. We were just one after another doing the pacemakers that fast.

The old pacers, I still remember that the old pacers, of course, Medtronic wanted them back, because they wanted to do analysis of failure, and I says, "Guys, we all know what the failure mechanism is. You're not going to learn any more. The other fifty pacers that you've already withheld are failures." I said, "I'm going to give them to the doctors." So I kept them and I polished them all up.

I told Medtronic that I was not going to return the pacers, that we were going to use them. There was not any new thing that you could learn from them, and I took them and I stripped the rubber off, had them polished, and I made little pen sets like this [points to one on his desk.]

I had a dinner, and I still have the pictures of this dinner and all the top doctors of Argentina, and I had a dinner, with their wives. When I got up, I made the dinner toast in honor of the wives. This is totally unheard of in Argentina, you know. Honoring a woman in those days, you know, a woman was one step above a slave in some of those countries. But we honored the women, and they said, "The reason we're honoring you is because we know that we kept your husband away from you many hours, in the middle of the night and all this, for all these failures that we had," and they really, really appreciated that they were being honored. Then we gave the pen sets to each doctor, "This set is from patient So-and-so, you remember, who had the failure." "Oh, yes, yes."

DR: You actually had the name of the patient.

MV: Well, no, we didn't. No, we knew this by the serial numbers of the patients and stuff like that, and it was nice. The dinner went off very, very well, and they appreciated

it, and we never lost any customers on that one, never lost any customers, even though we had some real tough times.

But it was then that it stuck in my mind that pacers had a very, very limited and a very unpredictable life. Pacers would, normally, if you were lucky, last you maybe twenty-four months, if you were lucky, but most of them would fail in a year to twenty-four months, and abruptly. If you had a problem, like, in this case, they had a battery problem, they would fail, boom, like that. In fact, we actually would put a new pacemaker in, and the new pacemaker was already nonfunctional.

DR: Oh, dear.

MV: Oh, yes. It was really a tough time.

DR: Pretty high failure rate.

MV: That's right.

DR: What were the main causes of the failures?

MV: The battery. The battery welds would break. I could go into it, but that would be a whole other new tape. But it was during that time that I recognized that pacing was not that reliable, I mean, it was a good therapy. When it worked, it worked and worked fine.

When I finally moved back to the States, there was the problem of the square peg in the round hole, or the round peg in a square hole. There was not a position for me at Medtronic, although Charlie tried to get a position for me, and there were several that I was a candidate for, it just wasn't working out. So Tom Holloran introduced me to a company that needed a sales manager and stuff like that, making a surgical light.

DR: Worn by the surgeon, or over the operating table?

MV: There's a fiber-optic light. You put it right at the edge of the site. It was a pole light, and it was good, but it had a very limited, limited market. I said to them, when I joined the company and I saw the problems that they had, I said, "I won't join this company as a sales manager. I'll join it as a president. I'll take it over and get it up," because it never made money or anything, and finally convinced the board that they should let me be the president, and they did, made me the new president.

DR: This company was?

MV: A company called Med General, in Minneapolis, small, teeny-weeny little company with very, very limited funds and stuff like that. So I helped them raise some money, and

I got them to be profitable.

DR: Was that your first experience raising money for a company?

MV: Yes.

DR: Because that's another thing that you're known for being very good at, and I'm just curious as to how you got started in this whole—

MV: Let me go back. Just before joining this company, Med General, I forgot the most important thing that happened was that Charlie had invited me to come to Minneapolis to be interviewed for another job within Medtronic, again trying to find a square peg in a [round] hole. I was swimming with some friends at the Marriott, which is now the Marriott Hotel near the airport. I remember it was March of 1971, and I was just coming out of the swimming pool. I had to use a paper bathing suit, and I was going back to my room to change clothes, when I ran into Bill Greatbatch. Of course, Bill Greatbatch was the inventor of the Medtronic pacer and had long left Medtronic. I said, "What are you doing, Bill?"

He said, "Well, I developed a new battery, and I'm going to be visiting Medtronic."

I'm just dripping wet, standing in the hallway talking to him. I said, "Bill, would you mind if I just change my clothes, and we'll talk?"

He said, "Fine." So I changed my clothes, went over to his bedroom, to his hotel room, and he showed me what he was doing. He had developed this new battery that he claimed would make a pacemaker last ten years, which at that time was just beyond the comprehension of mankind. A pacer lasting ten years was like finding a black hole in space, you know, it was just one of those rare things.

But, anyway, I said, "So what are you doing with the battery?"

He said, "Well, I'm visiting with Medtronic tomorrow to show them the battery, and we've been trying to work together on this battery."

I said, "Oh, great," and I wished him well, and that was the end of the conversation.

The following day, I had to really officially resign from Medtronic; there was no position. I picked up some severance pay, and I received the offer to join Med General. The story, I made Med General into a profitable company selling these lights, but I also knew that there wasn't a big market.

Then, by accident, I was at a show, a medical surgical show in Russia, in Moscow, when

a friend of mine, a very close friend of mine from Argentina, ran into me. He and his wife ran into me in Moscow, and I hadn't seen him since I left Argentina. I told him what I was doing and everything, and he said, "Well, look, I'm going from Moscow to France, and I want to introduce you to some people in France that might be interested in marketing this light that you have."

I said, "Fine. I'll meet you in Paris." So we meet in Paris, and he introduces me to this group, this company called ELA, Electronica Appliqué. I came to talk about the light, but over dinner, they said to me, "Mr. Villafañá, you are known for your knowledge of pacemakers."

I said, "Yes."

He said, "We want to get into the American market."

I said, "You want to get into the American market with a French pacemaker? Forget it. Don't even think about it. Go home."

So they said, "Fine," and we continued to have dinner. But over the dinner, all of a sudden, I had what I call a stroke of genius. I don't know if it was a stroke of genius or what, but I said, "If I was going to take a French pacemaker and go into the American market, the way I would do it is, I would go to Bill Greatbatch and take his new battery, develop a pacer in the United States, not in France, and hire seven top salesmen from Medtronic, and that's how I would do it."

So they said to me, "Well, we want you to do that."

I said, "Excuse me, gentlemen, but I'm busy. I've got a company to run."

They said, "No, we really want you to do that."

So I said, "Well let me just study it."

So when I got back to the States, I called Bill Greatbatch, and I said, "Bill, is that battery still available? What ever happened to the battery?"

He said, "Well, Medtronic turned it down." They had turned down the lithium battery.

"Okay. Why?"

He said, "Well, they don't think that it can deliver the four ampere-hours."

I said, "Bill, what do you think?"

He says, “Yes, I think we can do it.” I said, “Well, I trust you, Bill, better than the engineers Medtronic had at that time. So the plan was kind of laid in the back of my mind.

Then some friends came up to me and said, “Manny, would you help us form a new company?”

I said, “Doing what?”

They said, “We want to develop a company that makes test equipment.”

I had a lunch with them, and I said, “Gentlemen, there are thousands of companies that make test equipment. That’s not the way to go.” I said, “Why don’t you make a new pacemaker company.”

They said, “What? Are you crazy, go against Medtronic?”

I said, “Why not?”

In the meantime, I knew that the Med General light wasn’t going to make it. So I said to Med General, “Med General, why don’t we make a pacemaker. I think I could do this and do that, and Med General could own part of it, and I could set the new company up.”

They said, “No.”

I said to them, “You know, the train comes by once. I’m getting on this train.” So I resigned, and I said, “I hope you guys don’t mind.”

They said, “No, no problem.”

I said, “I need a release.”

They said, “No problem.”

So I left, and I went back to Bill, and I said, “Bill, how would you like to go to France?” And on a moment’s notice, he got on an airplane and he went France. The French guys didn’t know any English, I knew no French. Bill knew some French, but I knew Spanish, and the French guys knew Spanish. So between our broken French and broken Spanish and broken English, we had the French guys agree to help me set up a company. All I asked them for was \$25,000 to get started, thought I could do it. [Brief interruption.]

DR: You asked for \$25,000.

MV: I asked for \$25,000, and they said, “Fine,” and I went back, and I started to put together—but before I started putting together some people, I went to Medtronic and talked to Tom Holloran, and I basically said, “Tom, I’m going to start a pacemaker company. I’m going to work with Bill Greatbatch’s battery that you guys turned down.”

So I went to talk to Tom Holloran, and basically said to him, you know, “I’m going to do this. Would you like to do it together?” They said, no, they weren’t interested, and so they escorted me out the door. I remember he escorted me right out the door.

DR: So this is after you had left Medtronic.

MV: Oh, yes, after I left Medtronic. This is about—

DR: It’s the lithium pacemaker.

MV: Yes, this is about April, May of ‘71. No, no, I’m sorry this is—no, correction. This is about November of ‘71.

So then I talked to three other guys about putting the company together, and they basically said, “Okay, Manny, if you’re able to raise the money, we’ll support you.” So there I was out on my own, and by this time I had left Med General, I had no job. Then both my wife and my son went into the hospital. I had to remortgage my house. I think I had to remortgage my car. I don’t remember that for sure, but I was pinned against a wall.

It was at that time that I was working with a young attorney, Tom King, who really gave me a lot of support and guidance and was just a good friend, supporting me while I was struggling to raise money to get this project done. The French, in the meantime, weren’t coming through with their \$25,000. They were dragging their feet. In the meantime, I’ve got a family to feed. So I said, “Goodbye. I’m going to raise my own money.”

So I started pounding on the door and tried to raise some money, and the first break that I had was my jeweler friend, Marv Gustafson, was trying to sell me a new watch, and I love watches. I said, “Marv, I’m trying to start a new company, I don’t have any money.”

He said, “What is it about?” I told him, and he said, “Let me introduce you to somebody.” He introduced me to Craig-Hallum, and Craig-Hallum started to express interest, and they basically said, “All right. If you can raise \$50,000, we’ll raise another \$450,000.” That was fair enough. So we started to get people to put in money \$2,000 at a time. We got a few people, and we raised the \$50,000, and we opened the doors on February 4, 1972, to develop this pacer.

DR: That was Cardiac Pacemakers?

MV: That was CPI, that was Cardiac Pacemakers, Inc., and we got it started. That's how we started CPI. Unfortunately, I did not go back to pick up that release that Med General said they would give me. In fact, I remember going by the highway with Jim Baustert, and I said, "Gee, I should stop in there and pick up that release. I'll pick it up some other time," and I never did, and then when we became successful, they took a shot at us, and said, "Well, we should own part of that."

DR: They sued you, right?

MV: They sued me. It wasn't successful or anything. We kind of settled it for \$16,000, and it wasn't anything big. But, at the same time, Medtronic sued us, was trying to find out if we had taken any secrets or anything, and, of course, we didn't. We started from scratch, because you couldn't use their circuit anyway. Their circuit was designed for a different type of power source, and you couldn't do it. We just started from scratch. One of the guys that we hired is right next door, Rich Kramp, who is my president of this company. He became one of our young engineers, and he got the patents on the first lithium-powered pacemaker. These units are still running twenty-five years later. Instead of the one year to twenty-four months, we would have twenty-four years. There's a pacemaker right over there that's still running twenty-five years, running. This pacemaker.

DR: On the wall here.

MV: On the wall over on the right-hand side.

DR: Under the large case.

MV: The eagle, then the case, and then the pacer hanging on the wall.

DR: That's still running.

MV: That's still running, twenty-five years later.

DR: That's great.

MV: This pacer is about twenty-three years old, and that's still running. So, anyway, that's how we started CPI.

DR: Could you talk a little bit more about the other people you worked with there?

MV: The other guys were a guy named Tony Adducci, who was a product manager for

Medtronic, and we were friends, and I said, “You know, you’ve hit the wall here. You’re not going to grow any more than this. We’d like to take a flyer on,” and he joined me. But he would only join me if he brought in another guy named Jim Baustert. Jim I barely knew, and my original plans didn’t need him, but I needed Tony, so we had to bring in Jim. But Jim turned out to be someone who really, through his mannerism, was a good glue and a good supporter for me, and helped me a lot and all that sort of stuff. So he made a lot of contributions to the company, and he was a shrewd investor, too, because he invested and held onto his investment for years and years and years and became an extremely wealthy individual.

DR: Was he from the engineering side or the sales side?

MV: No, he was marketing side. He was a communication/advertising guy, which in none of my companies did I ever advertise. I really didn’t.

DR: Adducci was from what part of Medtronic?

MV: Product marketing. He would take a product—he worked on this product, for example.

DR: The Medtronic 5840.

MV: 5840, the external pacers. Then there was Art Schwalm. Art Schwalm wasn’t at Medtronic. He was at Medtronic, but left, and he was building mobile homes, but he had the production capabilities, so we went after him. First of all, we went after other people, and they all said no. There was Bob Wingrove that said no, and Dick Fast said no. Then we finally went to him.

DR: Why did they say no?

MV: No one gave us a chance. No one gave us a chance. So, Art listened and listened, and he said, “Yes, yes, yes,” and then finally one day, he said, no, he wasn’t going to join us, and we were right at the last point where we were finally getting some money, and if he said no, the whole thing fell apart. So everybody left the room. We were in my home, and I sat down, and I said to him, “Art, you can’t leave. You leave, my career is destroyed. I’m finished. You have promised to be with us. Now stick to your guns and be with us. This is not going to be an easy path. But what the hell are you doing, building homes? Come on.” He was building homes in Marshall, Minnesota.

DR: He literally was building homes?

MV: He was literally building homes in Marshall, Minnesota, building mobile homes. Sure enough, three months after we got started and I finally convinced him to get in,

three months later, that company folded. So he would have been out in the street, and that was the best thing that ever happened to him, because, again, all these guys became multi-millionaires with the success that we've had with CPI.

That went fine, and then about in January of 1976, by this time I had decided to leave. I was going to not put my name up for reelection to the board.

DR: Could we back up a little bit just a minute?

MV: Sure. I don't know what kind of detail you want to get into.

DR: Interesting history here. Well, as a historian, I love all the detail, but I know we don't have time for that. Going back to raising capital, you had mentioned briefly that you started doing that with Med General, and, of course, you had to raise capital for CPI, which you talked a little bit about. Could you go back to that first experience with Med General? What's involved in getting people to give you money for an idea?

MV: Well, in the Med General, it was a little bit easier in that on the board there were several members, people who worked diligently with the financial community. I was still a young man just learning about it, but I started to learn the terms, the S-1 terms and Reg-D, and all the regulations and stuff like that, and I started to learn that. They would put me in front of people, potential investors, and I would do my thing and say, yes, we're going to do this and this and this with Med General, which we did. We met our goals. But as I looked at the future, it was a very limited market, and they needed another product, and they didn't want to go into pacers. I said, "Nuh-uh. This train goes by once."

But it was with CPI that I took the little that I knew and started to really knock on the doors and started to meet with the investment community. I remember that the first guy that I met was a guy named Howard O'Connell, who was the president of Kinnard, John G. Kinnard. He said, "Manny, I love your idea, but we can't help you, because we were the original financiers of Medtronic, and we still have a working relationship with them, and we just can't do that." I did understand that. I could understand that. So, as a result, he wasn't able to help us. So that's how that worked out. That's how that worked out. From then, I started visiting other people in the financial community, and was really discouraged.

DR: What was the financial community like at that period of time around 1970, '71, '72, in Minneapolis?

MV: There were a lot of smaller companies. The Pipers [Piper-Jaffray] were small, the Dains [Dain Bosworth] were small. Craig-Hallum was very small, they used to call them bucket shops, bucket meaning you sell a stock for a buck. That's how they became bucket shops. There were a lot of small companies that don't exist anymore, and I've

forgotten their names.

It was interesting, we finally got a proposal from Craig-Hallum, in writing, and, simultaneously, we received another proposal from another company whose name I totally forget. I remember the guy, Art Kydd, who's still around, Art Kydd. The name of the company I don't remember, but his proposal came like a couple hours later. Right after I'd signed the first one, his proposal came, and I said, "You're late." Then, of course, the offering was one of the most successful offerings Wall Street has ever seen. The offering came out at \$4.50, started to trade at \$9—this is the first day—it started to trade at \$9, and closed the first day at \$11. When you think about, you don't see those. You just don't see those. You know, two and a half times your money the first day. Never, never.

DR: When did CPI go public?

MV: May 26th, 1972.

DR: So it was very early.

MV: Very early. Yes, we had nothing, just had an idea. That was another thing that we were public, we had an idea.

DR: So you got this original \$50,000 that you raised yourself, and then Craig-Hallum was going to—

MV: Do the public for 4.50 [per share,] because at that time the maximum you could raise in one year was \$500,000. [unclear] what they call a Reg-D. So that's how we got that.

DR: Isn't that unusual by today's standards for a company to go public so quickly?

MV: Yes, but we did it again. We did it several times after that. All my companies I've started very, very early, because I have a different mentality than other people when to go public. By doing it this way, I avoid venture capitalists, too. I never had a venture capitalist in any of my companies.

DR: Why did you want to avoid venture capitalists?

MV: Have you ever worked with venture capitalists?

DR: I can't say I have.

MV: All right. Do you have any children?

DR: I have two small children.

MV: Boy or girl?

DR: A boy who's six, and a girl who's four.

MV: See, you still have your first-born son. In the world of venture capitalists, you don't own one anymore. Let me leave it at that, because this is going on public record.

DR: So you had some negative experiences with venture capitalists that led you to—

MV: Just talk to anyone who's worked with venture capitalists. For most cases, it's not a pleasing experience.

DR: Are you talking about the individual so-called angels, or are you talking about the venture capital companies?

MV: Venture capital companies, venture capital, VCs, and you are not going to talk about that in this interview, because that's nothing relevant to the technical aspects of forming the company. I just didn't work with venture capitalists.

DR: That's interesting. So you got your financing basically—

MV: From friends and investors, and then Craig-Hallum came and did the public at \$4.50 a share, which, as I said, by the end of the first day was trading at \$11, and became a very, very successful offering.

DR: It strikes me that this is another form of sales, when you're not selling a product, you're selling a company or an idea.

MV: Sure.

DR: Again, you've been extremely successful at that. You're known for that. It's a little different, though, from working with doctors. You're working with people who don't have a technical background.

MV: They still put on their pants the same way. We had to educate them the same way we educated the doctors. We had to educate them on a new product. Pacer was new. It was new. I was in ORs [operating rooms] with doctors who had never done a pacemaker. I was in countries that never had done a pacemaker, I mean, I was in on the first implant of various countries in Latin America that had never done a pacemaker, while the newspapers were standing outside taking photographs and pictures, because this was a great event.

That's how early I was in this field.

So, teaching investors and brokers, I mean, they knew about pacemakers, they knew about Medtronic, the big success it was, and here was a kid that's going to challenge them. But we had things going for us. We had the promise of a longer-life pacer, and we knew pacing, and people knew that I knew pacing, so I wasn't totally—but I had never done a business. That was the challenge, and we did it. We did the company, and it's a very successful company.

Make sure that you leave here with a book put out by CPI on my life and CPI.

DR: I hadn't seen that. That ought to be wonderful.

MV: Yes, it just came out. Got tons of data on me, anything you want.

DR: That's great. I'll be up till two o'clock tomorrow night.

MV: Have you seen this?

DR: No, sir, I haven't.

MV: That has a history of CPI. I think the early history of CPI in there.

DR: I'd love to get a copy of that.

MV: So that was how we started CPI.

DR: There's a wonderful anecdote. Pardon me again, if I keep interrupting. It's a historian's curiosity.

There's a wonderful anecdote I think you mentioned at the *conversazione* about a wooden pacemaker they were using. If you could talk a little bit about that and other techniques you used to educate people.

MV: Well, in designing the pacer, we tried various different designs. Like here's an early design of trying to keep the thing thin, and just epoxying these two parts. This was the circuitry and this bottom part was the battery. But we recognized really early on that too much seepage would get in there, and you could really screw up your circuitry and all that sort of stuff.

So the engineer said, "Okay, we're going to come up with this design. It's going to look something like that."

I said, "Well, I got a trip to Europe to start setting up our first clinical sites in Europe, and when will you have it?"

They said, "Well, we'll have it," whatever date it was. Well, it didn't come about.

I said, "I've got to take my trip." So, Art Schwalm and one of his engineers just took a piece of wood, and they carved it, and they gave it to me, and that was it. I had to go overseas, and I still remember with Dr. Fontaine, who picked me up at the airport, Guy Fontaine, met me in Paris, Orly Airport. We met with him and then went out to visit other doctors, and one of the doctors asked me, "Well, great, this is all the technical. How does it look?"

Usually you pull out the pacemaker and show him. I didn't have one, so I pulled out this wooden pacemaker, and he said, "That's it?"

"That's all I got, guys." I mean, we're talking real early stage here, but we were able to convince him to implant this pacer. If you think how fast we did this, we opened the doors on February 4, 1972, had our first implant on November 29, 1972. Think about it, that's seven and a half months.

DR: Can't do that today.

MV: Cannot do that today. But it worked, they were reliable. Some pacers are still running twenty-some-odd years later, and it worked. But, you know, in any of these projects that we do, you've got to be able to sell. I give talks on selling. I've been asked by Harvard University, by their MBA program, to come and take a sabbatical and teach there, teach selling. No school in the country gives courses on selling. They may have marketing and all that stuff, but selling, just basic selling, is something you have to learn.

So, be it the financial person, or be it a doctor, or a nurse, or even a patient, I mean, you've got to sell them on the idea that this pacemaker was untried but seemed to have a capacity. In fact, we first guaranteed it for three years. Medtronic guaranteed theirs for one year, but we guaranteed our first one for three years. If you think what we had to compete against, it was a cakewalk. Here was this pacemaker which weighed 210 grams.

DR: This is the Medtronic Chardack-Greatbatch implantable.

MV: Pacemaker. That pacemaker was being made at the same time this pacemaker was being made. That one would last you twelve to twenty-four months. It was twice as thick as this one, weighed fifty grams more, and this one, we were guaranteeing it for a minimum of three. Shortly thereafter, we raised it to four years, and then shortly thereafter, we raised it to six-year guarantee. Okay? Give me a break.

DR: Yes, that's quite a technological leap.

MV: Right, we made a big leap. We had a chance to be number one, but we couldn't keep up our production. Our production guy didn't believe my sales projections. I didn't do a good selling job on him, because he curtailed production. He didn't want to expand the facilities and expand the hiring of the people and everything, but we could have sold gazillions of them. We lost our opportunity to get to first place, because around 1975, Medtronic leaped into lithium and started to catch up with us. So that's the history right up to that point.

There's a lot more history I know. I'd love to talk to you again, but we're going to have to reschedule for some more time.

DR: Right. Thanks very much.

Pioneers of the Medical Device Industry
in Minnesota Oral History Project
Minnesota Historical Society

May 20, 1998

DR: This is David Rhees. Today is May 20, 1998, and I'm here with Manny Villafaña, at his office at ATS Medical. Thanks again for letting me come to talk to you.

MV: Well, let's pick up where we left off. The era now is about January of 1976, in which at that time I was approached by Mr. Chris Possis and Dr. [Demetre] Nicoloff at two separate meetings, indicating some interest in having CPI [Cardiac Pacemakers, Inc.] pursue the design of a bileaflet valve.

DR: Could you just give me a little background on Mr. Possis and Dr. Nicoloff?

MV: Chris Possis, the late Chris Possis, was the father of Possis, I believe, Engineering Company, and then later on a division called Possis Medical, and had worked with Dr. Nicoloff in the design of the bileaflet valve, which offered central flow and a few other characteristics. Nicoloff was a cardiac surgeon at the University of Minnesota at that time.

DR: You had known them before?

MV: I had known Dr. Nicoloff before, but I had not known Mr. Possis before. At that time, I was the chairman of CPI, and was in the basic phase of phasing out of CPI and had already indicated that maybe I would not put my name up for reelection come May. Anyway, in January of 1976, they approached me, as chairman of CPI, to see if CPI would be interested in pursuing the development of this concept, of this valve. I presented the idea to the officers of CPI, and they elected not to pursue that business.

DR: What were their reasons for not pursuing it?

MV: We were in pacemakers, and we had more than enough work to do, and to pursue a valve would be something that would be taking the eye off the ball, so to speak. So, as a result, I indicated to them that if they had no interest, that since I was planning to leave CPI anyway, that I would pursue the idea myself. I then received a release from CPI to pursue it, which I did, and negotiated directly with Possis and Nicoloff to set up a separate company, which was St. Jude Medical, for which Possis received an equity position in the new company, as well as a royalty stream into the future. That was basically the beginning of St. Jude Medical.

DR: Dr. Nicoloff wasn't financially part of the company?

MV: No, he was not. He had a relationship with Possis which was totally separate from St. Jude. In the development of the company, we made Dr. Nicoloff a member of the Scientific Advisory Board, and also Chris Possis as part of the Technical Board. It was

actually a Medical Technical Board, so that would allow us to have Mr. Possis on that board. They both participated and contributed to the development of the valve, although we basically abandoned the original design and came up with another design, which became the St. Jude valve.

DR: And how did that process take place?

MV: Well, that process was a process of—

DR: Complicated?

MV: Very complicated process, and in fact, a very scary process, because soon after we began, we recognized that we had to abandon the original design. This is after we had started the company, after we had investors in the company, and our back was against the wall. But fortunately, through the work of Don Hanson, Bill Palmquist, Peter Gonbrich, myself, and with the guidance of Dr. Nicoloff, we redesigned the whole thing. Don, being the gadgeteer/inventor, under the guidance of Bill Palmquist, his boss, did the vast majority of the work, and Nicoloff made sure that we were not making any mistakes as we were going along.

But that process, amazingly, was that the process started, we opened the doors on July Fourth. By a month or two later, we recognized that the original design would not work, and by October of 1977, in other words, in about eighteen months total, we had our first human implant. So it was really an amazing feat for us.

Plus, we took the valve design and insisted that it would have two basic principles: number one, that it would be bileaflet, and, number two, that it would be made entirely out of pyrolytic carbon. Both feats had never been done before. Because we did not want to have a “me too” product, we wanted to be the redhead, if you want to use an old expression. We wanted to be different.

DR: And the bileaflet design was very different from the current designs?

MV: It was very different. The current designs were all monoleaflets, or a ball and cage-type design.

DR: What about the pyrolytic carbon?

MV: The pyrolytic carbon was a material that was developed by Gulf Atomic, which later became General Atomic, which later became Carbomedics, but at that time it was still Gulf Atomic, and was a material that was developed to encapsulate uranium pellets for nuclear reactors, a very durable, strong material that could take a lot of wear and tear, and had been incorporated in some of the early valve designs back in the late sixties,

early seventies. But no one had tried to make a valve in which the whole thing was made out of pyrolytic carbon. Still, those were some really new challenges for Gulf Atomic and for us. But we did it, and today the St. Jude valve is the most commonly used valve in the world.

DR: You said it was a challenge for both you and Gulf Atomic. So they must have been doing research and development work as well, to help you adapt the pyrolytic valve to the whole—

MV: Right. They were working, they had worked with carbon in making valves, they knew about the wear characteristics, they taught us about the wear characteristics, but the challenge was that no one had ever made an orifice out of pyrolytic carbon. It was always the occluder. It was always the disk or the poppet that was the pyrolytic carbon. The ring was a metal ring. In our animal work, we knew that there were some limitations on valve compatibility of the metal, but more importantly was that the way a bileaflet valve had to be designed, the wear characteristics would be focused on one point, and if you took one point and wore that one point, pyrolytic carbon against metal would have a high rate of wear.

So what we wanted to do was make that point, that single point, be pyrolytic carbon rubbing against pyrolytic carbon, which would have a much greater durability. The challenge, however, was that pyrolytic carbon is like glass. It flexes a little bit, but don't flex it too much, because then it will break into a million pieces. And no one had been able to do that, and for a time it appeared that we would not be able to do it. It wasn't until Peter Gonbrich came up with an idea of how to be able to flex the ring enough so that we could insert the leaflets into the valve, to be able to construct the valve. And that was the beginning.

DR: So it was the manufacturing process that was the critical part?

MV: Right.

DR: What was his innovation, exactly?

MV: Well, I don't know if that's—it's confidential, and I don't know if it's revealed or not, so I've got to—

DR: Okay.

MV: But it allowed us to make it. And Peter never really got much credit for that, but the fact was that I was there when he came up with the idea, and I was the first one to do it. But the thought was that, "If you can do it, Manny, anybody can do it," you know. And it did; it worked.

In setting up St. Jude, it was an interesting company in that it was the first company, one of the very first companies, that had to go through the FDA regulatory cycle, which was long, difficult, dangerous. They almost closed the company.

DR: Could you talk a little bit about that episode? I'm sure it wasn't fun.

MV: It was not fun. The law was put into place on May 28, 1976. Our company opened the doors on July 4, 1976. There were no regulations. There were guidelines, but no regulations, as to what one had to do to get a valve through the regulatory cycle, because there were no regulations. We went along with the guidelines and we would inform the FDA what we were doing, and they said, "Well, you know, we can't stop you, we can't tell you, we really can't say anything to you." And I said, "Okay, well, here's what we're doing. I mean, if you think we're doing something wrong, let us know." So we pursued and we did implants in the United States, we did implants all over the world, and we just kept growing and we grew very, very rapidly.

Finally, in 1980, four years later, in July of 1980, they came out with the regulations, and the regulations said that you were only allowed to have 250 implants that needed this kind of data, etc., etc. Well, at that time, we already had literally thousands of implants throughout the world, all under the guidelines. So they said, "Well, you have to stop and get 250 implants this way." And how do you stop a company that was already rolling, and growing and profitable, and etc., etc? So they almost closed us down.

Fortunately, we were able to negotiate and they let us continue to do our implants, and etc., etc. They even wanted to stop us from shipping overseas. It was a scramble. We really had to scramble. But the company survived, and eighteen months later was able to get its approval cycle done, etc.

DR: I'm curious. There were a couple of other heart valve companies at that time. Did they run afoul of the FDA as well? They were already in existence.

MV: They were all in existence, and anything before the law of 1976 was grandfathered, so they didn't have to go through it. The first valve that went through it after us, or while we were doing it, was the Bjork-Shiley convexo-concave valve, the CC valve, which, amazingly, went through the FDA, and, amazingly, failed. It caused havoc in the industry and with the doctors, because it had a very severe failure mechanism, where the leaflet would escape, and you had mortalities. So anyway, so that's what happened there.

DR: I interviewed Dr. Lillehei fairly recently and he just mentioned as I was leaving that there was an interesting story behind how you named the company St. Jude.

MV: You mention Lillehei. Let me get the record straight for the entire history of the

world. Okay? The design and development of the St. Jude valve had nothing to do with Lillehei. Okay? We began with the Nicoloff design. When we had to abandon that, Don Hanson did the design basically from scratch, and with our input we were able to improve on that, etc., etc.

It is true that Dr. Kalke, who was a resident or student or a young doctor working with Dr. Lillehei back in 1967, had developed a bileaflet design, but it was nothing to with us or anything like that. And we did not improve on that. We never knew about that until after we were finished.

Lillehei did not come into St. Jude until after the design was done, we were already in animals, and he helped us, of course, enormously, in our education and guidance, but nothing to do with the design. The design of the St. Jude valve, its design is owed to Nicoloff, Dr. [David] Friedberg the cardiologist, Don Hanson the engineer, with the support of all the other officers. But nothing to do with Lillehei. These are the facts, no matter what you hear differently.

Now, the name of the company, St. Jude, was due to the fact that back in 1972, when I decided to start CPI, my back was against a wall. I was broke. I had no job. I had remortgaged my house to get some money to pay the bills. My wife was in the hospital and my son was in the hospital. I went to church, just didn't know any other place to go, and knelt down, and in the pew in front of me was a prayer card to St. Jude. St. Jude is a patron saint of hopeless cases. In that prayer card, it said to do a novena, to promote the name of St. Jude, as a thanks for the favor, that if you receive the favor that you would promise to promote his name. St. Jude was the saint whose name was forgotten because of the similarity of St. Jude to Judas Iscariot.

Okay. I had nothing to lose. I started the novena, and shortly thereafter, things started to happen. I was able to get the financing for CPI, etc., etc. Then when we were doing CPI, Medtronic tried to shut our doors. They sued us for claiming everything, which was all false. So we prayed to St. Jude for help on that. We had employees, everybody, praying to St. Jude. That passed, and everything went well.

Then, as a way to say thank you, my third son was being born and I asked that my son be named Jude, Jude Villafaña, as a way of saying thank you and promoting the name. Fine. Unfortunately, he was born with a congenital defect that threatened his life, and had to be operated on eight times within the first two months of his life. Okay? But we continued the prayers. His condition was so dangerous that I had to baptize him. We didn't have time to get to the church to baptize him. I literally took him from the doctor's office to my home. I literally had to take him home, baptize him in the bathroom sink, and then take him to the hospital. That's how urgent it was.

Anyway, again things came to pass, and we had everybody—the church, two different

churches from their pulpit were requesting the congregation to say prayers to St. Jude, for Jude Villafaña, but that came to pass, too. He was operated on successfully by Dr. Brian Neel at the Mayo Clinic.

Everything went well with Jude. Then, as a result, when I started the company, again, to say thank you to St. Jude and to promote the name of St. Jude, I said, “Why don’t I start the company and name it St. Jude.” After discussions with our officers, particularly since we had a Jewish member as one of our officers, and particularly since we had Dr. Friedberg, who was on our Scientific Advisory Board, I asked Dr. Friedberg, David Friedberg, I said, “Dave, what do you think?” and he said, “Well, Manny, there’s no problem with that. You have to remember that St. Jude was a Jewish lad.” “That’s right,” I said. We were concerned, would we have difficulty with Mt. Sinai hospitals and all the Jewish clients that we may have in the future?

DR: Of course.

MV: As a sideline, later on, many, many years later, fifteen years later, twenty years later, we were invited to a party to celebrate Dr. Neel’s birthday, who had operated on Jude, and suggested that the party be held at my home, and that went well. But we found out that the birthday of Dr. Neel, who had operated on Jude, had saved his life, his birthday was October 28, which is the feast day of St. Jude. So it’s a long story and one that makes you think.

DR: That’s wonderful.

MV: That’s the story behind the name. Usually I charge you dinner to hear that story. But for you, Dave, it’s on the house today.

DR: I’m glad it had a happy ending with your son. That’s a wonderful story. Going back to when you started St. Jude, how did you raise the capital for that company?

MV: Well, it was relatively easy because we had come off a very successful venture with CPI. I mean, CPI was growing leaps and bounds. The financing of CPI was so successful. The investments in that made a lot of money for a lot of people. Then when we started St. Jude, we decided to do a private placement of two hundred thousand shares at \$1.65, and to buy one unit, you had to buy at least a 1,000 shares. I’m sorry. You had to buy at least 10,000 shares, which was—a unit cost you \$16,500. Well, today, that unit is worth over \$20 million dollars, you know, so it was easy. That one was easy.

What was difficult, however, was that when we ran out of that money, we decided to go public, and in 1977, the IPO [initial public offering] market was as dry as it had ever been in the history of Wall Street. There were only twenty-five public financings that year. Twenty-five. I mean, usually today, there are thousands of IPOs done in a year. This is

twenty-five. Not twenty-five thousand—just twenty-five. And we did one.

Then we ran out of money again in December of that same year. We did one in February, then in December we had to do another public financing. So that year, when it was dry as it could be, we did two financings in the public arena, and people wrote about us, how we accomplished that. Again, it was just, you know, the community knew us, knew we were serious, we were doing our job. And we did our first implant in October of 1977.

DR: Were those sizable offerings?

MV: No. The first public offering of St. Jude was 275,000 shares at \$3.50, which was a total of \$962,500, gross. Okay? We netted out, of that, \$866,000. You know, it wasn't a big deal. And then the second one that we did, which was in December, was for 210,000 shares at \$6.50, so, \$1.3 million. So it took us two offerings to only end up with about \$2.5 million. But we did it. Okay? And then we pursued and grew from there.

DR: So those were the only financings that occurred while you were with the company then, or were there more before you left?

MV: Well, there was another one that we were working on, but I left in between. There was another one, which was for 721,000 shares at \$26. That was a very big offering, and that was done in April of 1983. It was actually started before I left, but they didn't want to do it until they got FDA approval. Okay. I started it, got it all lined up, but then I left. The FDA approval came, and then I left, and then the offering was done.

DR: So, despite the bad market for initial public offerings, the financing really wasn't a big problem?

MV: At the time it was a big problem. I mean, think about it. The whole country can't do one a year, it's going to do two. [Laughter] You know, they were not easy, but we got them done.

DR: What made you think you could succeed when it was such a bad climate?

MV: Dave, when you've got to have things done, you do them. I mean, it isn't, well, what do you mean, do you think you can do it? I don't care if I think I can do it. We've got to do it. All right? I mean, people always ask that question. "Well, why did you think you could do it?" I don't know if I think I can do it. I have to do it. You don't have a choice. You go out and do it. You pound on the door, and if you fail, then the answer is, no, I couldn't do it. If I did do it, we did it.

DR: You mentioned that the St. Jude valve went on to become the most popular valve. Could you talk a little bit about how that happened, the initial reception? Obviously it

takes time for a radical new design to—

MV: It was a radical new design. It took time. It was a beautiful valve. At that time, it was the only one that was all black and it was shiny and it was very beautiful, very appealing, had some immediate low-profile benefits, had some immediate benefits that you could see.

DR: Low-profile benefits?

MV: Yes. In other words, it took a very, it was a very low profile, so in the heart, it took up very little space, and so there'd be less chance of anything around the heart impinging on it and things like that, which was an advantage over a single-leaflet valve. Doctors in those days were very interested in valves. They really studied them and all that. Today it's a much more difficult environment. And they were interested. They studied it for us, and we had a lot of people studying the valve, and it performed much better than we ever thought. Remember now, our original goal was to make a bileaflet, and to make it all carbon, just to be different. Now, necessarily would it be better? We don't know. But as it turned out, it was tremendously better.

DR: But you had to get doctors to start implanting it somehow. How did that go?

MV: "Hello. Hi, I'm Manny Villafaña," and we sell them the idea, you know. Let's study it, you know. Let me just tell you this story about a visit I had with Professor Binet in France. We only had at that time maybe twenty, twenty-five implants in the whole world. I went to see him and he saw the valve. I told him about it and he saw the valve and he kind of put it back on the table and he pushed it away. He turned his head and he pushed it away and he mumbled something in French. I said to the representative that we're sitting with, "What does he say?" He said, "Well, you know, he says it's a beautiful valve, but I don't think he's going to use it."

So I didn't say anything, and all of a sudden the professor, in broken French and English, kind of said to me, he said, "Monsieur Villafaña, do you know what you are asking me to do? You want me to try this valve that really has no history." I said, "That's correct." He says, "Do you realize that if I put this in a young lady and it causes a clot, and a clot goes to the brain, that her face is going to become distorted, or she may have paralysis or blindness, or, if we are lucky, she dies."

So at that point, the representative looks at me for an answer, and I turned around to the professor and I said, "You know, yes, I want you to try this valve, because if you don't try this valve, every day you put in a valve, a different valve, you are going to have strokes, you are going to have young ladies that are distorted, that their faces are distorted, and have blindness, paralysis. As you say, if you're lucky, they die on you. Because the present valves that you are using are causing that, and I am trying to find a

valve that doesn't cause that.”

Not long after that, he implanted the valve. But, unfortunately, the patient died. It was a bad draw of the cards, but he continued to use it and, of course, the rest is history. The St. Jude valve went on to be the number-one valve in the world. Okay?

But those are the things we had to overcome—the resistance. But yet through education, you know, “Yes, I don't know what this is going to do, but the one that you're presently using, we know, for example, that six to ten percent of those patients are having strokes. I'm trying to reduce that, and I'll never know if I can reduce it unless you try it and help. We know this [old one] is bad, we don't know if this [new one] is bad.” And that's how we educated them and that's how we converted them.

And the same thing when we were doing the ATS, if we're ready to talk about the ATS valve. It's the exact same thing. We're saying, “We know what we have. Can we improve on that? The only way we can improve on that is if we try to improve on it.”

DR: So the education process was mostly one on one between you and doctors?

MV: One on one. The doctor and I, we sat down. I traveled all over the world, and then we had people coming on board. Rich Kramp, who came on early on and helped in the development of all the sales forces that we needed, and management of the sales force, selection of the sales force, education. It's all an education process. That's the proper way of selling. If you're going to sell a technical product, teach, teach, teach. Educate, educate, educate.

DR: At St. Jude, were you using independent reps?

MV: We started off with independent reps.

DR: That you picked up from other companies?

MV: Yes, other companies. A lot of them were CPI reps that we had worked with before.

DR: St. Jude, of course, was very small when you started. I assume the company added many personnel as time went on.

MV: Standard company. We grew and we grew, like any other company.

DR: I'm curious where the manpower came from. Were you bringing in people from Medtronic or other device companies, or the computer industry?

MV: No. We had no valve engineer when we did this. Later on, after we had the valve

designed, when we were doing some work with the carbon, and understanding carbon, we brought in a guy named Sam Goodenough, who helped us, who had the experience with carbon. But the basic design was done by non-valve people, because we didn't want any myopia. The same thing that we did with CPI. When we did CPI, we had no pacemaker engineers.

DR: Did you have an R&D [research and development] department or lab, per se, at St. Jude?

MV: All the same—

DR: All those traditional—

MV: It was traditional. We're a traditional company, and we developed a valve. That was basically it. We were a very enthusiastic group and we ran against a company that at that time was the Bjork-Shiley valve, which controlled sixty-five percent of the market, and beat the pants off them. They don't even exist anymore.

DR: I'm not familiar with Dr. David Friedberg.

MV: Dr. David Friedberg is a cardiologist that presently lives in Florida, who helped me in the development of the CPI pacemaker. At that time he was in Milwaukee. Very knowledgeable in electrical physiology. Very astute cardiologist, in that he has a little business sense behind him. He knows when to make decisions. So, when we started the valve, we had Nicoloff as the surgeon and Friedberg as the cardiologist. And in all my ventures, he has always helped me, because he brings good, sound—he's very knowledgeable on everything. I mean, I've never even seen a man who has such a broad spectrum of knowledge, both medical and business. You know, I mean, you can ask him about toenails and he'll know things about toenails. But, of course, he's a cardiologist, a very astute cardiologist, and we wanted to have that experience.

DR: That raises an interesting issue. I've noticed that during your career, you've worked with a number of the same people.

MV: Well, we have a team. I mean, we do have a team. For example, in this organization here, my officers have all worked with me for fifteen, twenty, twenty-five years. People on the production line have worked for me for many years. My secretary, an accountant person that just left me, was with me for twenty years. We have people who just, when we're ready to do a project, we put them together. "Are you ready? Let's go and do another one." And if I wanted to do another project, it would just be a matter of phone calls. "Hey Charlie, come on, let's go and do something." You know, and it's fun. We all make a decent living doing these things, and they're fun things, and you go home at night and you're proud of what you've accomplished.

DR: That's great. You were mentioning Richard Kramp. He's with you now here and he was at St. Jude?

MV: And also CPI. He was the inventor of the CPI pacemaker, the world's first lithium demand pacemaker. He has the patent, and he made it for CPI. Then from there, he helped me at St. Jude and became my vice president of sales and marketing at St. Jude, and then from there he came here.

DR: So he started out as an engineer then?

MV: Started as an engineer. He still uses his technical background. When doing the valve, he's a co-developer, a co-inventor, of the ATS valve. There are three of us that are the inventors of this valve, and he's one of them. The guy who has the patent on the St. Jude valve, a guy named Don Hanson, it usually says, "Don Hanson et al." Well, on our patent, on the ATS, it says, "Don Hanson et al."

DR: A continuing theme.

MV: Continuing theme. That's the way we do it.

DR: And then I was struck at your *conversazione*, you showed a slide of, I think it was the first St. Jude Building, which I think was the same as the CPI Building.

MV: If it works, the recipe works, why are you going to change it, okay?

DR: CPI must have moved to other quarters.

MV: Right. Across the street. They went across the street and I took the old building.

DR: Where was that?

MV: Red Fox Road. The first—oh, we're going backwards now here. The first CPI Building was 2982 North Cleveland Avenue, over in Roseville. It was 5,000 square feet. The second building was on Red Fox Road. I forget the number. I think it was 1192, but it was on Red Fox Road. I'll tell you exactly what the number was. The number was 1140 Red Fox Road, and that was in Arden Hills. Our first building for St. Jude was 1140 Red Fox Road. They move out; we move in. Okay? It's simple. It works. And both of those companies were the most successful IPOs the country has ever seen. I mean, we're talking about number uno and number two-o. I mean, they were very successful IPOs. You know, like I said, a \$10,000 investment in CPI is worth millions and millions of dollars today. The same thing with an investment of that size in St. Jude. It's now worth millions.

DR: Was there any particular reason why CPI and St. Jude were located where they were, in that part of the metropolitan area?

MV: Yeah. We got cheap rent. There was a guy named Don, Don Roberts was the landlord, and he said, "Just take it and pay me when you can." He just let us use it, and it was just a little hole in the wall. I mean, 5,000 square feet is smaller than what you've just basically walked from there to here. It's very small. But we did it.

DR: While you were with St. Jude, did they move to a larger building?

MV: Yes. Then St. Jude, we expanded on that same building site. We went from about 18,000 square feet to 30,000 square feet, and then they negotiated to One Lillehei Plaza, which is over in Little Canada. It was interesting how we went to other sites in the city and they said, "No, we don't want you as our neighbor." I said, "Are you kidding me?" So Don Roberts, again, the landlord, said, "Manny, I've got some property over here in Little Canada." I went over, I loved the property, and I said, "Gee, Don, I can't pay you for that," and he said, "Build. You pay me later, don't worry about it," so we did it. We built a beautiful facility, we never had to pay for the land until later on, and he said, "You can pay me cash, you can pay me stocks," so we did. We paid him half cash and half stock, and we were very accommodating. Of course, the stock that we gave him is now worth a zillion dollars.

DR: He wasn't a fool. [Laughter]

MV: Yeah, he wasn't a fool. So those are the things that happened. You know, we were successful, both companies were very successful, but there was nothing, anything unusual or something that would be the secret formula or anything like that. There wasn't. It was just hard work, dedication, wonderful employees, employees that used to work and pray together, and we were successful with some new technology. We beat the pants off of the old technology. We developed a lithium pacemaker. Today, every single pacemaker in the entire world, 100 percent, uses the technology that we developed. Valves. We developed the first bileaflet valve. Every valve that comes out today is a bileaflet valve. The technology. Even the second generation, which we're doing here at ATS, is an add-on or is an improvement on what we did for St. Jude.

DR: I noticed in the ATS annual report that you made some—

MV: You've got the old annual report. We'll get you a new one.

DR: This is the 1996 one that I picked up the last time I was here, but there's a quote from you here that really emphasizes how important family is at ATS. Is that sort of a theme that has run through all your career, that you try to foster that kind of atmosphere?

MV: We always foster the family, and I don't mean the internal family, but I mean the families of the individuals. All my companies have had four-day weeks. We work in a four-day week here.

DR: Oh, really. I didn't know that. All your companies?

MV: All. CPI, St. Jude.

DR: Beginning with CPI?

MV: Yes. All. And the reason is that I want our employees to have more time with their families. We have a lot of women that work here. You know, they're working on the production line. They have children. They have daycare centers and all that. Okay. Give them an extra day with their kid. And in doing that, let me tell you what happens. Number one, it saves them money. That's one day less at daycare. Number two, they have time with their family. The family gets to like the company. Number three, they can do the errands that they have to do. Otherwise, they have to take time off from work. So it cuts down on absenteeism enormously. Little Johnny needs a new pair of shoes, little Johnny has to go to the dentist, little Johnny, you know, whatever. The mother can do that now, okay, all right?

And then from a recruiting point of view, I've got an advantage over any company that works five days. I've got four days, and, believe me, that helps us. And we need that. And it cuts down on your time, and, I mean, a lot of different things.

And you set an incentive. You tell them, "Look, this is our goal. If you don't hit that goal, we go to five days." You bet your sweet bippy we're going to hit that goal. Then if you have to go to overtime, for whatever reason, you know, you're growing faster than you anticipated, whatever, or there's a special need that we need overtime, it's easy to go from four to five days.

DR: Are you doing four-tens?

MV: We do four-nines in the summer, four-tens in the winter.

DR: So you started that at CPI then. That was kind of an innovation.

MV: I don't know if we were the first, but we were one of the first.

DR: What got you started on that idea? They didn't do that at Medtronic.

MV: Exactly. Exactly that. I think Medtronic had done it. I think. I'm not sure. But they

did it just for a short period of time. I did it all year-round. This is all year-round. And do I have turnover? No. Absenteeism? Very little. And am I profitable? We're the only non-approved FDA product company that's profitable.

DR: Interesting. How did you manage that?

MV: We're profitable. I mean, you know, we watch our coins and we're very careful. Dave, when you're interviewing this company or you're interviewing me, okay, we run our business differently. We're not a corporation per se with all its—we're family. We're very flexible, very caring, very concerned. We're a little guy. And when a company gets really big and I can't do that anymore, I leave. And I don't apologize to anybody for leaving. "Why would you leave because of that?" "Because I wanted to. I couldn't do the things I wanted to do anymore. I leave." I leave it in good, sound condition. I mean, this company is profitable, this company has money in the bank, has zero debt, has the best product, is growing very rapidly. I could walk out today and be happy.

DR: That's wonderful.

MV: It's different.

DR: So St. Jude started getting kind of big?

MV: St. Jude got kind of big.

DR: And so you—

MV: I left. I remember going to the board, I said, "Guys, come on, I want to get out of here. Let's find someone." I remember going to the board. Jack said he didn't want me to leave, Jack Youngbar, who was my vice president of finance, who's my vice president of finance here. Same team. You know, they're all here. If I walked in to Jack and said, "Jack, you want to leave?" and I said, "No, you can't, you can't leave. You're crazy, you're out of your mind." But I count on that all the time, but there comes a time when it's appropriate for me to leave, give growth opportunities for other people. I mean, Rich has worked with me. I'm sure he would like to take a crack at running this by himself. And he'll probably get it. I can't make that decision; the board makes that decision.

DR: So what came after St. Jude then?

MV: After St. Jude, I retired. I was forty-one years old.

DR: That's a little young to retire.

MV: Yes. I kind of retired, you know, and I collected cars and I had about forty-two cars

at that time. And about six months later I was bored with retirement. So a friend of mine wanted to start a company, and he needed to start a company, and he and I kicked around a few ideas. He said, “Well, Manny, this new field, lasers, you know, I’m going to get into that.” There was also another field of catheters, you know, balloon catheters, angioplasty and all that. And probably I made the mistake of saying, “Why don’t we combine the two?” And we developed the first laser angioplasty system in the world. That was GV Medical.

DR: What did the “GV” stand for?

MV: His name was Grabek and my name’s Villafaña. Jim and I pursued this business together. I made him the CEO, which I will never do that again, but I made him the CEO, and I was the chairman. We tried to work on it together, and it had limited success. We did it. We accomplished what we wanted to do. However, there was a rate of restenosis that was higher than we expected, so it was not an accepted form of treatment.

DR: Where was that company located, physically?

MV: Here. It was on this street. Annapolis Lane.

DR: Right on this same street here?

MV: Same street. We go the same streets, we do everything the same. [Laughter] Same landlord, same everything. And later on we had a little bit of difference of opinion on how to run the company, and so I said, “Look. You run the company,” and I left.

DR: How about the financing for that company? How did that go?

MV: Again, same way. We did a private placement. God, I don’t remember the numbers now.

GV was fully funded. We did a private placement and then we did a public offering. By the way, all these offerings were done by Craig-Hallum.

DR: Oh, interesting.

MV: And this offering was done. We did a million-share offering in October of ‘83, and I don’t recall what the price—I think it was \$5 a share. I think, but I’m not sure. No, the private placement was done in October of ‘83, and I don’t remember what the price was. I think it was \$3.50. Then we did a public offering in November of ‘84, at \$5.50, also by Craig-Hallum.

DR: The next company was Helix Bio-Core, is that correct?

MV: Right. Helix Bio-Core came next, which was in '87, after I had left GV, and I was not involved with anything, two engineers, two scientist engineers, approached me on the potential of growing mammalian cells. First thing I said to them, I said, "How do you spell that?" I didn't even know anything about that. But they convinced me that they had a technology that could develop into making mammalian cells to develop protein and new drugs, and these super drugs and all that. So I tried getting into the biotech area.

Later on, it appeared that the technology was not going to work. Later on in the lawsuit, it was shown that there were some fraudulent things that they had done, and they lost their shirt in the lawsuit. They brought the lawsuit against us. We countered it, and then that's when we found out all the bad things.

DR: Who's "they"?

MV: John Salstrum and John Holroy, but that's all public record now.

DR: They were shareholders or something?

MV: No, they were the so-called "inventors."

DR: Oh, the inventors. And they sued Helix?

MV: They sued Helix after we let them go. Then that's when we found out all the bad things. So they lost the lawsuit and they lost money in the lawsuit. But in the meantime, at that point, after we had tried it for a while, in November of 1990 we basically started working on the new valve. Then later on we shut down the Helix business because it wasn't going anywhere. Got rid of that, and we changed the name from Helix to ATS Medical. And the rest is history.

DR: So, ATS Medical, as an entity, started when, approximately?

MV: November of 1990. November of 1990 we started working diligently on the valve. Our goal was to try, again, to reduce thromboembolism, which is the clots that go to the brain, caused by valves. We reviewed the data that even St. Jude had published and they showed that the rate of clots going to the brain in the first year was about four percent. Another study that was done by the U.K. government showed that it was anywhere from four to six percent, and we said, "Hmm. Can we improve on that?" And so the design that we have, we feel does improve on that. In the United States, we cannot make any claims on that until we complete this FDA study that we're doing, but overseas we're in full marketing, and our data overseas indicates that we are doing it at a rate of about five to ten times less clots. We also have been able to reduce the bleeding complications. Again, overseas. We haven't talked about U.S. yet. And the valve is growing very nicely.

DR: How did you get into the valve research at Helix, which was focused on mammalian cells?

MV: Through a division. Through a division. It was a division. We brought in Don Hanson again, and we had him start working on a design together with Carbomedics, on a design that they had, and we took it and modified it quite a bit, just like we did when we started with Nicoloff. We took that design and changed it. Carbomedics had a design, we changed that, and we came up with the present valve.

In the same period of time, we had our first implant. We had our first implant in May 1992. So that's where we are today. We have 22,000 implants now. We've got about 250 of them in the United States. They're in a clinical study. We're profitable. We have about sixty-five employees. Growing very, very rapidly.

DR: I think the last time I was here, you mentioned that you're starting to develop your own pyrolytic carbon facility.

MV: Well, we are looking at that. We are looking at the possibility of doing that. We're studying different avenues. Because our eventual goal, we're going to have to either come up with a new, very, very agreeable contract with Carbomedics, or develop our own carbon. I mean, they're going to have to significantly reduce our costs, because we're getting beat up in certain parts of the world.

DR: St. Jude had a major crisis with Carbomedics. Was that while you were there?

MV: No, that was after I left.

DR: That was after you left. They kind of withdrew.

MV: They got into a pissing contest. I don't know if you want to put that in your tape. But they got into a legal disagreement on the contracts and the supply of carbon. St. Jude wanted to make their own carbon, and they got into a very difficult case there. It almost buried St. Jude. We tried to avoid that in our agreements with Carbomedics this time. We made a long-term agreement, whereas with St. Jude, it was always a one year. You know, one year, and every year, the pain and agony of renegotiating was too much.

DR: I think Carbomedics is still the only game in town.

MV: The only game in town, yes.

DR: I wanted to ask you more about the doctors that you've worked with. One thing that I saw in some of the literature was that, for instance, you had worked with Dr. Lillehei's

brother, Richard Lillehei, and that was way back at CPI. That's a little detail, but I was just curious about it.

MV: Again, when we started the idea of making a pacemaker, we knew that we were going to need a surgeon to help us, guide us through. And at that time, Richard Lillehei was known in the community for doing pacemakers. He had worked closely with Medtronic and he was an approachable kind of person. So I went to him.

I remember distinctly, very distinctly, as if it was yesterday, I walked into his office and I showed him what we wanted to do. We wanted to use a new power source from a miniaturized circuit, the whole thing, and end up with a smaller pacemaker that would last a much longer time. That was our goal. And I remember him sitting behind a desk, and I'm talking to him, and he gets up, walks behind me, closes the door, comes back, and he says, "Do you really think we can do this?" And I said, "Yeah, I really think we can do it." And he says, "Great. I want to beat my brother," his brother being C. Walton [Lillehei]. Because C. Walton had worked with Medtronic on their pacemaker, the early pacemaker, and he wanted to do it better. And I said we could.

He was truly unbelievable. He let us use his facilities, he didn't charge us. I mean, later on, at the end when we were finished, he said, "You know, Manny, I've got to charge you for the use of the facilities, or I'll get in trouble with the University." I said, "Well, how much do we owe you?" He said, "Would \$2,500 be too much?" I said, "No, that's fine." It was just a token. But he was wonderful to us. And then he did the third implant in humans.

The first implant Dr. Friedberg did, who was the cardiologist in Milwaukee. And the second implant was done by Dr. Bernie Goot, in St. Paul. And Dr. Lillehei, Richard Lillehei, was supposed to do the second one, but what happened was, it was pushed to one o'clock in the afternoon. So Bernie did his like nine o'clock in the morning and then Richard did his, he was the third one, but Richard actually implanted the first animal, the first lithium pacemaker in an animal.

And I tell you, we had a wonderful time with him. He was so supportive. He was a very electrifying man. If he was to walk in this building, you would feel it, even though we're here and the door is way over there. You would feel his presence. Wonderful guy. I had a great, great relationship with him.

DR: So he worked for CPI for quite some time.

MV: Then he died.

DR: And then he died soon after that?

MV: He died at the age of forty-nine. He was practicing for the Boston Marathon, and there's a great debate as to how he died. He died jogging on a beach. There is a theory that he had atrial fibrillation, fell down, head first, that caused his neck to break and he suffocated from the sand. But did he trip and go like that, or did he fall from atrial fib, some electrical problem with his heart, from doing so much exercise his heart enlarged? I mean, there were a lot of theories behind it, but the immediate cause of death was suffocation from the sand.

DR: That's a shame. You also worked with Dr. C. Walton Lillehei at various stages of your career. I remember seeing him in some of your slides.

MV: It was interesting that we met a party that Richard Lillehei was giving for B.J., his wife, and there were about nineteen tables. I remember nineteen tables, and table number one was Richard Lillehei and children and his wife, that's all. Table number two was C. Walton, Kaye Lillehei, another couple, one or two others, and myself. Table three, you know, went down the line.

So by that time, I had started working on St. Jude. I had the valve implanted in—we were starting our animal work and everything. The valve was designed and implanted. Walt said, "Well, Manny, when are you going to put me to work?" And I said, "What are you talking about, Walt?" He said, "Well, Manny, I know you're working on a valve. I'm sure you can put me to work." So I said, "Are you kidding me?" He said, "No." I said, "I have to think about it."

So I got up, walked out to the middle of the dance floor, and I tapped Rich Lillehei on his shoulder. I said, "Excuse me, Rich. Quick question. Your brother asked me if I could put him to work." He said, "Manny, if you did that, I would be forever indebted to you." Because at that time, no one wanted to touch Walt. Walt had gone through some very difficult, ugly publicity, and no one wanted to touch him.

DR: From the tax—

MV: Tax thing, right.

DR: Tax problems.

MV: All right. He had come back from Cornell [University]. He was fired from Cornell, and the whole thing. No one wanted to touch him. There wasn't work. I had the problem that I had Nicoloff. I had to go back to Nick. I said, "Nick, how would feel working under the shadow?" I mean, Walt cast a big, big, big friggin' shadow. And Nick was gracious, and he said, "I think we could use him. I'm not afraid of that."

So all of a sudden, I called Walt to my office a couple of days later and I said, "You

could help us by teaching, educating our employees, helping us with our animal work, give us some guidance there. I can't pay you anything." Later on, I gave him a stock option, which is worth a zillion dollars today. But again, he had nothing to do with the design of the valve. That was done. The valve was done. But later on we used him to promote the valve, and he had all the contacts in the world, and if I wanted to get into any country, the red carpet was laid out for him, and I would tag along. He was instrumental in the promotion of the valve, but not in its design. It bothers me and it bothers Nick that he makes claims to that, which is wrong.

DR: Sure. Well, I'm glad you clarified that.

MV: I clarify it. I was there.

DR: What about some of the other doctors that you've worked with over the long term? I remember some of the people you mentioned in the *Conversatione*. I'm not sure you've worked with all these people, but some of the people you showed in the slides included Dr. Zuhdi from Oklahoma.

MV: Zuhdi, and Barnard. It's the picture right there, with Lillehei in the middle. Barnard, who did the first heart transplant, who is from South Africa, again, was extremely gracious to me when I was introducing the CPI pacemaker into South Africa. He met with me for a long, long time, and this is when people maybe could get a five-minute meeting with him, and he gave me like an hour and a half.

It was nice, because I was from Minnesota and he had studied in Minnesota, so I was like a newspaper to him, coming down, bringing news about Minnesota and all that. He said, "Oh, and by the way, what are you doing? Are you doing the pacemaker?" I said, "Yeah." And he began implanting it and supporting us.

Then when we did the valve, again he was gracious enough to give me all the time necessary. He loved valves. He tried to invent a valve himself. There is a Barnard valve. In his book, *One Life*, he writes about the fact that a valve is the hardest thing a man can make. He devoted almost a whole chapter on his work in trying to develop a valve. He was extremely interested in valves. He helped us by getting us started in South Africa.

In fact, one day we were deciding to have a symposium and we would bring all the doctors from throughout the world and we said, "Who's going to be the moderator?" You know, we threw names on the table and everything and I threw the name of Barnard, and everybody kind of laughed at me. They said, "What are you talking about? You're going to get Barnard to be your moderator?" A little teeny weeny little company, and we've got *the* most famous surgeon at the time, because, you know, it was right after his heart transplant. I said, "Well, my mother said ask. Sometimes you get slapped, sometimes you get kissed."

So I picked up the phone, right there, everybody sitting there, I picked up the phone, he answered it, and I said, “Chris, I need a favor.” He said, “Yeah, what do you want, Manny?” I said, “Look, I’m going to put a little symposium on. We have doctors from all over the world. Could you be the moderator?” He said, “What’s the date?” So I threw out a date, and he said, “Yep, count me in.” And I said, “Chris, I can’t pay you anything.” He said, “No problem.” I said, “I’ll get you the airfare and you come on out.” He said, “Fine.”

Hung up the phone, and everybody just stood there silently, like, “Do we believe this, or we don’t believe it?” I said, “Guys, he said it. I mean, what can we do?” So of course, as we got closer to the symposium day, you know, we wondered if he was going to really show up. And I would call him and say, “Yeah, okay, I got it all set up. You’ve got flight so and so, and so and so.” I said, “God, he’s got to be here.” Until the last day, until I went to pick him up at the airport, we never knew he was going to be there.

But he graciously—he was a fabulous moderator, because he was challenging. You know, they’d be talking about mortality, like they said, “Well, we implanted a zillion valves or a hundred valves and we have five percent or eight percent mortality.” And he said, “Manny, what’s this mortality bit?” And I said, “It’s common. They have a mortality.” He said, “We don’t have mortality.” I said, “They’ve got mortality.” “Well, we’ve got to talk about it.” “Well, talk about it.” And he’d get up and he said, “Now let’s talk about this mortality. What is going on here?” I mean, he would lay into these doctors, and he was a dynamic leader of that symposium. Sure, we talked about valves, but we talked about also surgery and the challenges, and what are you doing in cardioplegia, and are you protecting the patient, and all this sort of stuff. That symposium was a dynamic success because of a guy like him. Came out of nowhere to support us.

DR: And because you had made that contact.

MV: Because I just made that contact. That’s the key in all the successes we have had. I mean the success of this company. We know the doctors. We have been there with them. I have a picture on the wall there of a doctor in his underwear, in a lake, standing in a lake with me, having a contest, who could stand in the lake because the water was so freaking cold. And he’s in his underwear. How much closer can you get to a doctor than that? And he’s the largest implanter of heart valves in Australia.

You have another one up there with the largest implanter of heart valves in the U.K., and he just wrote a book, and whose picture is in the book? My picture’s in the book. Okay? All right. Where he names all the pioneers of heart surgery, he’s got me down as a pioneer. So those are the kinds of relationships, that’s what makes us successful, in that we can knock on the door and they will open the door for us. Now, once we go through the door, we’d better have something good, or they’ll throw us out. But the point is that

in getting anything introduced, you've got to be able to open the door. And remember what I said before? Educate, educate, educate. But you can't educate through a closed door. So that's the key.

DR: Wonderful. I started off by mentioning Dr. Zuhdi. Is he someone who you worked with?

MV: No, Dr. Zuhdi I didn't work too closely with. He worked very closely with Barnard, and one day when we were doing GV, I get a phone call. Sitting down at my desk, I get a phone call and it's Dr. Barnard. Barnard, by this time, was working up in Oklahoma with Zuhdi, and he said, "Manny, we are a leader and we want to be in the forefront, and we understand you're working on laser technology." "Yeah," I said. "Can we come up and see it?" I said, "You're going to come up and see it?" "Yeah."

So he brought Zuhdi. That's when that picture was taken. He brought Zuhdi, about two other surgeons, a bunch of cardiologists, and this little company, GV Medical had, standing there, you know, Barnard, Lillehei, Zuhdi, and a bunch of other doctors. This little teeny weeny little company out of nowhere. But why? Because we have these contacts, we have these relationships, and that's what makes us successful. People have said that the biggest strength of ATS is the relationships that Manny had. If I got hit by a truck, what would happen to ATS? Well, I'm hoping that now the valve can carry it, you know, the history of the valve.

DR: So Walt Lillehei did some work for GV Medical as well?

MV: Right.

DR: You showed a slide of Dr. [Charles] Hufnagel from Georgetown, but maybe you didn't have a direct relationship.

MV: Oh, yeah. Hufnagel was the guy who implanted the first valve in the world. In fact, he planted it in the descending aorta, which wasn't really inside the heart. You know when your aorta comes out. So he went right in through here, got in there, and put a valve in that descending aorta.

I remember he wouldn't give me a meeting when I was talking about St. Jude. He said, "I'm tied up in surgery all day," and I said, "Look. I know you've got to get to the hospital before you go into surgery." He said, "Well, yeah, I'm there at five o'clock in the morning." I said, "I'll be there at five in the morning." He said, "No, you won't." I said, "I'll be there at five in the morning." So I got to the hospital before he got to the hospital. When he went to open that door, I was standing at the door, and we talked about valves. We really talked about valves, and eventually he used the St. Jude valve, but that was my only contact with Hufnagel. But I was there. I met his challenge.

DR: Was there a Dr. Gray at the University of Minnesota, cardiology?

MV: Dr. Richard Gray, who is now at the University, who is now, I don't know if he's the head of cardiology for the University of Minnesota, but he's involved with Regions [Hospital] and the University of Minnesota and Fairview-Southdale [Hospital], that whole group. He is the key cardiologist now. I think he's the head of cardiology, but I'm not positive.

Well, he worked with me at St. Jude, and he's now a medical consultant for us here at ATS. Again, in the early days of St. Jude, he was instrumental in writing all the papers, a vast majority of the papers on St. Jude. He studied the St. Jude inside and out. And when he would present at the symposiums, the doctors would come just to listen to him because he really knew the St. Jude valve. He really knew valves. Great speaker. Very methodical. He would take the data from the surgeons and then present it. He's now with us. Again, we've got everybody that's anybody on this project. That's why we're going to be successful. That's why we're going to be number one. This company will be number one in valves. You've got it in here [the tape recorder,] right? Okay?

DR: It's recorded for posterity. Well, that might be a good place to end things, since we're over our time. Thank you very much.

MV: All right, Dave. Thank you.

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