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The Perfect Storm in MedTech (Entire Talk)

Josh Makower, *ExploraMed*

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Josh Makower, CEO of ExploraMed, speaks briefly about his experience working in medicine and technology. Dr. Makower also discusses at length the numerous political, financial, and regulatory hurdles against future medical innovation, and calls for audience involvement in the tangled web of healthcare, patents, and insurance reimbursement.

Transcript

It is my pleasure to introduce Josh Makower. Josh is an incredibly impressive fellow. And I'm sure you will agree with me at the end of this hour. He is the Founder and Chief Executive Officer of ExploraMed and also a venture partner at New Enterprise Associates. I got a chance to get to know Josh because he is a co-founder of the Biodesign program at the med school and teaches over there as well. But one of the things that is most impressive about him is that he has over four dozen patents in a huge range of medical fields, including cardiology, ENT, general surgery, drug delivery, orthopedics, and neurology. And he has also been involved with starting six different companies. He's going to tell us today about the perfect storm in med tech. And he is going to use his experiences in his own companies as a backdrop. Thanks so much and welcome, Josh.

Thank you, Tina. Thanks a lot. Thanks for coming out for this. I appreciate it. So I'm just going to walk through a little bit of background and talk about a recent company experience and then really hit on to the big topic, which is some of the challenges that we are facing right now in med tech, specifically, and try to get people active in this space to get a little activism going and maybe help reverse the course of some of the changes. So this is a diagram of my background all in one big picture. It starts off with a background in engineering and business and medicine. And I got my first experiences in business at Pfizer, working as first a technology analyst and then ultimately starting an in-house incubator at Pfizer, which was called Pfreshtech, with a "P-F" because it was "P-F" for Pfizer. And our mission was to really identify a process for innovating new medical technologies and to ask the question, "Is it possible to innovate inside of a big company?". And we discovered that the answer was yes, it is possible to do that.

It's possible to have a reproducible process that one can use and if you follow that process you will create new ideas that are pretty impactful. The challenge in a big company comes when those ideas are actually created, how do they actually wind up becoming fully funded and allowed to exist? That's where the challenge comes. So the challenge is not how to find and create them. That can be done quite routinely with the process, but the other elements are things that cultural in a big business are the big challenge. Once I left Pfizer after getting an MBA at Columbia, I went on to meet and was introduced to John Nehra at NEA. That was 15 years ago. And we sat in a burger place, In-N-Out over in the City and sketched out on a napkin what ExploraMed was going to be. As an incubator at that point, there really was no med tech incubator. And the incubator concept most people were considering was placed where you build a building and make a bunch of offices and then people come in and use the conference room. And this was a very different kind of concept where we would basically allocate money to the pursuit of verifying, finding, and validating an idea that could become a company.

And then once we've thrown everything that we could at it to make sure that it could stand on its own as a company, we would start the company with the goal of reducing the likelihood of failure and try to fail fast inside the incubator and then get

these things out earlier. And so that's basically what I've been doing for the last 15 years, is producing medical device companies, three of which have been acquired at this point. And along the way I ran into Paul Yock and together we created the Biodesign Innovation Program. And I'll talk a little about that. But in the broad spectrum, this entire phase of my life from Pfizer onwards, let's say last 20 years, I've really been addressing this singular issue, which is to make people try to rethink about how they think about who an innovator is. If I say, "What's the first thing that comes to your mind when you think of an innovator?", you will probably think of somebody with crazy hair, locked away in a basement or a garage, working and tinkering on something, probably not very good at social skills and somewhat removed from society. And then all of a sudden a brilliant vision comes to them. They build it and before you know it they have some amazing new invention. And unfortunately that's what we've been led to believe. Our society has brought us down this path.

But it couldn't be further from the truth in terms of what it's all about. And so the real concept is that we are all innovators. And we all have the potential to innovate. And some of you are actually going to be really good at it. And maybe you don't know it yet because you haven't had the opportunity to train to be one. And so if you can identify that, obviously some will be more skilled than others. There's obviously some natural talent, like with any kind of sports or whatever. I'm not the best basketball player even though I know how to throw one. But the concept is if you can develop it in people, you can teach them. They can get better.

They can learn that discipline and with that discipline just become really excellent at it. And we've demonstrated this for multiple years. And people have come in who had no patents before but really had the desire and basic fundamental education to do it, come out and become real innovators and start companies and do great things. And they do it better than they might have it if they were not being trained. So important elements: access to the customers, the right environment. You got to have an environment that accepts failure, accepts the fact that we don't always get it right the first time and embraces that in the pursuit of the ultimate solution to a problem, a good team, the right people, people that can work together and of course the right amount of resources. And in just its basic form, this is the process. And I think the most interesting thing about this process that people don't really think about is that it starts with deciding what you want it to be before you've invented it. And that's a different concept for some people. They think, "Well, I got to think of an idea of what it should be." But actually if you think about what it needs to be before you invent it, then you'll know when you found it.

And starting with that strategic structure, it has got to be a business of a certain size. It has got to address a certain population. It has got to have intellectual property protection. It has got to be able to be achievable within a certain time frame. Whatever your parameters are, it's going to be different for an individual versus a big company versus a small company. So those are all different. But when you figure out what that is for you, it really sets a framework that you can act on. The next fundamental step is another one that seems relatively obvious but it's amazing how few people do it, which is to focus on the need. And when we say focus on the need, I see some of my fellows here in the room. They know what that means.

It sounds so simple to do, of course. You're going to look at a need and then you're going to solve it. But there is a discipline to that because as human beings we desire to not be in an uncertain place. We want to have certainty. We want to know what the answer is. We want to run to the answer. In fact as soon as we think of the first idea that we can think of, which usually happens as soon as we start getting exposed to problems, we come up with an idea. And then that's the only thing that's filling our mind, is the solution. But what happens then is you fall in love with that solution. You can't get it out of your mind.

You can't change. You can't think of anything else. So the discipline is actually to not invent but to actually focus on the problem and to spend the appropriate amount of time really digesting that problem, living in that problem, understanding the parameters. Where are the needs of this problem? What's the specification that needs to be met to solve this problem the best? And when you've developed that discipline, you're able to release yourself from this desire to get to certainty quickly. And you can live in that place where you can really see the problem for what it is. And that's what we've done in every one of the companies that we've started. We've been in that place. And as a result we've created something that other people have never thought of before. And so that is where the whole process value is. The rest of it is all straightforward.

Once you really have that problem specked out, brainstorming is easy. I mean in fact, you came up with so many ideas you couldn't believe it. But here's what we got going into, we've got a great specification of what it needs to be once it's invented. And that helps us very quickly figure out which was the best idea. And we are able to divorce ourselves from just loving one idea and move on to the one that's right. OK. So we've reduced this into a much more elaborate process which is detailed in the book that came out that we put out a couple of months ago and that we use as a textbook for the Biodesign course here at Stanford. But I just mentioned this as a backdrop because it really is a fundamental aspect of how I've gotten to where I am today and what we try to train people to do. So that's the background part. Let's move on to the entrepreneurial story part.

Every time I look at this picture, it's really a fun picture for me to look at. It's John Chang's first day at what was then called ExploraMed NC1, New Company 1. And here we are. We look a whole lot younger and definitely a lot less battle scars, wrinkles on our face, et cetera. And amazingly that was only six years ago. But still, it's amazing what a business can extract

from your life. But there we are, first day on the job. We don't know what we're going to do. We have no idea. This is the first day, blank sheet of paper.

And that's something that's some part of my model. It's a little different than other incubator models because I start with the person. So my whole approach is that person is a fundamental basis around which we build the company. They have to be trained. They have to have the right experience. They have to ready. They have to have been successful. They have to know how to get a product from concept to commercialization before. But maybe they've never started a company before. They've never done it on their own before.

But they're ready. And they've got the right kind of heart and soul, ethics, all those things that are really important that go into someone who can be this role. And that's the role of project architects for me. So there we are, first day, kind of fun memory there. So this is what we came up with as we began to try to understand the needs of the area of chronic sinusitis. That became an area of interest because I was a chronic sinusitis sufferer. And I was very interested in trying to find a solution. But when I thought about chronic sinusitis, I thought about "-itis'. It must be an infection probably addressable by drugs. So I didn't even expect that we'd find any device solutions.

And being a device person, I thought that was what I wanted to do. So my criteria was it has to be a device solution because if it was going to be a pharma thing, biopharma or what-have-you, that's not my expertise. And I knew that that wasn't what I could do. But that didn't stop me. I just said, "I'm going to learn about this thing and see what it needs to be." So we came up with this structure. We came up with an engineering concept of sinusitis. And what we have here is we realized that there are two components. There is a bony scaffold which really supports the mucosa that lines the sinuses and a dynamic component which is the mucosal surface. And that mucosal surface can swell. And if you've got a really tight passageway because of the bony structure and then the mucosa swells, well the whole thing blocks off and a cascade of problems start happening.

And you get acute sinusitis and with all that swelling in certain people who have that certain anatomical structure, they progress into a chronic sinusitis. And they can have pain for years like I did. I had consistent chronic pain, inside your head every day. Wake up in the morning, go to sleep at night and all you're thinking about is, "How do I manage my day so I can just get through it and not have a headache?" I wasn't even that bad. But people would say to me, "You're not bad enough for surgery." I was thinking to myself, "How bad do you need to be to get surgery because this certainly feels pretty bad?" So that was the motivation for Acclarent, what we came up with. And this is the "Aha!" picture. We spent a lot of time looking at this need, trying to understand it. And I looked at this picture out of the corner of my eye. And it looked like an angiogram. Now for those of you that aren't into medicine, an angiogram is a situation where you're injecting a contrast agent, something that actually prevents the penetration of x-rays, into a structure within the body.

And you're sending x-rays through. And as a result, you get this pattern which is basically showing all the structures where the contrast agent isn't. But you see this pattern of the blood vessels. It looks a little bit like a tree because the blood vessels branch. And you can see where the blood vessels go. And you can also see where they're tight and where they have little lesions inside the blood vessel. And that's the basis upon which they direct angioplasty catheters, to go put those little balloons in there and dilate those tight spots. When I looked at this, I said, "You know, I wonder whether it's possible to put a flexible catheter like a balloon catheter that they use for coronary angioplasty into the sinuses and do the same kind of thing. Could you dilate the sinuses like that?" And so that was the idea for Acclarent. We tried it.

It worked. I'm going to fast forward. And this is what we were able to accomplish in the last six years. We were able to take that concept to commercialization in 18 months. Basically nine months in, we were in patients. Nine months later we were through the FDA and we had it on the market. We file lots of patents. We're able to raise a lot of money to do this. It took a lot of money to do it. We created a lot of publications, a lot of clinical data.

To date we've treated over 100,000 patients now. We treat about 350 patients a day worldwide. Revenue rate, greater than 100 million a year, 375 jobs. And it was acquired for actually 120 million net of cash, 7.85. So there was cash on the books. That's the published amount that is actually 20 million for the acquisition of the business. So when you look at that, you say, "Well, gee, it sure looks easy. But man, do we have challenges!" And that's the part that I don't think a lot of people realize: the challenges that we have and the challenges that the business still has, quite honestly. The biggest one was the one that I was the most disappointed in, being a physician myself, was the physicians' unwillingness to change. I had this idealistic view that you come up with a technology that really makes people better.

It's easy to use. The patients like it. The outcomes are better. You save tissue. You save the patient. It's all good. How can somebody not love that? And the answer is, well, because that's not the way people were trained to do it. And there isn't reams and reams of data and it's new. And so why should I do that? Get out of my OR. So that was quite interesting.

Beyond that, the next thing that was somewhat disappointing were the harsh tactics that were used to try to undermine the

company and the struggles that we had with some of the leadership and we still have, quite honestly. The piece that I didn't understand going into this, usually I have this matrix of things, "You got to check that box, check that box." I didn't have a box. I'm trying to understand the politics within the society itself. That was not something I realized was an important element of trying to navigate a technology. I guess in retrospect it makes sense. But I just didn't think it mattered. The answer is it matters. You've got to know who's who. Certain people need to be involved because if they're not, they get angry. They're people and people have emotions and that's the way it is.

So I think in a lot of ways our early fervor and excitement and enthusiasm was really misunderstood by a lot of that clinical community in the early days. And there were a lot of misunderstandings that really delayed us. And because of this in the early days I think we struggled to survive. And that was part of it. And we haven't really solved these issues. They still continue and they will continue. This isn't just ENT. It's other spaces as well. It's something that if you decide to innovate in this space you need to be aware of. There is well entrenched ways that things are done.

And you think about how you compellingly make those changes not just with the clinical argument but with other arguments as well that get change to happen. But when I look back at what are keys to success were, the idea worked. We were able to navigate the FDA process. It was predictable. Investors had confidence in our patents. They knew that eventually we would get protection and then that would be powerful and we can enforce those patents. We had ready access to financing, able to maintain great clinical advice. We work closely with our clinical advisors, get them in the lab, pay them appropriately and incentivize them appropriately to take time out of their practices to spend with us. We were able to go into a scenario where the reimbursement was already there in place for the procedure. And we were able to quickly establish it and get it covered under that umbrella.

We were able to track great people who worked really hard and never gave up. But when I look at this list and I think about some of the challenges that now face the med tech industry, this is what's at risk. Is the opportunity to do this again. Given what has happened within the last just couple of years, just within the last two years, there have been some dramatic things that have happened. And that's what I'm really going to talk about for the rest of the talk here and hopefully try to get some of you to care about this and want to be in the space to take some action and help make things better. We are essentially facing what is essentially a perfect storm in med tech. It's the global financial crisis. It's the certain aspects of health care reform. It's not all bad but there are certain aspects that are quite damaging for our industry, limitations on the ability to interact with physicians, certain aspects of patent reform that are quite scary, changes at the FDA potentially devastating, and a broken reimbursement system that really penalizes things that are new and potentially better and puts a really high bar in their success. So that's what we're going to talk about.

So let's go through each one one-by-one. First thing is this whole global financial crisis that impacted the VCs. You probably heard about this lots of times from other speakers. And as a result, venture funds are really funding the companies that they already have. There is less and less opportunity for new companies. So this is the backdrop. What's going to make this better over time, the markets have to turn around. People have to believe again and that will happen. But I really put the slide up, just lay the backdrop as for all the other things that are going on right now in our industry. The reimbursement climate as I mentioned is exceptionally challenging.

I mean most people don't realize that there are three fundamental elements to actually get paid for a medical technology. First there has to be a code. So if you've invented something new, there is no code. Well that could take several years just to get a code. Well once you get a code, you're going to think, "Hey, we're home free, ready to go." No, now you have to have coverage. People have to agree that they are going to cover that coded procedure in their payment system. And private insurers, what's their motivation? There is some extra money that they have to pay out. So they are going to set a high bar. CMS is the same thing. They are worried about expense.

So they are really going to put some significant scrutiny on deciding that they're going cover it. So now once you cross that barrier, you got coding and coverage, what are they going to pay? Sometimes they decide to pay less than the price of your device. Where does that leave you? So you got to fight these battles every step of the way. That's what's ahead. And sometimes you get a code that is like a category 3 code. There are different types of codes. If you get a category 3 code, you're like in a penalty box for potential years, because basically you're experimental and don't come back for certain amount of time. I mean, imagine the venture people paying while you're trying to go through this process. It's quite devastating. So that's already there.

These are the things that were already there. We were already dealing with them but in the context of some of the other things I'm going to mention, again another layer of complexity that people have to realize how difficult it is to navigate a new medical technology. Let's talk about patent reform a little bit. I think here there were lots of lobbying efforts of myself and Ed Brite and folks in the Foundry, really our med tech community as a whole. We have made some major progress here. I think the change in the patent commissioner to David Kappos has been a major breath of fresh air. He has a great group that he has brought with him. He understands the importance that intellectual property plays for med tech especially. And he has been very

clever in the way that he has tried to go about it. So I feel much better about this slide than I did let's say a year ago, when the previous patent commissioner I think really in his mind was really hoping that the way that he would deal with the patent backlog is just, "If those damn inventors stop inventing things.

We could get rid of this backlog. That's a big problem. It's just too inventive." That's not a good way to go for America. Healthcare reform, there was lots of uncertainty. Well now we have some certainty. And really as a whole, health care reform for the med tech industry isn't that neutral. I don't think it's going to help promote new technologies or innovation. I don't think it's going to hurt except for three very important issues. The big one is this medical device tax. Now every time you hear people complaining about taxes, well, everybody is going to pay taxes, too bad.

But let me explain why this particular tax is exceptionally damaging for innovation in med tech. And I think you'll appreciate why people are so upset about it. It's not a tax on profits. It's a tax on revenue. The other thing to recognize is that when you have a med tech company, you could have revenue of $25, $50, $75 million in revenue and still not be profitable because of the costs of actually getting the people in there to train appropriately, paying for the regulatory clinical studies. All of this stuff is expensive. And so with Acclarent, we did not see any dollar of profitability until we approached $85 million run rate on a yearly basis. And so when you think about that, wow, that means that venture people, investors are going to be writing checks to the government for the privilege of investing in medical technology. So it's really devastating. Not only do med tech companies now need to raise money to pay for development, get the sales going, all that kind of stuff, now they're going to have raise money to pay the government to be allowed to have the privilege of not making any money until they reach profitability.

This just isn't going to work. So we got to fix that one big time. Comparative effectiveness, I think we have yet to understand what that is, potentially scary for novel technologies if they're going to say, "All right, you fledgling technology, let's compare you against what we've been doing against the past 40 years when it hasn't even really fully developed yet." That could be really scary. But we don't know what that is. Hopefully it will would be executed in an enlightened way with respect to novel technology. Payment reform, et cetera. Let's talk about the Sunshine Act, which is a component of health care reform so you can understand why people are a little upset about this. Now I believe in transparency. I think transparency is a good thing, to know what's going on. But at what level? What level really matters? Right now the current law says any med tech company that provides something of value, it could be lunch, it could be two Starbucks coffees, of $10 or more has to be recorded and published on a website for every physician interaction that is in that category.

That means that if you think about the administrative costs of that and who is going to pay for that, it's going to be the health care system. We're trying to reduce costs here. And so there is an obsessive focus on this cash as a motivator. But $10? Come on, give me a break. I mean $10 is not going to make doctors forget what the right thing to do is. We could set a little higher limit. It might be a little bit less burdensome. This is exceptionally burdensome. But here's the big thing that really irks me, because whoever came up with this law has obviously not stepped foot into an academic situation where there is no money. But believe me there is lots of conflicts in power and prestige and political power.

And being right could be like such a much bigger motivator than ten bucks. That's what people forget. And unfortunately, what has happened is anyone who has some financial interests has been removed from the debate about new technologies. Yet all the people who have all sorts of academic conflicts and political conflicts are still in the debate. And that's really concerning. And as patients, consumers of health care, we should be worried about this, because guess what? We fought a lot of physicians on the way to build Acclarent who did not really see the vision, who did not like it. They did not want things to change. They liked it the way it was. They thought it was appropriate. They did not believe that the technology could work and they really tried to stop it.

Imagine if the only people who could decide on the future of novel technology were people like that. That's what we may be facing if we don't take a better appreciation of what real conflict is and instead of eliminating conflict of interest we manage conflict of interests. We acknowledge it. We expose it. You have a relationship, you got to say it, all that type of transparency. But if we try to cross or make a line, then the only people who will be making decisions will be those that are not informed. And that's very dangerous for patients. So the FDA, are you depressed yet? Here we go. The FDA's mission is a valid one. It's to provide reasonable assurance, safety, and efficacy and to promote innovation.

Sometimes people forget about the second bullet here, promote innovation. What does that mean? And how is it being interpreted? When it was all set up, there was supposed to be a least a burdensome standard upon which this would be implemented so that companies would be allowed to survive because one could try to eliminate all possible risks and kill any possibility that any innovation can survive because there is always a risk. It's almost unavoidable. You can't eliminate all risk. So what has happened is after Obama was elected, a letter was sent to Congress and Obama by a group of disgruntled employees at CDRH claiming that the management of CDRH is in cahoots with business and that they're not making the right decisions, et cetera. And so there has been a lot scrutiny. And in fact, a lot of the people named in that memo are now gone. There was an investigation. And I think the investigation showed that there was no wrongdoing by those people. But what's happened is there is now a wave of a fear.

What you have to realize is the people that reviewed these incoming applications of the FDA generally are well-meaning, scientifically-oriented people who recently have exited school. And they are full of ideals and they feel tremendous responsibility for our society that they need to protect everybody. But they don't have a lot of experience. And they don't have a lot of exposure to the real risks and benefits that patients and physicians face every single day and how willing some patients and some physicians might be to take certain risks. And look, we do it all the time. We accept certain amount of risk in all of our activities in life. And especially when we need a therapy, we accept some of these risks. Believe me, if we took a poll right here, maybe we should, how many people would like to avoid all possible risk and what the impact of that would be on the innovation and the opportunity to be exposed to new therapy? We just need to be educated. And today we're educated better than ever. You can get so much information off the Internet.

An article comes out on The New York Times. It's all over the world. Practice patterns can change overnight. So we're not dealing with the situation where once this thing is released, if it's not right, it can't be fixed, it can't be recalled, it can't be dealt with. There is those opportunities. But because of this whole thing, there has been a whole desire. There should be no fast path. The people view this 510(k) process as a fast path. It isn't a fast path. It is faster than PMA hopefully.

But it doesn't mean that it hasn't been scrutinized. Many 510(k)'s go through clinical trial. So there is a lot of misperceptions. And I think as a society, here's the message for you and whoever is listening, we got to decide what we want. We want new medical technologies. We want to see progress and innovation. We have to accept a certain amount of risk. It comes with the unknown of something new. But that doesn't mean you have to get that therapy. But should we prevent others that want to get an exposure to it? Should we prevent everyone from having the opportunity to get exposed to it? How much of a barrier do we want to create in front of our ability to gain access to new technology, to have that opportunity even though we know it might not work for everybody? We want to understand what those risks are.

We want to understand what the safety balance is. I think we don't want to have a organization stand in our way of access to what people and the rest of the world really have access to. And that's what's going on right now. Many technologies are available overseas that are not available here and it's just because of our process. So this is an issue. So we discussed this. The big issue is, and my concern, I'm even sharing this with you, is that if we don't fix it, then the bright minds, the creative people who are looking to build their careers, we're not going to be able to continue to bring them into it. Especially we've been so fortunate for so many years to have so many great smart people innovating and creating fantastic technologies that are going to advance patient health. And we've experienced that benefit. And it's evident by the improvements that we see every day, the advances, the ability for people to live longer, healthier lives.

We've come to enjoy all of that. That has been based on a foundation of innovation. I don't think we want to give that up. And I don't think we want innovators and bright people going in other places. We want them to continue to come in the industry. So why should we care? This is almost a quote. I won't to attribute it to anybody. But we've enough innovation in medicine. We're done. It's like John Lennon, "All the songs have been written." You know what? Maybe some people believe me.

Maybe there's a little bit in the background. "Maybe if we knock out the med tech industry, we can save health care costs," some people said that. "Well it's all this technology. It's causing all this expense. Let's get those CT scanners out of the hospital." You know they believe that innovation is driving up the costs of medical care. And you've probably heard this. It's OK, you might even believe it. I'm going to give you some facts. Maybe we could change your mind. First of all, med tech is a strong economic force in the United States.

It is responsible for a tremendous number of jobs, very high paying, high skilled jobs. But it's very fragile. When you think of med tech, you might think Johnson &Johnson, Medtronic, some big company, Zimmer. But the reality is med tech is 80% small companies. Little companies that make a widget that connects up to an inflation device that connects up to a dilator. Lots of little companies with small numbers of people in them and funding from venture capitalists looking for that investment, that return ultimately for their efforts. It produces a reasonable chunk of the GDP. I mean it's small, but the important thing is it's one of the few industries that we have in the US where we have a net trade surplus. We're actually exporting more medical device. We're the only country that actually exports more medical devices out.

So it's one of the positive industries that we have in the US. And the impact is quite significant for our own population as well as populations across the world. And most importantly, med tech can't possibly be blamed for the increasing health care costs. If you look at health care spending in the United States, it's greater than 2 trillion. Med tech, spending on medical technology as a whole is 5% of all health care spending. So where's all the rest of it coming from? If it's not the big CT scanners and the disposable instrumentation, where is it going? It's services. It's people. It's jobs, actually. It's nurses and doctors and administrators, et cetera. Now I think that some of this can be, if you look at the inefficiencies, where is the opportunity to save money? Probably on the IT side.

Maybe we don't need three people to touch a document before it finally gets to the insurance company, things like that. It's not med tech. It's not the technology's not to blame. It's easy to point to because you got a big $2 million CT scanner out there.

But that isn't the big part of the costs. And that's what people don't understand. It's very unfortunate. What have we accomplished is tremendous. If you think about the human suffering that med tech has actually addressed it's very significant. I mean angioplasty, the things that we take for granted.

These were innovations. Small companies, small inventors that created these technologies in the hope that they would not only be established for the benefit of humanity but that they could create a thriving business that would employ people, that would make money and the investors that put their money into that to believing it would beget some kind of return. That's where it was all based on. If we're guilty of anything, it's actually prolonging life. That's probably expensive. We've increased the life expectancy significantly. Americans spend 56% less time in the hospital compared going back to 1980, than they did in 1980s. So that's yes, technology probably has something to do with that. And that's probably expensive because those people are living longer. They're consuming more health care resources.

We have an aging population. That's probably the biggest driver, the aging population. If you look across worldwide, it's not just the US that has a baby boom, worldwide baby boom. This is what's driving health care costs. It's the biggest driver of health care costs. We have an aging population. People are being treated for many more things than they used to be. And that is where it's coming from. So what do we have to do? We've got to make sure we have a strong patent system. I think we're making a really good progress there.

We have to think of a better way to reimburse new novel technologies. I mean this is something that really needs to be addressed. And I think you want it. When you go look in the news and you hear, "Hey, balloon sinoplasty, new way to treat chronic sinusitis," you want that therapy. You don't want to go get cut up and have surgery. You want to have the opportunity to have something less invasive. You don't want everybody have open chest surgery when they could have angioplasty. So we want these procedures that can make our lives better, faster without so much trauma and pain. So we have to figure out a way to pay for those. And we need a system that allows novel technologies to get a foothold without starving them and only the survivors that go though it, that can last that process, are left at the end.

We need an FDA process that is predictable and that we can navigate with reasonable cost and still provide reasonable assurance of safety and efficacy. And we've got to think differently about conflicts. We have to manage conflicts. But we should not exclude conflicts. People who may have conflicts need to reveal them. But to exclude them from the debate, to basically categorize all of their ideas as tainted would be very unfortunate. It really is not the way we built the country that way. We have everybody's voice and everybody gets to have input. We just recognize from what background and influences they come from. And that should be openly acknowledged.

But we can't exclude people from the debate. And we need to reinforce as a society how important innovation is to all of us and how important it is that we strike some kind of balance in the safety that we expect. Even ourselves, we have to realize we can't live in a bubble. When we get into a car, we don't go and believe that it's General Motor's fault if we get into a car accident in the parking lot. That's the way we have to look at it. Unfortunately that's the way it is. I mean, we can't predict everything that's going to go on in the biological system that we're trying to address in med tech. We wish that there was a perfect model, that we could get everything out. But things happen. We learn things.

It's that learning that allows us to make products better. And it's that learning that allows us to iterate. And if that iterative loop is delayed significantly because of regulatory delay, then we are going to see things that are wrong that we got to fix. And they won't get to the market for years. I don't think we want that. We want a rapid innovative system. That's what the 510(k) system was developed to do. It was to build upon the innovations of the last innovator by some incremental improvement and just to be able to get that out fast so you could continue innovating and advancing medicine at a great pace as opposed to waiting for years for the next incremental innovation to appear in the market. To do all these, we will really repair our industry, continue to bring bright minds into it and really drive our economy. So for those of you in the audience who are listening or present, who are in a med tech company, it's your company or whatever, you got to become a member of one of these societies.

It's very important. You need your voice heard. This is happening to you. All this is happening right now. As we speak, there are meetings in Washington every week. You got to get on the roster, be a part of the process. If you're not, you can be a part of the process, too. Learn about it. Get involved. Talk to Congress people directly.

Write to them. Get involved. Express your views, either side, it's OK. It's important that we all take very quick action because it's changing right now. The impact of what is going to happen within the next couple of months could affect your children, yourself, your parents. These are very impactful things that are going on right now and so your voice matters. So make sure you're a part of the debate. We still have time to act but the wave is coming. Thank you very much. So, questions I guess.

Yes, we have some questions. I have a comment and a question. Yes. The comment is in terms of the parties and players

that are against innovation. It would be very interesting to compare them on job creation metrics. And I will bet you the fewer jobs they create, the more they are against innovation for very understandable dinosaur-type protecting old technology reasons. But my question is what is interesting to you in comparing incubators across the great divide between the public and private sector, because you have a revolving door in Washington. I've also heard that a DNA RNA type patent was reversed recently. So is there anything interesting to you when you look at these small business innovation research grants that I guess are across several federal agencies and how effective those are compared to private sector incubators? So the question is, is there a difference between a private sector and a public sector innovator? Yeah, I think there probably is. I think that the model that we really try to execute on is one where we can create the greatest opportunity for patients that also represents a sustainable business.

And that's an important component because in our current setup, there just isn't the resources. I mean who's going to develop all this? Who's going to pay for it? I mean it's amazing because the challenges that we have in some of the companies is they say, "Well, all of your trials have been sponsored by the company. So how can we know we can really believe them?" I said, "Well that's OK. Why don't you guys run a trial?" "Well we don't have any money for that." I mean how are we going to advance medicine here? Where is it going to come from? This is the issue. I mean, either there needs to be that money allocated for it or it's not available and private industry has to do it. So it's either way. But I think that right now anyway, a lot of the public kind of activities are focused on basic science and very valid and important stuff that has a place. But it isn't all commercializable and not all of it is transferable into broader applications because it doesn't have necessarily the mind set of how do you actually also make this a sustainable business? And so it doesn't necessarily get up there. I have two questions. So the first question is to what extent could these kinds of issues be outsourced to legal warriors, and to what degree? Because this seems to be detracting from your time inventing things and making new applications or even enjoying the benefits of what you created or basking in the glory of your creation? I like basking.

I like to bask more. So how can you be shielded from having to worry about this at the expense of creating new technology? I don't know. The question is, how come I'm doing this and how could I not have to do it? I wish that there were a different way. But the truth is that the way we do it is we all get involved. The answer is everybody who cares about what I just talked about today gets involved. If this touched you in some way, get involved. If you know somebody who can have influence, make sure they understand your point of view. If you're just a patient listening to this, make sure you express how you feel because there is a perception out there that we need to protect everybody. We need to protect everybody from companies trying to make money selling technology. But this is the way our society is built.

We're in a capitalist society right now still. So as long as that is the case, you're not going to see new things happening unless there is some business part of it. There's got to be some profit opportunity for these things to be created. It's just the way it works. Who's going to put the money into investing in these companies, right? So we've got to get involved. So I think the answer is for me as running an incubator, I've got several companies in the game. So I can see how this wave is affecting all of them at the same time. Maybe that's part of it. That's why the guys at the Foundry and myself and other incubators and other people who are involved with multiple companies like myself, to us it's like you watch this wave. It's affecting every single one of our businesses, the VCs also.

But I think patients and innovators have a unique opportunity to have a voice here because unfortunately big companies have been cast into a bad place. Venture capitalists have been cast as they're all just money people. They've become just big companies. They're these big monolithic things. So that leaves the rest of us. If they're being isolated and excluded from really having any voice here because they're not viewed favorably, that's where patients do need to get involved. Innovators create jobs and technology to help people in the med tech space. We need to have our voices, and all of you. If the only part of this is that you're a patient, you need to decide. And if you agree with what I've talk about today, you need to get involved.

One of the common arguments I've heard is that FDA acts as a check and balance to the companies that might be trying to further their personal interests. I just want to hear your thoughts on where is that balance between the rights of the patients to be like "I want this experiment done on me" versus the government trying to protect people from getting exploited. Yes, great question. The question is what's the right balance for the role of the FDA. There is an important role for the FDA. And really for many years, the FDA created challenges for us in the med tech industry. But those were for the most part, I think reasonable. And there's an appropriate amount of scrutiny that technology needs to be put through. We don't want the FDA to go away. I mean it's an important part of what we do.

This should be a regulated industry. There should be standards, just like there are in other countries. We have the CE ISO standard and that works very well. The ISO CE process is exceptionally navigable, predictable and successful. What happens here in our country, unfortunately, is that the waves of the media, the waves of politics kind of wash over that whole system and influence it. That doesn't really happen as much overseas. It does a little bit but to a much lesser extent. And because of that, what happens is something shows up in The New York Times. Somebody is outraged in Congress. They bring the FDA in and say, "How could you ever have let this happen? You guys are not doing a good enough job." The FDA is just trying to do what

they're supposed to do.

They're public servants. They're doing what they think the public wants from us. So they're getting that voice from Congress, "You guys are not tough enough." And then the next thing that happens is some struggling medical device company brings this issue like, "We can't get this thing approved. The FDA is standing in our way. How are we going to get it done?" And they go to their congressmen and they say, "That's ridiculous, I agree. You guys are not letting technology out to patients." I mean it's just back and forth. They're being slapped back and forth. It's not fair. It isn't right. But that's part of the problem.

So we need to agree on what those reasonable assurances are, safety and efficacy, and stick to it. Let's make it predictable and allow companies to say, "Here's the checkbox. If I do these three things, it's OK. It's not going to be subjected to some other level of theoretical review because they're so afraid that if they let it go, they're going to get slapped down again." And the reason is it's just hard to predict everything. In real life, the clinical trials by their nature study one element of the disease with one aspect of the technology. And we just can't simulate the real world environment in a clinical trial. There's just too many variables. We'd never learn anything. I mean, we'd be treating everybody anybody. You're just trying to get all the inputs.

So to do that we have to be very specific. We have to narrow it. But in real practice every day, doctors do what they think is best for the patient. They take a technology and they use it to help somebody. Sometimes it works, sometimes it doesn't work. And that's just the reality of where we are. So I think if we can all accept what that reality is, then we can accept when sometimes things don't go right. But we don't necessarily have to blame the FDA for all that. I mean if there were something that was wrong and it was hidden or that kind of bad stuff, I'm not excusing any of that. There has been some of that in the industry.

It's not good. It doesn't help anything. So we're not trying to talk about that. What we're talking about is the general standard being applied for everybody. It just needs to be fair, predictable, reasonable. And as long as it's all those things, it's OK. There's a good place for regulation in the industry. I have a question. I'm actually surprised to see that you put the comparative effectiveness research in the category of potentially dangerous things. Because it seems like for a number of these issues around entrenched practices or having fair processes for reimbursement, conflicts of interests, that comparative effectiveness can move in that direction.

Exactly. I think it's a great point because I fundamentally believe in the general thinking behind comparative effectiveness if applied appropriately. But it can be also applied inappropriately. Let me give you an example. When angioplasty was first introduced, the balloons were the first generation. After a couple of monkeys and some animal experiments but who didn't really have real cardiac disease, they needed to go start working on patients. And they got it pretty successful. But it really only addressed very few lesions could be reached by these things. And they realized, "It's got to be a little more flexible. It's got to be this." And then they made it more flexible.

Then they realized, "It's got to be different pressures because sometimes you get a really tight calcified lesion and other times you don't." There was just no way of simulating these. So then they did that. And so if you looked at it over time, eventually the therapy got developed through lots of these experiences. These technologies didn't necessarily hurt anybody. But they just didn't work as desired. Then they ultimately got cardiac surgery. Now a couple of people probably also got hurt. But it was a new technology. But over time that therapy has become what it is today, which is a tremendously successful fantastic alternative to coronary bypass surgery. OK now we can compare it.

But think about if we compared it back to when it was first introduced. It would never have existed. We would not have balloon angioplasty or stenting available to us today if we subjected that technology at that time to compare it to the existing cardiac surgery. Now I go back further. Let's look at cardiac surgery. And anyone who knows the history of cardiac surgery and what it took to develop the right perfusion pump without clots, being able to sustain people without damaging their brains, to be able to sustain hearts in a still mode without damaging the hearts, we accepted at that point in time the risks because of the severe consequences of not doing something, right? It's not pretty, but it's how medical technology has gotten to where it is. It's part of the innovative process in this space. So I think applied in the appropriate way at the appropriate time, it will allow us to proceed and innovate; applied inappropriately, nothing new will ever be established as valid enough. So that's the answer.