Applying an Entrepreneurial Mentality to Medical Devices

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Richard Satava: My background is I am a surgeon. I spent 23 years as a combat surgeon in the military, three combat missions that I served on, and in 1992 I went to DARPA. How many know DARPA? Great. Alright. So I'm not going to have to explain that. And this is kind of entrepreneurial at its core. Many people look at us and say, “There's the government’s venture capitalists,” and to a certain extent that’s very true. We're not vulture capitalists because we use your tax money. We're simply venture capitalists.

But what I'd like you to do today is to tell you a little bit about the government’s approach, the Department of Defense’s approach, to entrepreneurship and what the process looks like for acquisition, if you will, and then go into a number of the technologies that were developed, some of which I developed and others had done that as well, and a little bit about what I've been referred to, which is called the technology harvester and why that has some relevance.

To begin with, a test. How many of you know what this is? This is a biological molecule. It's an information system and it's an energy system. Does anybody recognize this one? Alright, well, let me rotate this 90 degrees. And so anybody recognize this? Sure. DNA. It's about a completely different perspective, and I think that’s where we need to be going. Clayton Christensen said, right, about disruptive visions, if you will. Yogi Berra framed it differently and he said the future was not what it used to be, and that’s profound in the sense that what he was saying that the things that we have learned, the things that we have integrated into our daily thinking, are outdated and probably false. We're in the Information Age, but most of us were educated in the Industrial Age and there’s a whole different set of perceptions and interpretations that we carry along with our baggage. And our younger generation, of course, gets it. They're
digital natives. I'm a digital immigrant, more or less, and then some people are just digitally dumb.

So the problem that we have is transitioning and beginning to think in the information space. We define that slightly different. You are probably digital immigrants because you really kind of get what information science is all about, but unfortunately, and to my interpretation, most of what the people in medicine and healthcare look at as Information Age is translating what we used to do from a typewriter to a computer or from a written database to an electronic database, and the Information Age is much more profound than that.

So what is a disruptive vision? An example here of course is Henry Ford, and I love the quote that he gave. He said, “If I asked people what they wanted, they would have said a faster horse,” and that is true today. It's about understanding what the fundamental question is and what they're really asking for. They weren't asking for a faster horse. They want to get from point A to point B quicker, and the only way that they knew was to go ahead and speed up the horse. But if we look at, what is the evolution of point A to point B? If you had a book and you would want to take it from point A to point B, you would walk it, and then we got to a point where we could ride animals and get there faster. Then we had carts and vehicles and we could hold a bunch of them and move them even quicker with multiple animals, then we got mechanical vehicles, and then a disruptive vision hit – the ebook. We can have everything that you want from a book on your Kindle or on your iPad without physically sending the information that's key to what you want to know from point A to point B. Simply download it in 30 to 60 seconds and you have it available. And this entire chain that we have built up over thousands of years of taking physical objects from this place and taking to that place is completely revolutionized. So this is an example, if you will, of the power of the Information Age and really looking at the fundamental principles, how it is different.

So in my role as a technology harvester, horizon scanning, I have the opportunity, because of the 12 years I spent at DARPA and the four years at medical research come in, to get into many communities. I'm a trusted source in the sense that, as you well know because we were responsible for classified material, people would trust us with their information, we are walking NDA and we have access to the broad spectrum. Whether it be from academic, federal labs, FFRDCs, businesses or various large industries, we have access to, and the
opportunity there is to share information, particularly information or new ideas and concepts or technologies that most people don’t have the opportunity to do. And these are a number of the things that we use for that, not only literally visiting place to place or going to conferences such as this one to get a broad perspective, but also the opportunity to go ahead and have access to the wide variety of databases that are there, and quite frankly many people continue to send information to us hoping that will stimulate new ideas and so forth.

One of the things that I learned about at DARPA was when you come up with a new idea, one of the first things that you want to do is, so what is the standard that we have today? The standard is basically the best of breed is a 360-degree view. Look at it from all different perspectives, the users and the manufacturers and the company and so forth. But I think that one thing that I was talking about at DARPA is we need to take the 180-degree view, which is what? You look at what the current standard is and assume that’s exactly the thing that you do not want to do. You want to start a new business with exactly the opposite.

And this came out of Clayton Christensen’s book, although he never really spoke about it. But if you read from his book what he used as examples like large [00:06:51] to small [00:06:52], crane operators to backhoes, steel industry to micro steel industry that went to Japan, all of these took what is the standard that we use today, what is the way that our customers tell us we want and this is how we want to do things and look at it from entirely different perspective, which is why I showed you DNA in the beginning. So this is a methodology that you can use. Can I do exactly the opposite of what’s available today and get a better product out of it?

So it’s about rethinking the status quo, and this is what I think our greatest entrepreneur of this era, Steve Jobs, was, and his quotes I think are also very telling. So time is limited. Don’t waste it living someone else’s life, something that's already been accepted and everybody believes in. Don’t be trapped in dogma, which is living with the result of other people’s thinking. Be innovative, be creative. So this is the direction that we need to go, I do believe.

So in healthcare, what do we want? There are expectations out there by our patients. I remember a year or so ago sitting down with a patient that had a hernia and they wanted to start off by showing me the other children’s pictures and their vacation they went on, and finally I got them to say, “And why are you here?” “Oh yes, I'm here because…”
And then when we decided what it was, she said, “Okay, what do we do now?” I said, “Well, I need to do a final diagnosis.” And so she said, “Oh, we need lab test taken right now.” And I said, “Well, I have an ultrasound and I can look at it.” So I, “Oh, you've got an ultrasound and you do have a hernia there.” And she says, “Great. What happens?”

And I said, “Well, this is going to need surgery.” She said, “Well, can we do it now?” And I said, “Well, this one we're going to have to schedule. I can't do it right now, although maybe in the future I'll show you high-intensity focused ultrasound that may eliminate the need for actually doing surgery on it. But I can't do it in my office now.”

She said, “Okay. And it's not going to cause any pain, is it?” And I said, “No,” “And when I leave I'm going to be cured, right? I won't have to come back and ever see you again, will I?” And I said, “Probably not.” And then she said, “Okay. And could you hurry up? I've got to go pick up my child from a soccer game today.”

So this is what we want, and I think this is what everybody wants. Why did I go through this here little story? And the reason being is that this is a benchmark that we want to see how close we can come to with a product.

We want to meet our patient…or our users’ expectations, and the closer that we can get to their expectations; the easier the sell for the product is going to be. But our expectations are high, but now our challenges are getting even bigger. There are significant changes in the population as a whole and some of the approaches in the past are no longer as applicable as they used to be.

So let me tell you a little bit about understanding research as part of the entrepreneurial enterprise and show you where we go on that in terms of new technologies.

In the military, they call it the acquisition process. It begins with, say, a soldier who says, “I need a new helmet that’s laser-resistant.” “Well, I don’t have one of those.” So we have to begin with R&D. Research and development begins the acquisition process, and then you go through all the various steps as we go along, what is called life cycle management, and using descriptions such as the technology readiness levels. And then when you finally finish it and you get your FDA approval, your marketing and so forth, then you finally have to dispose of it.
So what does that process look like? And I've seen the complexity that you've talked about particularly when we're relating to FDA and those types of regulations. This is the Department of Defense, NASA, and NIH’s roadmap for developing a new product, and so this is what you go through whether you know it or not.

And the incredible part about this is when you start talking to researchers and you want to start a new product, they think, “Well, I have this new idea and I want 50 or 75% of the royalties.” What they don’t realize is they’ve done less than 10% of the work and the investments in it. So R&D is really down at the very beginning. When you finally get here with your prototype, then you have to go through the FDA, which we've been struggling through with today, and finally you get it approved, but then you've got to manufacture, commercial, marketing, and eventually it has to disposed safely, and that’s the responsibility in the business.

I only put this out to recognize how hard your job is. Even if you’ve got a great idea in your new product and you want to move forward, this is just the beginning of an extraordinary, long, difficult, and expensive journey particularly in healthcare.

One of the things that will help you are technology readiness levels. How many people know them and use them? It's a language, if you will. You can find it on Wikipedia, which is a very nice, simplified version of it.

But if you want money, particularly if you want it from the Federal government and any of them, if you can go ahead and tell them using the terminology in the levels here, it will be greatly to your advantage because what you'll be able to do is submit a proposal in a language that the program managers understand, because they get money depending upon the level of readiness of your technology. It will do you no good to submit a proposal to DARPA to do a clinical trial because by law they are not allowed to do it, so why bother submitting? No matter how revolutionary you may think, we have to go to medical research commands and so forth in order to get that color of money.

So I just want to put this out that there are ways if you learn the language to increase your likelihood of being funded. And we know the role of the scientists in the development of a new product and of the different people that are involved in there, and there are a couple of chasms in there. There's the Valley of Death, which I'll show you in a moment, and then there's another one, a second chasm with after you got your product the
expectations frequently are higher than what you can actually match. It's been overhyped by the media and so forth, and that’s another area that's very difficult that very few people pay attention to.

So this is what the Valley of Death looks like. The government will help or outside people will people help you with funding, but then you get to a point in time where the government says, “Well, this is far enough along. You need to create a business or you need to find an exit strategy.” But on the other hand, those who are investing in you want it further funded. They don’t want to take the risk that’s in here and we end up with what we call the Valley of Death. And so this is very common. People have known about these for decades.

What most people haven't paid attention to is the second valley, which is the second chasm, and that is you’ve got everything you've got, your FDA approval, you're ready to go, and you go out marketing, you find out nobody really wants it after all. It's kind of been overhyped, if you will. You can't meet the expectations. And it was Gartner who brought that to our attention, if you will, which is Hype Cycle and the sense that you start with the new technology and people see it and they have these great expectations on what’s going to happen, and then you don't meet those expectations and then it begins falling down. You have to do the hard job of the research to validate that in addition to getting the product out, and finally it actually gets out in there. So these are some of the issues that I see as challenges and barriers to actually getting what would appear to be a simple, new innovative product actually out in the marketplace.

So enough with the boring stuff, let's have some new toys. And so what I'd like to look at as a different way of technologies that you might want to look at as something that you can take advantage of, something that may leapfrog you and put you out of business. There are technologies out there that I think that are coming most people aren't aware of, and they're either complimentary to and you should see how you can integrate with them, or they're going to be competitive to you. Few of them will be completely irrelevant to where you're going.

One of them, and my area of interest, is robotics and robotic surgery. Here is the system here. I would commend to you that you think of this not as a medical device. This is an information system. It happens to have arms and legs and so on and so forth, but in the paradigm of the Information Age. What’s really important about the robot are not the parts but it's the software that controls it. Without the software, it's safety factors, the
redundancy, failsafe, graceful degradation, and so forth, that robot is truly useless. So it's a combination not only of the physical device you're doing but the information system that controls it.

But the beauty of that is that this is an information system and it's one that nobody’s taking advantage of. I've seen a lot of talk about approval processes and so forth. I haven't heard a lot about sharing information back and forth across the electronic medical record. The electronic medical record has been talked about, but this is a device as an information system that generates information.

The first time I operated on a patient without ever looking at them was when I did laparoscopic surgery. I never saw my patient. I looked at a video image, which is information about what’s going on inside. The first time I operated with a robot is the first time that I not only saw my patient but I never touched them. I moved my hand, the electronic signal information went and it cut, sewed or whatever I told it to do. So I became an information manager, if you will.

And if you look at other devices today, your CT scanner, that’s not a digital imaging device, that’s an electronic information eye, if you will. And if you look at the things that you're doing from the perspective of an information system, these are things that you cannot physically integrate but you can if you use the information systems that control them.

The interesting thing about a robot is that it's bought by an enterprise, usually a hospital of some sort, but it's used by their physicians. There is an enormous amount of data.

Big data is generated during every single operation and not a single piece of that is used. Why is it that every time I do an operation and I'm finished, I have to go out and dictate an operative note? The robot knows more about what I did than I actually can remember. We should be able to collect and automatically print out an operative report.

We have to change instruments. The da Vinci is only allowed to have five uses, and then you have to throw it away. And it automatically can communicate, although it doesn’t directly with your central supply for just-in-time inventory and so forth. Very, very few healthcare use the systems that have been set up in other areas as well. So this is just to emphasize that there is an enormous opportunity from the devices that we have and the communication back and forth between them.
We decided that we were going to go ahead and not only build the robot but see if we can build an operating room based on manufacturing principles in which we got rid of everybody in the OR except for the patient.

And when you think about it, what does my scrub nurse do? Well, she changes my instruments. Well, we have tool changers for that in industry. And what about my scrub nurse? Well, she gets new supplies and so forth. Well, we have supply dispensers, automatic. So we built an operating room with no people using the currently available robotic system but it's generic and it can be used with some other systems as well.

And so I would say, “2-0 chromic catgut,” it would go to the dispenser, bring out the suture material and hand it to me if I were ready. If I wanted to change my instrument, I'd say, “Scalpel for the right hand,” it would grab the scalpel, wait until I held out my hand, removed the clamp, and replaced it with a scalpel. It can do this in 11 seconds and it can do it with 99.96% accuracy, almost as good as my scrub nurse.

So we have systems that are available there and they're trackable, but so far we haven't moved forward in them. So why would the government spend 30 to 50 million dollars building systems like this? Well, one of the problems that we have is the “far forward battlefield.” We don’t have a bunch of doctors and nurses there but we do have a few medics. So here is the concept video that resulted in developing robotic surgery and the operating room of the future until we go to the next generation. The scenario is what would happen when a soldier is wounded out on the battlefield away from medical facilities? Well, we have a robotic extraction vehicle that you see here, we have two prototypes of that, and we put our robotic operating system with telemedicine into an armored vehicle, a Bradley 557A. Then we began what would conceptually be robotic surgery for damage control on the battlefield. You scan the individual to see where the damage is and send that information back to your surgeon, and then the surgeon can begin operating. If you need to change tools as I showed you, we have the tool changers, and if you needed new supplies—and this represents fibrin glue to stop hemorrhage—we would have those available as well. Not only are we using mechanical instruments but we're going to more and more towards energy-based systems, things such as lasers and ultrasound, plasma and so forth, which I'll be talking about shortly. And then when everything was completed, you automatically evacuate the patient into an unmanned air vehicle to the closest MASH hospital.
When we developed this concept video in 1995, everything that you see in that video was available to us in industry. We did not have to invent a single thing. It was a matter of systems integration. And so we did not have the opportunity to complete this because we demonstrated it can be done, and they said at DARPA, alright, our job is over. We invented something new and we proved it could work, and we moved it out into medical research command. The budget came, R&D got slashed, and so now this is on the shelf collecting dust. But the concept is valid, and whether or not we do it no longer is a technical issue but it's rather one of, “Do we want to really do this? Is this going to be cost-effective? Are we going to have a market?” and so forth.

So, many of the things that we have out there we have been working on for a generation or more. For example, we funded UC Berkeley and Robert Fuller’s lab and Eric working there on a cockroach. I mean, I hate cockroaches, but anyhow, it is the most efficient motion machine on this planet. And the concept was, if we can learn how this could be so efficient, perhaps we could run our robots better. One night, students snuck back into the laboratory, they disconnected the recording wires from the probes in its brain, connected them directly to a joystick, and began driving the cockroach around the laboratory. Three-and-a-half million of your dollars to drive a cockroach around a laboratory.

But imagine—look at your cell phone, you've got that tiny little camera—imagine if we would have put those on, say, a thousand of these little cockroaches and sent them into the World Trade Center, into Haiti during the earthquake, to the tsunami. I mean, these can go places that people or even dogs can't go. They probably could have found many, many people that were trapped under there perhaps, saved hundreds if not thousands of lives. So maybe it wasn’t so stupid after all. But that was the beginning, if you will, of the biomimicry and the bioinspiration efforts at DARPA.

Here is another one right now that is being developed at the University of Washington, Daniels laboratory. This is a moth, a sphinx moth, but when it's in the pupa stage they open it up and implant a transceiver, a receiver and transmitter. When it grows up, it grows in around the neural crest and it actually embeds it in there. And so these little moths now, they're not very little, they're about this big, when they grow up and they emerge from their pupa, you can actually fly them around remotely like you would find an airplane, but it happens to be within a living system. So we're beginning to integrate, if you would like,
the capabilities of biological living systems and the mechanical systems that support them.

And you saw earlier the given capsule – this is what used to be an endoscope. I see some of you squirreling around, you know. You've had your colonoscopies and you know how hard it was. Well, now we broke the tip off of it, embedded everything into the tip, and you swallow this pill, and as it goes through every 30 seconds it sends a picture to your belt-worn computer. And about 18 hours later it's passed, you take the video, give it to your gastroenterologist, and he will be able to go ahead and make your diagnosis. So we're moving biomimicry, if you will, away from large devices that we use to smaller devices that mimic some of the functions that are biological.

And here was the next generation “the ability to control these,” if you will, a couple of large EU projects running around five to 10 million dollars per year, multinational ones, and these are some of the devices they began building. This is one that kind of crawls around inside the abdomen or chest, has manipulators, and it's actually able to operate on things. Whereas this one would be in a fluid-filled cavity like the bladder somewhere, and so you can't walk around, you kind of propel yourself around. And this might be for inside one of the lumens like in the colon somewhere and it'll wiggle its way through. So they're looking at different ways and they can make them extraordinarily small like this tiny one that you can actually put into blood vessels and allow it to swim upstream and so forth. So we are looking at how far can we get smaller devices into the body and be able to do therapeutics with them.

Femtosecond lasers. Who knows what a femtosecond laser is? Yeah. Who cares what a femtosecond laser is? Yeah, I care. And why do I care? Well, a femtosecond laser is you shine on laser light and when you pulse it really fast, a femtosecond per pulse, which is $1 \times 10^{-15}$ seconds, if you take this pulsed light and you put it on an individual cell, you can make an incision and open it up and begin operating on the individual parts inside of the cell, mitochondria and so forth. At the University of Dundee in Scotland, they’ve actually gone ahead and gotten into the nucleus, removed bad genes, and replaced them with good genes, giving a new definition to what is genetic engineering. You can do that today and many biologists have been doing this for well over a decade by using some of the computer-controlled systems that we've got available to give them micron-level proficiency. However, we have that because the current robotic system that we have, it's accuracy is 10 microns, which is enough to allow us to
operate on individual cells if we would choose to do that. No one’s explored that area. They're very busy from a business standpoint increasing the revenue and getting enough robots out there at this point in time. But this is an unexplored potential that we may be able to use because the precision of the robot will allow us to do something we have never been able to do before.

And here is an example from Dundee. This bright spot is a gene that has just been replaced and these other genes here are other genes that are defective that can be replaced as well. Where most of this activity occurs is at the cell membrane. And this is an ion channel, and this shows you that we can actually stimulate the ion channel to open up and we could put individual proteins, transcription factors and markers one by one into the cells that we would choose.

So when we start looking at these and we start using things such as femtosecond lasers and radiology with the precision of tenths of a millimeter, is this now surgery or is this radiology, or what is it? Is the future surgeon going to be somebody who sits behind an x-ray screen and use this, for example, something like the CyberKnife that allows them to get an accuracy of 0.1 millimeter on tumors and so forth? You can couple those with markers, individual markers for individual cells, so that only the cells that are marked are the ones that are going to be damaged.

And so we're looking at developing hybrid operating rooms that are a combination of imaging suites as well as surgical suites, and we're seeing the beginning of the appearance of these. These are extraordinarily expensive because you've got the big expensive CT or MRI in addition to the expensive operating room. So rather than spending four to five million dollars, we're pushing the limits up to seven, eight and 10 million dollars just for the basic operating room that’s a hybrid operating room. We're not sure where it's going but it looks like there is a pathway to the future, which I'll be talking about in a moment.

But I’d like to just finish with robots because I love them so much. They're so cool. DARPA has a new program, the rescue robot, if you will, and this, it's anthropomorphic. It looks like a human. We don’t need a robot to do that, and besides, we can't build one. And then a friend of mine, Mark Raibert for Boston Dynamics, built Petman. This is probably one of the most sophisticated. His next generation is called Atlas and it's being used. But this is a program that is not programmed. This robot has modules called subsumptive architecture in
them that communicate with each other. You give it a high-level instruction, go from point A to point B and pick this up, and come back. And it navigates its own way. It's able to go over different obstacles, if you will. If it's bad, [00:29:34] it has to do it's pushups, if you say here. But it's truly the next generation. It's got about 10,000 sensors on it, it's got [00:29:41] a brace that's a good AI program that helps control it, and you saw the next generation of robots, where we're going.

So these are the things that we have there, things that are going to be coming out. We don't have to invent them. They're already there, and the question is, how can we implement them? Can you integrate this in your overall plan for what you would want to do? Can you build things that would supplement this and be part of them rather than be replaced by them?

So our current trends today in intervention have started with open surgery and luminal surgery, then minimally invasive like laparoscopy, multi-invasive, which was robotic, and where we really want to go is to noninvasive. And we've had our instrument development on there and if you look toward the end there, now that we're robotic, what comes after robots? The next generation, I believe, is something called directed energy surgery, and this is significantly different because it allows us to do it noninvasively. I've showed you one or two of the opportunities that we have, say, like with the CyberKnife. That's noninvasive surgery. Kill the tumors, kill the things without having to make an incision. The patients love this because there's no pain involved. They come and then they go out as an outpatient and so forth.

So we have to rethink how we're going to do therapeutics or interventions, if you will, and I believe it's the flow of information that controls energy and that’s going to guide the future of most of our procedures. The fundamental change is going to go from physical objects, if you will, [00:31:14] tissue with instruments, the tangible things that you feel inside you, the devices will go to intangibles like information and energy and the interaction of the two of them. So it's about exploiting the energy spectrum and the information space, and I think that's a new definition for what is the Information Age. This interaction is key.

The electromagnetic spectrum is out there. I mean, we're surrounded by all forms of energy. It's this big. Industry is using this much of energy in x-ray, ultrasound and so forth. Medicine is using about this much. The opportunities are huge if we can control the energy with the information,
and that’s the direction that we would need to go. This is about all we're using at this point in time of this massive amount of energy that’s out there and how we can exploit it.

So I think the time has come, and the reason I think the time has come is because I saw this video is because I saw this video by the Navy. Instead of sending their destroyer out with 80 people about 120 million dollars in cruise missiles, they send them out with eight people and one laser, and then they challenge them with 20 different unmanned air vehicles, and from two miles away they were able to destroy within three seconds each of those that were coming towards the ship. They weren’t even within range of their missiles that they carried. So the point being is that we've got the systems, particularly the control systems that I mentioned, that are so important. If I can control a device to focus on approximately one square foot and follow that and track that for three to five seconds, certainly I can have a desktop device that will look down at the micron level. So we have the capabilities to do that. We’ve been testing them in the biological field, in cell biology with genetic engineering. Why this is important is when you put the two together, the device that you’ve developed and software to control it, you can develop a single instrument that performs diagnosis and therapy in real time at the point of care in a handheld, portable and low-power instrument that eventually could be autonomous if you put closed-loop feedback into it, and eventually it may end up as a home consumer product.

So let's digress for a moment why this is important, what the implications are. For about 2000 years since Protagoras made the statement, “Man is the measure of all things,” we have used man as the measure for all things. How many feet did you walk to get into this room? How far is a yard or a meter? Well, actually in 1453 it was defined the distance between the nose and the tip of your finger by the silk industry, and what they would do is they put the bolt of silk up and they grab it, and they'd go one, two, three. Those were the measures. And when you look at it, until just recently, everything has been on the macro scale, but in science we’re down on the micro and all the way down to the nano scale. We have a new way of perceiving the world, one that we never had before. Sure we had microscopes and we had telescopes to increase our view of the world, but that was only for a few very, very special people, but now in the future we have the opportunity to move to a totally different scale.

And Richard Feynman was right in 1959. He said, “The future is in the world of the small.” That's where we're going, and for the first time we
have the capability not only of diagnosing or looking at this but actually manipulating at that level. What makes it possible, it's a combination of information and energy that results in an intelligent system. So for engineers that are out there, if you send some form of energy into anything that’s living system, you perturb the system. For example, if I shine a light onto a cell, it either absorbs or transmits it, and the difference between what I send in and what comes back is going to be my diagnosis because each living system is totally unique. So I can make a diagnosis by shining a light, shining an ultrasound, shining a terahertz millimeter wave, any one of these spectrum of energies that are out there, and then I could make a diagnosis from it. But if I take that information and immediately feed it into a device for turning on and turning off, say, a therapeutic modality like laser in order to cut and coagulate high-intensity focused ultrasound for ablation and so forth, then we end up with a closed loop. So I can send in a test to find out what my cellular diagnosis would be, and then I can ablate that particular one or I can enhance it, I can give it an extra energy to change the level that it's moving at. This closed loop is a very profound change because this now makes my instrument intelligent. It will know exactly what the configuration of every single cell is as it queries each one.

So with this, we can do a closed loop in 50 milliseconds, but what does that mean? As a surgeon, that means I can do 20 complete operations in one second or in a minute I can do 1200 complete surgical procedures. I can't even do 1200 in a year, and here now I'm telling you I can do within one minute 1200 operations, but it's at the cellular level. The reason that that’s important is that we can identify cell by cell whether it be cancer, whether it be inflammatory bowel disease, whether it be wound healing, to either destroy, apoptosis or ablation, or to stimulate, angiogenesis or VEGF or some of these others that we know that turn healing mechanisms on, and we can do it cell by cell just by sliding our instrument over it, if you will. So it gives us the opportunity to use energy to control the biological processes for either destruction of tissue or for healing of tissue.

So here are some examples of what we have available. High-intensity focused ultrasound. That yellow dot went on. Let's see if I can run this again. And when the yellow dot goes on, the ultrasound coagulates the tissue inside of the lens without causing damage to the outside. It's called an acoustic window. You are able to focus it to a point so that the only damage occurs exactly where you would like to have it, and you could measure that, you can modulate your energy to the frequency, the power
settings and so forth, to the exact depth and precise point that you would like to.

[00:38:18] is very interested in that. Using their hemorrhagic model, which is to lacerate the internal iliac vein inside the abdomen of a pig, every one of the pigs that you would lacerate, you would cut this vein, they would bleed to death in 15 minutes, 100% mortality. So here you see the Doppler image of that vein being cut, the artery being cut, and now it's bleeding to death. But we had the high-intensity focused ultrasound, so they pressed the button and they looked, couldn't see...oh, there's a little bit [00:38:50], so they went ahead and pressed the button again, and what ended up happening is when they checked it there was no more bleeding. Normally, this would be about a one- to two-hour operation, and they were able to do it in less than a minute without causing any incision whatsoever.

Imagine if someone’s out on the highway and they're injured, they've got blunt trauma, they’ve got a tear in their liver or their kidney, a medic runs up and goes, “Hmm, well, I see where the bleeding is,” and presses the button and stops the bleeding and the patient is cured. Star Trek, anyone? No? It's a new technology that we've been developing based on the premises that I've told you about information and energy, and we could move further in other directions as well.

An area that is a great excitement to me that's brand new, it was approximately six years ago something called cold plasma was discovered by the physicist. Normally, plasma means, what happens when lightning strikes? It energizes [00:39:53] all the air and it converts it to its more elemental forms of energy. So it destroys the product but it creates energy in its place. And so someone just recently discovered how you can do that with low power without all the fancy other equipment like vacuum and noble gases and so forth, but simply by pressing the button you can create this plasma. Why this is important is that we now have enormous amount of free energy that’s there that you can begin manipulating biological systems.

In the cloud that we create [00:40:27] from, it's a little purplish-colored cloud, you can see it right there, we have charged particles and free electrons. We've got reactive species, nitrogen and oxygen. These are responsible for our most basic biological principles. These are the things that turn on and turn off most of the mechanisms that we see that are used in medicine. We use drugs to carry various types of drugs into the body, and what do they do when they get there? They react and cause these
electrons to move or the reactive nitrogen species to interact with the systems. We also have UV light. We have high temperature, electromagnetic pulse which is responsible for disrupting adhesions between cells. So there's this energy that's in there and we're beginning to realize that our biological process of life at the molecular level has to do with moving around electrons or other forms of energy, and we now for the very first time have instruments that not only can detect what’s going on but we could add or subtract energy from it and actually turn on and turn off specific molecules. This is a revolutionary concept. Right now plasma is limited to the surface. We're using it for things like sterilization and wound healing, and we're looking at other areas. We can selectively turn it on and turn off. These are the things that we've been able to turn on and turn off like angiogenesis for healing. We can also incite apoptosis.

An interesting thing is that high-energy plasma in the past had been used for sterilization, but it was too difficult to use. You had to have monster instruments and so on and so forth. We've discovered that cold plasma does the same thing that hot plasma does, and why is that exciting? There is no known biological agent that is resistant to 30 seconds of exposure to plasma. Can I repeat that? No known biological agent that is resistant to 30 seconds of cold plasma. We've investigated it. We took blood samples from our soldiers that died in the battle [00:42:36] from overwhelming antibiotic-resistant bacteria, subjected them to these, and it killed every one of them within 30 seconds, and we would repeatedly take the few that weren't killed, [00:42:53] them, and through multiple generations, at least six generations we have data on that they cannot develop resistance. And this plasma does not injure cells. The going hypothesis on that right now is because our DNA is controlled inside of a nuclear membrane, which has a number of important chemicals in there like [00:43:14], which destroys nitric oxide and prevents it from damaging. But all other known biological agents don’t protect our DNA or RNA, and therefore they get totally disrupted by this process. We have to learn more about this. This is only six years old. It didn't exist six years ago, so the opportunity now is enormous to be able to move forward.

So these are some of the things that we're already looking at and investigating for clinical applications, if you will. Am I getting close? Ooh, I got to hurry up here. The University of Tennessee just discovered that they could put a marker on a brain tumor and then they would shine a specific wavelength of light into the skull, activate the markers, and kill the brain tumors. So now we know how to kill brain tumors cell by cell.
that are individually marked without even doing surgery, without giving you terrible poisons like the ones that we use in chemotherapy or immunotherapy simply by marking them and giving them the right light. This has been going on for a long time.

Here is food processing, to give you example of what’s out there. The chickens go past for inspection. Before, they used to have one check in every hundred. You would swab it, in two days literally you’d find it. Now as each one of these chickens go by, they rotate around and they do two-and-a-half chickens per second. They laser-scan them, not too different from this laser scan that you got in the grocery, match it to a database and determine whether or not any one of a hundred different pathogens are on there, and they go through this. So we should be able to in healthcare leverage off of this. And they also have coupled it for automatic milkers and so forth. So I think what the future is looking at is a combination of image guidance and intelligence systems with energy to take us to a noninvasive form of therapy, which we’re calling directed energy surgery.

So I have a few more…how much time do I have? I'm getting close.

Alright. [00:45:39]. These are probes that we put into the brain of monkeys, and these monkeys, what we would do is we would teach them if they would move the red dot to touch the green dot, a robotic arm would come and feed them. It takes about six weeks to process the signal, pretty much like we did with the cockroaches, but then what we did is exactly the same thing that happened with the cockroaches. You take it away from the recorder, you hook it directly to the robotic arm. It took the monkeys about two weeks to realize they didn't have to move their hand in order to get fed. They just had to think about eating and the robotic arm automatically fed them.

So this was translated into an IRB-approved protocol in a quadriplegic that you see here, Mark, at the Rhode Island VA. He has the probe in his brain, he'd had it for three months, and Mark drew a circle, and so you see he's trying to draw a circle with his thoughts. They made a little program so he doesn't have to call the nurse every time he wants to turn the television on or off or to change the channel, and so here is Mark turning and turning off the television, changing the channels and the volume and so forth.

One of the students ran down to the prosthetic lab—this wasn’t planned as part of the research—and hooked up the prosthetic hand, and said, “Mark, can you open and close this hand just by thinking?” It took him about 15
minutes but as you see now in this raw data, the first time that a human ever opened and closed a prosthetic hand simply by thinking. So DARPA began its next-generation intelligent upper arm prosthesis and it's in progress at this time and it will eventually be able to be connected directly to the brain. But perhaps we'll be able to provide a device that sends the signals without putting probes into the brain. Now, this is going to be extraordinarily hard. The signal-to-noise ratio is so low. But perhaps five, 10, 50 years from now we'll actually be able to have a device you could pick up the individual thoughts and be able to control devices with them.

And we may be even sooner than we thought. This is a very interesting experiment out of USC. This mouse has a tiny little 50-micron fiber optic probe in its brain, and with that they were able to look at the cells, see which ones were firing off, and they discovered that there was a pattern: Every time he turned left, they had these specific neurons that were activated. So what they did was very similar to what was done in the monkey. They focused it on each of those neurons and he was walking around at random, and then they started stimulating the neurons and the mouse started [00:48:13] turning these left-hand circles exactly as he had thought. So they said, “Wait, that's really cool. I could make him do what I want to do.”

But the next thing that they did was even cooler, and what they did is they sensed when he was going to turn left, took that and sent it over to the second mouse. And so every time that this turned left, he made this one turn left. He sent his thoughts from one mouse to the other. What would we call this? Mental telepathy, anyone, sending a thought from one person to another? We may be on the threshold of some new way of discovering information and transmitting it. So don’t invest too heavily in your cell phone companies. We may have something else coming forward.

We're replacing body parts, if you know, and we're growing new organs. We've had clinical trials that demonstrate if you harvest the patient’s stem cells, you grow the new organ and you take out the bad one and put the new one in, they do not reject it. They now have an organ without having to go through chemotherapy, immunotherapy and so forth. This is truly profound.

As a surgeon, I know 23 operations to operate on your stomach. What am I going to do in the future with this technology? One operation for your stomach and only one. No matter what’s wrong with your stomach, I'm going to take it out and give you a new one, one of your own that you
won't reject and you don’t need chemotherapy for. And all other industries except healthcare do this. They take your car in, they don’t fix anything anymore. They find the bad part, throw it away, and give you a new one. Time for healthcare to catch up.

And we're looking at printing these organs with 3D printers, and 3D printers are going to be a revolution beyond just healthcare and we need to be part of that. For example, in our fundamentals of robotic surgery, we had to develop a new system and a new device in order to test how well people trained in robotic surgery. We built it with a CAD/CAM and then we printed it out, and now the people can have in their training center not only the device but they can print new parts. They don’t have to go out and order any because all they have to do is reprint them from them.

So [phone rings]…don’t you just hate that? I thought that was off.

So I think the 3D printing is going to be a huge step in the future, and it has applications already that are just beginning to surface in healthcare, replaceable parts that are printed out that are patient-specific as you see here. And as Dan showed you, we can print not only biological parts but electronic parts together as a single device as in the lower right-hand corner. It may be more important than the Internet. But think about this: If we can do things like create organs and dispose of patient amenities, if you will, right in the hospital, we don’t have to have people manufacture them for us and ship them all over the place. There's no delivery, minimal inventory, it's just in time, custom-made, and you can recycle it locally as I'll mention here in a moment.

So here are some things that…how much do these cost? Probably cost pennies to manufacture and they cost us about 125 dollars for them. If we print them locally, we have them when we want them, don’t have them standing around, we can sterilize them with plasma or some other form and use them immediately. So we have an opportunity now to get the relatively straightforward, low-cost 3D printers, make them available, and create the things that we need when we need them.

This is very interesting. There is a company out there called Filabot, and what it does is it takes old materials that were used to print things, reprocess them into the filaments, and allows us to go ahead and use that to print something new. It's kind of like the ultimate recycler, if you will. If you don’t like the piece of equipment you have, you put this through the Filabot, you reduce it to its basic chemical processes, and then you feed it
back in. Talk about something that’s going to revolutionize the way things go. There are certain products like milk bottles and so forth that you can reprocess, use them into the Filabot, and create things that you would want or need. And so I think that that’s going to be one of the huge advantages in the not too distant future.

I'd just like to mention suspended animation because I think this may be the opportunity to replace, if you will, anesthesia. Brian Barnes in Alaska discovered that the Alaskan ground squirrel does not hibernate because it's cold, it hibernates because he turns himself off. We don't know what the signal is that turns him on and off; however, it activates the hypothalamus to send out a chemical that goes to every cell in the body and basically turns him off.

And Mark Roth discovered a way to do that with hydrogen sulfide, and I watched him one day in the laboratory when he put a mouse underneath the ground and gave him some hydrogen sulfide gas, and he was dead in three minutes. I said, “Mark, dead.” He says, “Yeah, I know.” And I said, “Well, what do we do now?” He said, “Go for lunch.” Alright. So we went out for lunch, saw a couple more experiments, came back about four, five hours later, “Mark, it's still dead.” And he said, “Patience.” He takes the top off of it, he whips it up, gives it a little bit of oxygen, and the mouse wakes up, looks around—he hadn't had lunch—finds the maze, runs through the maze, and starts feeding himself. So we think that he was completely intellectually intact.

So what does this mean? I said, “Mark, what’s going on here?” And he asked a question. He said, “What would you do in your life that takes the most energy?” I know what you're thinking. No, it's not sex. It's dying. Because we have something called the agonal gasp. At the very end, you shut everything down, you're basically auto-digesting your body in order to create energy to save your heart, your brain, and your kidneys. And so according to Mark death is an auto-digestion, but he said, “If I block all the enzymes that are needed to begin the auto-digestion, you can't die. You're not alive because nothing’s moving, but you can't die either.” And he said, “The only thing I can give as an explanation for this is this is a form of suspended animation.” So far he's had it up to two weeks in small animals like rats, and he's beginning his large animal trials as well. And he's converted it from a gas into a liquid form that he could actually give IV. So this is going to be an exciting area to look for, and I'm excited because if I can use that I won't have to worry about my patient moving, my patient won't bleed while I operate, and certainly it will numb the brain
to a point that he can't remember anything. And when surgery’s over, we'll 
reboot the system.

So, do I have two minutes or do I need to stop? Okay. Because the most 
important...oops, sorry, that wasn’t [00:55:20]. I keep on putting that one 
in. Is that we have to make sure we do the research so that we don’t have 
some unknown, unintended consequences. But this is raising the issue. 
The technologies I've showed you are raising the bar on the moral and 
ethical issues. We human cloning, we said we can't do any of it. That’s not 
the answer. We now have genetically engineered children. And so the 
question is...if you have a child with an abnormality, the government’s 
going to ask you to have another child, to harvest the cells from that one 
and give it to the genetically deformed, disabled person so they can have a 
normal life. The question is, what happens if the family doesn’t want to 
have another child? Is the government going to be responsible for taking 
care of this poor, disabled child for what few years they have left in their 
miserable condition at hundreds of thousand dollars a year rather than 
giving them a short 30,000- or 40,000-dollar procedure and giving them a 
normal life? Who’s going to make that decision?

We know at least three ways to extend the life of a mouse –apoptosis, anti-
telomerase. What happens if I do? I could give it to your granddaughter. 
Now, she is going to live three times, 210 years. What is that going to 
mean? We heard from Eric Rasmussen about the problems that we have 
with increasing population. What’s going to happen when people can live 
for 200 years? Who’s going to get this technology, everybody or just 
limited to certain persons? It's here. Should we use it?

I said we can grow any part and I said but except for the brain, but in 
Vienna we got people even trying to grow the brain. So I can replace any 
part of your body, but the question is if I do, are you still human? What is 
it that makes you human, this flesh and blood that you were born with that 
I can now replace or is it something more?

So I would like to close—and thank you for your tolerance—with 
probably the most profound question that our technologies raise today, and 
it comes from Francis Fukuyama’s report to the biomedical commission 
from the president and he turned into a book called Our Posthuman 
Future. And this is what he thinks is the most profound question, and it's 
for the first time in history that it walks on this planet, a species so 
powerful that it can control its own evolution to its own time and own 
choosing. That species is Homo sapiens.
That’s not a patient species.

We're not going to wait 500,000 or a million years to evolve into something new. So I ask you, “What are you going to make as the next species on this planet to follow man? Because that decision is up to you.”