

## **Norm Dann**

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*Prof. Art Erdman:* I'd like to introduce Norm Dann and I'd like to tell you a little about the award that he's getting today. I'm going to read from our website. "This conference award has been established to honor those who have demonstrated outstanding dedication to the Medical Device Community over a sustained period. The recipient has a history of contribution to the common good, growth and excellence of the medical device enterprise in the region." So it's really focused on someone that is giving to us all. So I'm pleased to have Norm receive this award. We started in 2006 and I'll read out some folks who have received this award: Peter Gove now retired from St. Jude, Dale Wahlstrom we know at that time was at Medtronic, Fred Colen from Boston Scientific, Rebecca Bergman from Medtronic, Rich Nazarian from Minnetronix, and Tim Laske from Medtronic.

So this year I want to tell you a little bit about Norm Dann. Norm, we're going to build you up so high. We're good friends. He received his engineering degree from Penn State. He was Senior Vice President at Medtronic. He eventually became a general partner and co-founder of Pathfinder Venture Capital Funds. Founder of the Dann and Company, a board member of many medical device companies, one being Aria CV, a spin out of the Innovation Fellows Program. John and Karl stand up. You're a big success. Norm was a big help to them. (applause) They're out there and we've had some innovation and entrepreneurship sessions. Talk to these guys. Wonderful technology and they're raising money and its hard work and low pay and many hours. But they're going to do it. We're proud of them and we know they're going to succeed.

Norm has been working with medical devices for a lot of years and we have him as an Adjunct Assistant Professor related to the Innovation Fellows Program. He is on the advisory board for the Institute for Engineering in Medicine and helped the university move towards where it is today and where it's going in the future. My experience with Norm is that he's got tremendous wisdom and in a way it's humble. He always says I don't know about this but...and then twenty minutes later your hand is really tired from all the notes you've taken. He also tells you if it's a bad idea very quickly. He'll tell you it's a bad idea or it's a good idea or he can add to it. He's so encouraging. So Norm please get up and give us your wisdom. How's that for pressure? (applause)

*Norm Dann (ND):* I first met Art several years ago before there was a biomedical engineering program and Art was one of the few, maybe the only guy I met here that spoke about medical devices. Not only did he speak of devices but he recognized that we had this industry in town, a lot of companies making medical stuff and they not only needed trained people but they needed a flow of ideas and new products. So this meeting is really a testimonial to the work Art has done over all these years. I just take my hat off to him. He made it happen. He's quiet. Doesn't argue a lot...but the son of a gun can turn around and it's going on. He has a unique capacity for getting things done.

I also want to tell you that I'm under a lot of pressure putting this talk on today. I have members of my family present. That's something I never want to do. I have my son-in-law Luke Weisberg who is my daughter Janet's husband. My daughter Marlane and her husband Brad Brown and their daughter Adrienne who, by the way, just produced a great-granddaughter for us. So last but not least, my wife Beverly who has been putting up with this...it will be sixty years next month. (*applause*) You didn't think I'd remember the number. (*laughter*)

Since I've been retired...this is sort of a joke...I eat lunch at home quite often. We have a noon hour lecture. Just so you know, Bev, if Brad has not already spilled the beans... this is number twenty-three.

What I want to do in the next few minutes is give you a bit of my perspective on how this thing happened, this industry. Where did it come from? It, by the way, started in this country. It's very unique to this country and I'm old enough to have watched it from its birth to where it is. I'd also like to speak a bit about what's been going on for the last ten years the industry has slowed down. It was a rapid, really very fast growing business and it's flattening out. I'd like to speak to that. Then a couple words...maybe what you ought to think about doing to reinvigorate and get this medical device industry growing again.

In order to give you the history I have to start talking about my father. My father and his family immigrated to this country in the early 1900s from Eastern Europe, actually a little village near Vilnius, Lithuania. He was the oldest of his siblings, nine years old and needed to go to work. As a young man with probably the equivalent of a grade school education. He had an uncle who worked as a painter in the maintenance department of Western Reserve University in Cleveland where they had immigrated. He got my father a job in the department of pharmacology, really starting probably washing glassware, helping the professors put on the demonstrations for classes and kind of helper for research and so forth. He was at the university for some thirty years and during that period he developed a complete machine shop, a glass blowing facility and a photographic laboratory. By the way, as a youngster, it was a wonderful playground. I learned how to run a lathe and do a lot of fun stuff. That was where we spent Saturdays and some evenings. During that period he invented several devices including an intermittent positive pressure device, a resuscitator, for newborn infants although it was originally developed for use on dogs.

The interesting thing is that this was going on all over the country. In the basements of universities around the country, in most medical schools there was a guy like this. In those days you did not open up a catalogue and buy the research instrument of choice. There weren't any. I remember in my father's office at that time there was a couple of catalogues from Germany and there were microscopes made in this country and other things but the majority of the research instrumentation was built...it was handmade. What happens in the scientific community of course is that the researcher would footnote at the bottom of his paper that the colorimeter or whatever he used in his experiment was made by Mr. So and So at the University of Texas and the three other guys that were working on that kind of problem in the United States or maybe around the world would correspond and eventually buy that piece of equipment. So what began to happen was really the development of a cottage industry. Some of these people started little shops adjacent to the university. But the reason was to support research.

After World War II, Congress decided that we ought to cure cancer, heart disease and stroke and they appropriated a large amount of money for that time. That money all went to the National Institute of Health. I think they purposely knew that the National Institute of Health could not spend all of it and so the NIH started going around to medical schools with the dual purpose of not only adding to the funding of research, but to improve the education of physicians, to improve the quality of the medical schools and indeed they did. Medical schools started to look a lot better and this little cottage industry started to grow with the impetus of a considerable amount of research money flowing from the government. I hate to tell my Republican friends but this business was built by the government. They didn't know it. It wasn't the plan but this is where it came from. Without that funding we wouldn't be sitting here. About the same time health insurance came in and health insurance is now helping improve the hospitals.

I think what caused the shift from research to clinical, the dog labs turning into something applied to human beings, was open heart surgery. You all know a lot of that history because it took place right here.

Keeping a patient alive on a table for six or eight hours in those early procedures required a lot of skill and instrumentation. You not only needed obviously the heart pump to replace the function of the heart, an oxygenator to replace the lung, you also needed physiological monitoring, EKG, blood pressure, and you needed blood chemistry. You could not send a sample down to the lab and wait for the answer to come back. You had to have the information right now. And it was not unusual during those days that the dog labs had much better equipped dog surgeries than the human surgeries. As a matter of fact, in my own experience I recall helping move equipment from the dog lab, wiping it off with a little alcohol, and moving it into surgery because these surgeries were few and far between and they were scheduled. The residents and techs had been trained in the dog surgery and they went across the street and went to work. Most of those early patients were children who were born with physical defects and if repaired, these kids did beautifully. They grew up to be very healthy adults. Those surgeries were pretty successful and this area of medicine started to grow. During that period of course the chief of surgery was

usually the guy doing the open heart surgery. He literally ran the hospital. He brought his research grants across the street into the hospital. Most of the early equipment was bought with this research money and then with the advent of the insurance money hospitals began to see this meant a big business. They began to equip and build these facilities themselves.

As all this process was going on of course, these cottage companies, a few of them that we can identify here locally, grew up to become large companies. By the way, up to this time, there were no major U.S. companies in the business. I remember General Electric made a pacemaker for a while. I can still see the ad picture. They had a little boy running through a wheat field; it was a Life Magazine full page spread. I remember...I was at Medtronic in those days and we said that ad cost more than the whole industry sold that month. I think somebody on the board must have woken up and said, do you know how much liability there is for us? And G.E. got out of that business. That was the end of that. Most of the major companies looked at this as something that was interesting and nice to do, but clearly not enough of a business to warrant their investment and liability risk. So the industry grew out of these fledgling startups.

Now interestingly, the business model...figure most of the medical device companies were built by people who were technically oriented, not your classic market driven financier or shrewd operator. These were people who just learned how to solve a problem that were leading the field. What that model says is that you solve a technical problem in the best way possible you can come up with, the most elegant answer you can come up with, and notice that cost is not the issue. You're not looking for the most economic approach. You're not trying to sell this in the most efficient manner. You're just solving the problem the best way you know how. This practice continued as the business became clinical because after all the people buying the product didn't pay for it. Somebody else paid for it. It was paid for by the insurance company or it was paid for by somebody else. So I can tell you, we solved many business problems in my era by simply raising the price. It's a very wonderful way to run a business.

Now unfortunately this era is over. I know those of you that are connected with the major companies are probably going to be uncomfortable with what I have to say, but the model that this industry has been running on is over and it needs to change. Our history is resplendent with examples of companies who didn't get the message. Think General Motors. They made a lot of money on Cadillacs and cars with a lot of souped up stuff on them but I guarantee the stripped down Chevy was a loser. Their model worked for them for a long time; then they went bankrupt. They figured out that I guess we do have to make a car people want to drive and gets decent mileage and is reliable. That was a revelation. Think Eastman Kodak. Think U.S. Steel. Think IBM. These were all the leaders in their field with all the money in the world, all the brain power in the world. You have to say to yourself what was going on? And what's going on is that big ships are tough to turn. I'm listening carefully for what guys like Omar Ishrak are saying, the CEO of Medtronic. I think he gets it. He's a very bright guy. I think he really understands that he's got a challenge. I'm going to lay out what I think his and the others' challenges are. It's not going to be comfortable. It's a disruptive situation because the business

model needs to change. You're either going to hit a brick wall like these other companies did or you're going to be smart enough to figure out that the world isn't the way it was. There's a new set of criteria and you cannot let the cost of health care overtake our economy. When I started in the business I think health care was probably two or three percent of the GNP. Today it's seventeen or eighteen percent and growing every year. You can't keep it up. It's not going to happen. Whether you're Republican or Democrat, it's not going to work. So it is not a political thing. It's a financial impossibility.

There are three things that I can think of and there's probably more that you can think of that have to change. One of them has a lot to do with you folks sitting in this room and that is designing the right product in the first place. What are the criteria that you're using to end up with the product? Are you really looking at the market? I remember a previous president of Medtronic getting up and saying in answer to a question from the floor about the sale of defibrillators and how is that going to keep going and his answer was that we only have ten percent of the world market. I believe he was correct. They only had ten percent of the world market. But at \$35,000 they weren't going to get much of the other ninety percent. As a matter of fact, in one of the presentations in the meeting yesterday, one of the development directors at Medtronic stated that the company is only growing at one percent a year. The core pacemaker and defibrillator business is actually decreasing. The newer businesses that the company is in are growing but they're too small to have enough impact yet. So the massive part of the market isn't going anywhere. You could lay that off against the recession and say well, things have been a little slow. But this has been going on too long for that. This has been ten years. It is much deeper than that. I don't think you can use that as an excuse. We need to recognize, as many people have, that if we're going to engage in the world market we have to satisfy the world needs as they exist. We have to make a product that they can afford and the product not only has to be geared to their price range and do what it has to do. It has to be easy to use. The cost of training and support is also a factor. So while the product may be complicated, it needs to be easy to use. You have to think Apple. Look at their products. They are intuitively simple. They're very complex machines and they're beautiful. When you see a three year old running an iPad you say they've got it. It's intuitive. Somebody picks the thing up and it works. Medical devices need to be like that. It doesn't have to be that you spend four years in residency to learn how to use it. It should be intuitive. We have the intelligence and the systems today to do that. So that's A; we need to start by designing product that fits the market, not our ideal of what the most elegant solution to the problem is and we'll charge whatever it turns out to be. That business will probably exist for a long time but it's going to be a sliver of the total market.

Number two has to do with the cost of marketing. Now when this industry got started, the docs weren't trained in schools to use this stuff and the industry needed to take on the responsibility of doing that education. So we built into the cost of marketing hanging around the hospital, going into surgery, putting on seminars, flying people all over the world, doing all this stuff because these people needed this hand holding. Now that got built into the system. I would say we are

now a mature industry not a little fledgling growth industry where you can get away with anything. If you compare our industry with other mature industries, my sense is that we have twice the marketing costs of other mature industries and that's not sustainable. We need to get in line. What does that entail? I think what it might entail is stripping out all those services because doctors don't need help anymore putting a pacemaker in. Trust me, the residents do it. It's easy. Okay? So if they price the product delivered to the door ready to go and said to the customer what you get for this amount of money is this product. If you want hand holding...if you want somebody to come in and go into surgery with you, if you want a tech to come by and give a lecture, here's our hourly rate. We'll do that. But not to lay that burden, that cost, on top of every product which is the way it is today. There is a massive distribution system set up which is part of the strength of these companies but a lot of it is not needed. Those services are not needed for a vast majority of the products. You do need it, of course, when you bring something new. Then you've got to do that additional training and support. But you don't need to lay that across the entire product line because the market is now very well educated and knowledgeable. So that's two and that will cause, by the way, a massive disruption in the way companies are now organized. That's why it's so difficult to do because you have to tell a few people to go home or reorient their job.

The third thing which our good friend Amy indicated has made an enormous impact on this industry. Amy Klobouchar yesterday gave you a lot of good information on what's going on legislatively regarding change and I believe the FDA really does want to change. It's also a huge bureaucracy and it's very difficult to make changes rapidly but I'd like to come at that from a little different perspective. Part of the problem is we have taught the public that FDA approval means perfection. If you have an FDA approved product means it's perfect. And by the way, if it fails, we're going to sue you. I used to tell docs that the only thing I can guarantee about this product is that one day it will fail. We've done a lot to try to figure out how to minimize and understand the modes of failure so it will cause the least damage and so forth but this thing is going to stop working one day. It isn't that we did something wrong, it's just that man can't make a product that runs forever and does wonderful things and so forth. Now we've learned to accept risk in our daily lives without a problem. We get in and drive our cars every day with thousands of people getting killed on the highway and all kinds of terrible things not even in the news. I mean it's not newsworthy and we don't think a thing about it. We're not going to give up driving our cars just because X number of people get killed on the road today or cross the street or roll out of bed or whatever we do. We accept that risk but when it comes to medical instrumentation it must be perfect. It's a re-education thing of, by the way, there is risk in everything we do and you have to deal with risk-reward. I'm old enough to remember this business before we had any regulation. Device regulation didn't come in until 1976. I can't remember docs killing a lot of patients by the way. They're trained to be extremely conservative, very cautious, and they did a thing that their years of education taught them to do and that is to look at each individual patient and make a risk-reward analysis. By the way, the products weren't nearly as good as they are today. Trust me. The products were quite

unreliable. By comparison the products we have today are really magnificent. This stuff was pretty crude and yet we put it in human beings because the doctor made this decision that said what are the alternatives for this patient? Is this a reasonable risk to take? And they made that decision. I want it clear that that is very difficult to legislate. We have kind of stripped that out. We have said to the doctor, don't worry. It's either FDA approved or it's not FDA approved. If it's FDA approved, use it. By the way, the FDA doesn't regulate the practice of medicine. There's a lot more variables here than have to do with just designing the product. The doctor that uses it can really cause problems, do a lousy job. Yet it will be the manufacturer who will carry the burden of proof if you get a problem even though in fact maybe the product wasn't used correctly. The FDA does not have the ability to control the whole process. They only have control at one end. And we've given people the false illusion that this thing is perfect. So what should we do about it? I mean besides educating the public that there is risk in everything we do in life and this is no exception. We're going to do the best job we can to minimize their risk and to educate the user on what those risks are. We have to have clinical experience. You can design for the rest of your life an invention and you will not know if you have a reliable product until you use it. Now one of the big differences in medical devices then, and let's say drugs and other things, is that the design and development of the medical device goes on forever. It doesn't stop. You can come up with a new molecule for a drug. You're done. The only thing that changes would be the way you manufacture the molecule or you may change the dosage but you never change the molecule. It either works or it doesn't. Now with a device I can guarantee you that the first device you develop...in fact it's a phenomenon that I've observed that when you come up with the initial design it is probably the most complicated version of that thing that you'll ever see. The more you think about it and work on that thing, the simpler it gets. You begin to realize what's critical to this thing and what's not critical, what you really need, what needs to be fine-tuned, what you can do without and over time that device will get simpler and simpler and by the way that means more reliable. But this does not happen in one stroke of the pen. It's one of the problems that the initial invention may not be used in the clinical product. By the time you get to the production product you will have modified this device several times to get to something that really works in humans. Part of the problem here is that if you get this product to a certain point with FDA approval and make that forever, that is not reality; that process is not practical. What we need, in my estimation, is the ability to get into the clinical setting earlier under very controlled conditions where we perhaps limit patient selection criteria and the simplest and easiest application, learn from that and begin expanding that application as we move along. Today, there are literally thousands and thousands of patients that have not only the disease that you're dealing with but also other complications. You're dealing with a myriad of factors and the original criteria for which the product was developed probably no longer totally fits. So you need to be constantly monitoring. I don't believe you should approve a product and put it out on the market and say we are done. I think the device should be followed forever. We should not wait until we get failure reports to say oops, should we recall? I've sat in on those meetings where the company now needs to make a decision. Let's see. We've got

how many thousands of these products out? We've only had four patients die. Should we or shouldn't we? If we say there is a problem, we've got to not only tell the FDA we've got to tell all the doctors in the world, we've got to tell all the patients in the world. That's really a massive disruption and it is going to cause a major change in our income. Then you have guys that are trained as statisticians that say, you know, that's only a quarter of an eighth of a point. That's really pretty good guys. It's not your kid that just died. So I can tell you that those decisions are difficult and you've got financial people sitting there saying we've got a quarterly financial analysts meeting coming up and this is going to put a dent in our earnings. So you wait. You just pick up a paper and read about why didn't these guys recall this product earlier? How come you've got these problems? They knew about it so the question is, is it a problem yet or isn't it a problem? I have to tell you the story about a pacemaker called the Zytron. Had a little problem. It was one of these products that was just beautiful. In the first three months we sold 30,000 products. It went like wildfire but it had a peculiar problem. It was the first pacemaker that exhibited a late failure mode. In clinical trials on this product which we'd run for six months it was perfect, just humming along. It was beautiful. This product for the first time had a different type of circuit, not transistors and discrete components. It had an integrated circuit. Unfortunately the circuit was in a solder-sealed can which wasn't like today's hermetically sealed can. But we didn't know that. At any rate, Dr. Chardack called me from Buffalo (worked with Greatbatch, the inventor of the pacemaker) with his gravelly voice and he said, "You have a problem". That pacemaker needs to be recalled. We had put pacemakers into fish tanks at body temperature and we had some pacemakers begin to fail in the fish tank. We only had ten pacemakers and I think one or two failed fourteen months out. Again the statistician said that's pretty good and the manufacturing guys said yes, but we made changes in manufacturing and we won't have that problem anymore. So we said oh, it's okay. It turned into a massive recall, just about brought the company down. I remember a lawyer saying to us one day that a class action suit on this case could be more than the net worth of the company. So I understand this problem but I think it can be alleviated by not getting to the point of saying we have an approved product, it's all done. We only have a product for this kind of experience in this size and type of population. As we expand the market we will have continuous monitoring, proactive in bringing back data, making changes, permitting them to go on. Even that game when we know there should be a change in the product we sit around and say now wait a minute. Is this just a letter to file or do we have to reapply to the FDA and get this thing approved again? And believe me; if you have to start over again with another FDA approval you don't do it. They try to get away with it's just a letter to file. So we're hiding behind that facade. We should admit that devices require an evolutionary process and have to be regulated as an evolutionary process that permits us to constantly upgrade product and constantly give feedback on a proactive basis and continually improve the product. Because that will best serve the patient, the physician and the economy.

I think that's enough on that. I want to end then on an upbeat note. The fact of the matter is that, "we've only got ten percent of the market", is still pretty much true. So the upside of this whole thing is that we have an enormous unmet world market if we have the right product at the right price delivered under the right conditions. The good news is the standard of living in the world is going up and many more will be able to afford more expensive products although they're not where we're at. As a matter of fact many in the U.S. can't afford our own products. China, Brazil, India and other countries are recognizing the need for improved health care and will provide tremendous opportunities for the right products and services. If we satisfy these market needs we'll have unbounded success. So with that I'll shut up. (*applause*)

*Prof. Art Erdman:* We got a lot of wisdom today. I'd like to award Norm with the traditional globe you can take home and I guess we're about session time so please one more time thank Norm. (*applause*)