>> Glenn Scimonelli: Hello, and welcome to this media briefing on FDA's Medical Device Innovation Initiative. I'm Glenn Scimonelli, and I'll be your host for today's webcast.

Each year, millions of patients benefit from innovative medical devices that reduce suffering, treat previously untreatable conditions, extend lives, and improve public health. The FDA's Center for Devices and Radiological Health or CDRH is responsible for advancing public health and facilitating innovation to help bring novel technologies to market and make the medical devices that are already on the market safer and more effective. FDA recognizes that transformive innovative devices present new scientific and regulatory challenges. To ensure continued access to new devices which often fulfill unmet public health needs, FDA is launching the Medical Device Innovation Initiative, a comprehensive plan designed to address some of the barriers that can impede a product's timely progress to market.

Before we hear about more of this from our guests, let me introduce Dr. Margaret Hamburg, commissioner of the Food and Drug Administration, joining us via phone. Welcome Dr. Hamburg.

>> Dr. Margaret Hamburg: Thank you, and good afternoon. It's a pleasure to speak with you today on the topic of innovation. Unfortunately, my schedule will not allow me to stay for the full duration of this briefing, but I really did want to help to open it. I'm very excited about today's announcement. This initiative has broad implications for how the FDA does business, and how we support and will continue to support important opportunities for innovation.

And as you'll soon see, this really is quite an extraordinary initiative.

More broadly, this is a critical moment for innovation for our agency, and for our nation. The pace of biomedical discovery continues to accelerate, and the stakes have never been higher. By the end of the decade a combination of trends, including international competition, will test America's role as the global leader of product in innovations and as a nation we have important choices to make about how we move forward.

As we do, the FDA is eager and prepared to help lead the way. Our agency is charged with a very significant task ; to protect and preserve the health of the American people. And to succeed in that mission, we must not only ensure the safety and efficacy of our nation's supply of drugs and other medical products, as well as the safety and wholesomeness of food, but also foster the scientific innovations that make new and better products more available for the American people.

Both roles are central to delivering progress for patients and consumers and also impact our economy by encouraging consumer confidence, growing key industries and creating jobs.

Of course innovative products that are truly transformative present unique challenges. So we at FDA are rolling up our sleeves and proactively rising to these challenges. We want to ensure that our agency is a consistently powerful catalyst for innovation, and the initiative we're announcing today is at the forefront of that effort.

As you'll hear from my colleagues in a few moments, sdmch, medical device initiative includes a novel variety review pathway for bringing pioneering products to market swiftly and safely, and notably, it promotes the exchange of ideas among external and internal innovators, device experts and FDA staff, building a framework for recognizing promising ideas early, and incentivizing innovations for years to come.

In fact, the pilot device for the priority review pathway is an example of this spirit of collaboration, and a product of a recent memorandum of understanding with the with defense advance research project agency or DARPA an agency of the U.S. Department of Defense, responsible for the development of new technologies.
This initiative is an important step for our agency, and it's an important step for the future of innovation in medical devices and beyond.
In the months and years to come, we will continue to apply the key principles of this initiative, a predictable streamlined regulatory pathway, and a strong science base, to all of FDA's work, and more broadly, fulfilling our fundamental public health mission.
So I'm very pleased that you're with us this afternoon to hear about this important new initiative, and I thank you for your time.
>> Glenn Scimonelli: Thank you so much, Dr. Hamburg.
As part of this new initiative, FDA is outlining additional actions it might take to encourage innovation, streamline regulatory and scientific device evaluation, and expedite the delivery of novel, important, safe and effective innovative medical devices to patients.
Here to talk about this are Dr. Jeffrey Shuren, director of the Center for Devices and Radiological Health; Dr. Jonathan Sackner-Bernstein, the newly appointed associate director of technology and innovation. And joining us via satellite, Dr. Geoffrey Ling, revolutionizing prosthetics program manager at DARPA, the defense advanced research projects agency, located in Arlington, Virginia.
Welcome everyone Jeff let's begin with you, why don't you tell our viewers about this new initiative.
>> Dr. Jeffrey Shuren: Thanks, dplen, according to a recent report by PricewaterhouseCoopers, the U.S. is the global leader in medical device development. This didn't happen by chance. We're the leader in this field because we've combined our traditional of ingenuity and innovation with our desire to help and to heal. By being leaders in medical device development has obvious nick benefits for the country. It benefits American patients, too, by getting them the latest technology and next-generation products in a time leeway.
But we won't remain the world's leader for long if we do not invest in innovative science and innovative oversight. To successfully achieve our mission to promote and protect the public health means to strike the right balance between innovation and safety.
We must assure that our oversight doesn't stifle innovation, but rather, encourages innovation while maintaining a commitment to safety and effectiveness upon which Americans rely, and that other countries follow. We must turn what has long been considered the Valley of Death into the Pathway to Success.
We can accomplish this by providing clarity and predictability in our regulatory expectations, so industry knows what they must do.
We can accomplish this by putting our considerable experience and knowledge to use to help industry bring safer, more effective devices to the American public.
We can also accomplish this by identifying and facilitating the development and assessment of truly ground- breaking technologies.
Today we are proposing an nve that builds on work we've already done over the past year to set the ever- swinging pendulum in the right place between innovation and safety.
The innovation initiative will address three main dwols goals. First it will accelerate the

development and regulatory evaluation of innovative devices that will help transform to transform an area of health care that will address an unmet medical need. Second it will strengthen the U.S. infrastructure and promote high quality regulatory science.
Finally, lit help the FDA better prepare for and respond to transformative technologies and scientific breakthroughs.
Details on the initiative and how it addresses these goals are outlined in a report we published today on our website.
I'd like to take a few minutes to talk about some of the initiative's proposed actions that speak directly to the agency's commitment to build a tradition of innovation and safety.
Perhaps most exciting is our proposal to establish a priority review program for eligible, new medical devices that demonstrate the potential to revolutionize disease treatment, diagnosis, or health care delivery, and that target unmet medical needs.
Under the innovation pathway, the FDA's medical device center would commit time and resources much earlier in product development so that innovators of new, safe and effective technologies can reach the U.S. market more quickly and efficiently.
We will choose and monitor qualified project applications through the new center science council, which will be comprised of medical device center senior managers and experienced staff.
We will assign a "case manager" to each selected product to help sponsor navigate the innovation pathway and establish a primary review team earlier in the development process. Within 120 days from acceptance into the pathway, the review team, using an interactive process, will develop a memorandum with that sponsor that describes a proposed road map and timeline for device development, assessment, and regulatory review.
Because these are novel technologies, it is likely they will raise new scientific and regulatory challenges.
So key features of this pathway will be identifying and resolving these issues early, in part by leveraging scientific expertise outside of the agency from a new network of experts we are in the process of creating.
Clinical trial protocols would be developed by the sponsor and the Center through an interactive process, and have flexibility built in, to allow for repeat testing and re design.
By front-loading our resources, we can reduce un necessary delays and review these devices for approval in roughly half the time it takes for the typical premarket approval, or PMA, application.
Just to be clear, devices that utilize the innovation pathway must still adhere to the regulatory standards for new applications. Just because a device is accepted into the pathway doesn't mean it's destined for approval.
To assure that the Center continues to help drive the development of pioneering devices I've created a new senior position, associate director of technology and innovation, and have named Dr. Jonathan Sackner-Bernstein to that post.
Jonathan is going to talk about the pilot project for innovative technologies. Welcome, Jonathan.
>> Dr. Jonathan Sackner-Bernstein: Thank you, Jeff, it's really exciting to be here, especially at this point in time. As we launch this initiative. That includes the pilot program of this innovation pathway.
What I'd like to do is first just reiterate one of the points that Jeff made, which is that

we're not focused solely on technologies for the sake of their innovative approach, or their newness. Rather, we're focused on technologies that can change the way medicine is delivered or the health care system works. So we're talking about the potential for major transformation.

And in that spirit, we have a preliminary product that is early in its development, which is the first candidate in this program, and we're pleased to have colonel Ling here who will go into it later, but what I'd like to describe is in general terms what his project is about, so everyone can get the sense of the kind of technologies and promises from a clinical impact point of view that are out on the horizon.

The program is referred to as the revolutionizing prosthetics program, and its focus at this point is to create an arm and hand with near-natural movement. And you'll see it shortly. But what it's going to mean is that the function of the hand will actually be reproduceable by this device.

And if that weren't enough, the next part of the program is to create the tools and the technologies that allow for that arm to be controlled by the brain. In essence, by putting a sensor on the surface of the brain.

This has potential impacts that's really almost un imaginable for those affected by paralysis, quadriplegics who have no use of their upper extremities who can't feed themselves or shift around in bed or get out of bed into a chair, or those affected by a stroke, for those who have suffered an injury that leaves them without an upper extremity or from congenital abnormalities without an upper extremity.

So the impact is really pretty dramatic for those people, and colonel Ling will review that in more depth.

One of the amazing lessons we've learned already is it's not just the technology that's incredible, and the target population that's incredible, but it's actually the entire program that has incredible number of moving parts.

Funded by DARPA, it features the work of a number of universities and corporations spread across the country.

What we're going to do is really focus on one of the initial prototypes in just a minute, but first I just want to make sure that the impact of this is clear, so people understand the kinds of products we're focused on.

I think back to a classmate of mine from college who lacked an upper extremity, lacked an arm, and had a prosthesis, the kind that most of us are probably familiar with, the hook. The metal hook that allowed her to grasp, and really perform an incredible number of functions and perform really at a very high level. But what it didn't have was it didn't have the thumb, the opposable thumb that separates us and that allows us to perform so many higher functions with manual dexterity.

It's pretty amazing that it's been one hundred years since the patent was filed in this country for that hook, and now we're on the cusp of going to the next level.

So what I'd like to do right now to give you more tangible insight into the potential impact is share with you a video that allows you to see the functioning of this arm.

So we'll show you this arm, and you see it here, this is an arm prototype being demonstrated to show the near- natural movement of the hand and arm.

Now, a normal upper extremity including the hand and fingers, has over 20 different ways, 27 different ways it can move. This hand at this point is built to perform all of them. And as you see, it even can move between the -- touch the fingers to the thumb tip

in a way that would allow for great dexterity.
Here's an example of being able to pick up an object, move it, manipulate it.
One can see the potential with this kind of movement for performing the kinds of activities of daily living that the paralyzed can do, a person -- can't do, the person could use this hand to answer the phone, to feed him or herself, potentially even to get out of bed.
Now, this may not seem like much like you're seeing right now, but imagine being paralyzed from the neck down, not being able to feed yourself, to be outfitted with this arm, if indeed it proves to be a efficient safety and effectiveness to warrant getting to market and allowing someone to take a drink of water, something that people can't do when they're paralyzed.
So the potential impact to some very basic human functions that make those who are affected by these disorders feel like normal people is truly phenomenal to consider.
Now, here's an interesting part. The engineer operating the arm actually makes a little mistake here. See, the wrench drops and yet the device has enough dexterity to get the prosthetic hand back onto the wrench, and pick up the object. And perform the function.
Now, I'm not suggesting that wrench maneuvering is the critical task that people who are paralyzed need, but it shows the degree of control that this arm prototype has at this point.
Now remember, this is a prototype, and there's still the component of studies that include placing the sensor on the surface of the brain, and performing the clinical trials to provide reasonable assurance that that's a safe and effective approach before this would make it to market.
But the time line that DARPA proposes tends to be pretty aggressive. comren Glenn very impressive. Thanks very much Jonathan. Joining us via satellite now is colonel Geoffrey Ling, who is -- the prosthetics program.
>> Dr. Geoffrey Ling: Thank you for allowing me to participate in this break through in Food and Drug Administration and as a member of DARPA and Department of Defense I'd like to thank you all for thinking in an innovative way with your innovative initiative, a hallmark of DARPA that innovation is in fact what we do, and I'm so pleased to be partnered with an agency that also feels the same way.
What we're trying to achieve in the revolutionizing prosthesis program is very much what Dr. Sackner-Bernstein had just articulated to you and what you saw in the video.
But I want you to take your imagination and take it to another level. This is truly transformative. Why is that?
Well, the obvious engineering is a major achievement. That arm that you saw is anthropomorphically just like the arm that each of us now has attached to our own shoulders. It looks like an arm, it weighs like an arm it functioning like an arm.
Most critically in the next step. The next step as Dr. Sackner-Bernstein said the next step is develop and place that chip on the surface of the brain so that now the patient only has to think about moving their arm. You do not think about extending your shoulder, extending your elbow, extending your wrist, opening your hand to pick up a ball. You only think about I'm going to pick up the ball.
And that's precisely where we are headed.
If we can achieve this, with this prosthetic arm and hand, think of the other technologies that will soon follow.

The other assistive technologies that you, the patient, may now think about doing whatever task you might want. To run, to climb, to manipulate a keyboard. Any number of host of other things that are not even imaginable today, now become in the realm of possible.
And that is exactly what this program is. So look beyond the fact that it is a robot arm. It is not just a robot arm. It represents the ability now to now go and say what can I link directly to the brain, so that now these tools, these assistive tools, will function just like our native limbs do. And that's really the direction that we're taking. And this is in fact truly an innovation initiative for what it represents.
Now, speaking to you as a DARPA program manager, where I tell you about the nuts and bolts of this project, a project that four years ago was nothing more than our imaginations, and four years today as you see the arm that you see, and the chip that is ready to go be implanted in our first group of patients. Is remarkable. This is not a 40 year plan, this is a four-year plan. And I'm very excited about what will happen over just the next one or two years with the help of our good friends at the Food and Drug Administration.
So from that standpoint, it is a wonderful thing.
But I want to speak to you again in my other path and that is I am a colonel in the United States army I have a soldier I have served in theater I've taken care of wounded soldiers, Army, Marines and say sailors and I'm proud of it but I'm more proud of the people I took care of. These young men and women who are now on the front line across the world, across the globe, represent and defending those principles, those freedoms, that are what make America great, are very special people. They are very deserving patients. Because what they do, in the places and the manner in which they have to do it, many of them get hurt.
And one of the goals that we have at DARPA is to re store them the best we possibly can. To take them back to where they were. That is our goal, that is our dream.
So that we can give back to these fine young service members the level of function that they had before they got hurt, such that they can remain on active duty if they so wish. If they do not wish to stay back on active duty, that they can regain their place in society, do all the things that they had hopes and aspirations to do before they entered military service. That is to raise families, that is to have the job that they want, that is to hold their child's hand and feel the sensation of that, and to be able to respond in the way that each of us do when we hold our own children's hands.
To do that we've embarked upon the program that you have seen. But you always worry. You worry that good science, good engineering, will come up through the edge of the Valley of Death that Jeff had spoken about. And I'm so pleased that our friends at the FDA have decided to challenge that notion. They have to do due diligence to the very important place that they have in our society, that is, to protect Americans against things that are dangerous, things that don't have the efficacy that are promising, so on and so forth, they must do due diligence to their mission . But that mission does not have to clash with the mission of folks like us, who are developing these new technologies.
In fact, they can go hand in hand. And that is why this medical device innovation initiative is such a wonderful thing.
But it speaks loudly to something else that I want to share with you. These fine young men and women who are injured, and how we are trying to push this technology as fast as

possible, so that they can regain their function, and do it in a timely, expeditious manner. But working with the FDA, and the FDA rising to this tremendous challenge shows something to me. They are patriots, they are what make America great. They are the -- they represent each of you out there in the audience right now. I know that each of you out there would want to reach out and help these fine young wounded Americans.
And each of us each day thinks about them, and we hope to, keep them in their prayers and in our thoughts.
But what we want to do is do something tangible for them.
And I cannot help but stand back as an American soldier and salute the fine folks at the FDA for doing what they are trying to do. Do due diligence their mission, but to change their process so they can expedite taking care of our most deserving patients. And that is, the wounded American service member. Thank you.
>> Glenn Scimonelli: Thank you very much colonel Ling. Let me turn it back to Jeff Shuren for more insites in the innovation.
>> Dr. Jeffrey Shuren: Thanks again, it will help under development realize its potential, there are other parts of the innovation initiative that we think can also advance medical device development. To remain the world leader in device innovation west, we must have robust research infrastructure in this country and promote high quality regulatory science, the science of developing new tools, and approaches to assess the safety effectiveness and quality of medical devices.
One of the ways we propose to strengthen device research is by creating a voluntary third party certification program for medical device test centers across the country. Eligible test centers would have expertise in both device design and the conduct of high quality clinical studies.
Unlike a drug, whose active ingredient does not change and whose inherent flaws cannot generally be fixed, a device can be improved through changes to its design or composition at any time. By incentivizing universities and other institutions in a competitive way to combine expertise in developing and in assessing devices, they can help find and fix problems earlier.
In addition, because certified test centers would have well-established safety records, we would permit them to conduct first-in-human studies at an earlier stage in device development. As a result, the device development process would become more predictable, safer, and less costly.
We also need to investment in people. Unlike the pharmaceutical sciences the U.S. education system has few programs in device development. To train future innovators, we will work with academia, industry, and the health care community to develop a publicly-available core curriculum in device design, testing, regulatory processes, and post- marketing surveillance.
And we need to expand our efforts to develop new regulatory science.
CDRH has 20 laboratories with roughly 130 scientists engineers and clinicians actively engaged in about 70 regulatory research projects such as developing more accurate measures to assess the effects of new anti-cancer treatments on tumor size, and creating computer models that may help reduce the number of people on whom an experimental device must be tested.
In the coming year we'll be announcing parpts that leverage government and private sector resources to create new tools to accelerate the development, testing and

manufacturing of tomorrow's medical break throughs.
Another way we propose to strengthen regulatory science is by providing clear guidance on how sponsors can best leverage data and research conducted outside of the United States.
A great deal of research today is conducted overseas.
Over the years, we've had difficulty accepting much of this data for a number of reasons, including issues related to poor quality, non-applicability to the U.S. population.
We will provide industry with clear guidance on criteria and circumstances under which data developed over seas could be used to support device submissions. More clarity in this area could result in better data and less of a need to conduct additional clinical studies.
This often means a smoother review, less cost to companies, and fewer risks to patients from investigational devices.
We will be discussing the innovation initiative at a public meeting on March 15th of this year. We will be looking for comments on the pathway, our plans for test center certification, guidance on overseas data acceptance, and the several other critical pieces of our innovation commitment.
This isn't an ordinary initiative, and it's not the kind of proposal you're used to hearing from a regulatory health agency. Much of what we do -- the critical, necessary foundation of what we do -- is focused on reviewing manufacturer submissions for premarket review, and monitoring devices already on the market for continued safety and effectiveness.
Last year, as part of our 2010 vat jick priorities, the Center started a sea change in how we approach public health. We did this after taking time to listen carefully to what our constituents -- industry, patients, health care professionals -- had to say about our operations at town hall meetings and other venues across the country. We listened, and responded.
We responded by taking strategic steps to move from our Center from an effective, but mostly reactionary -- regulatory body to an innovative government facilitator. We have begun to move strategically and me thodically toward becoming a public health agency that uses our unique regulatory vantage point to encourage opportunities for medical device innovation while at the same time strengthening the safety and effectiveness of existing and future devices.
We responded to the call for greater predictability and clarity by conducting a comprehensive review of our 5 10-K program and how we use evolving science in decision making. Following this assessment, we announced just a few weeks ago 25 specific actions we will take this year to strengthen our premarket review programs by making them more predictable and transparent.
Unlike other countries, the FDA sees and reviews important information on medical devices both before and after they enter the U.S. market. When we share what we know, we can make the next generation of devices and those already on the market safer and more effective.
We took this approach last year with infusion pumps, automated external defibrillators, and medical imaging technologies that emit radiation such as CT scanners. Our efforts are starting to pay off. In the upcoming months we'll update the public on the progress we've made so far.

We've also responded to requests for federal agencies to better collaborate, to stimulate new technologies and better clarify requirements for their use in the U.S. We established an interagency Council on Medical Device Innovation. We formed new strategic alliances with council members, such as with the Centers for mairkt and Medicaid services to create a parallel review process and with the federal communications commission to clarify the regulations of wireless, mobile health care applications.
And today's innovation initiative is our response to requests to address unmet medical needs by proposing solutions for truly innovative technologies.
En currentlying facilitating innovation isn't just about faster review times although sped yen sea is key.
It's about smarter regulation and sharing our experience and knowledge with industry and users to make devices better for patients and practitioners.
We must continue to transform the medical device center into a nimble and flexible agency that can continue to support the U.S. as the leader the medical device innovation, and make good on our commitment to the health of the American public.
>> Glenn Scimonelli: Thank you, Jeff.
Now we'd like to open our phone lines so that you can ask questions of our three guesses and they're Tang by here.

Our phone number is 800-527-1401 . Again, that's 1- 800-527-1401 While we're waiting we do have a question here standing by.
Someone out there is concerned about our resources.
So Jeff why don't you tell our viewers how we're going to take on these tasks with the resources we have at hand.
>> Dr. Jeffrey Shuren: Well, in light of our commitment to meeting the goals, and predicting premarket review programs, making significant investments in the innovation initiative is a luxury we can't afford.

Although in light of our current resources, we cannot yet make a radical overhaul of our programs. We can lay the foundation for the new paradigm we propose, and we can take just a handful of products into the new innovation initiative.
>> Glenn Scimonelli: Thank you. And we're standing by for calls. Jonathan, why don't you sort of brainstorm a little bit and maybe sort of think about some other areas that innovation might be coming into the medical field, and using this initiative.
>> Dr. Jonathan Sackner-Bernstein: Well, one of the things to realize is that there are a whole range of innovative approaches that can be applied to health care.
We've talked today about one that is very complex, the approach is complex, it's almost science-fiction like.
That's certainly a realm that we're looking at, and within the products that we have, as well as looking outside our agencies in other organizations.
We're certainly interested in facilitating organizations that are not as complex. If you look back in the history of health care, some of the greatest innovations have been the simplest. Now, we won't need an innovation pathway for when someone realizes they make the equivalent observation in the importance of hand washing to prevent surgical infections, or when people started to realize they can take the electric light bulb put it in the operating room and make it possible for surgeons to operate not just by touch, but also by looking.

We're interested in facilitating all sorts of innovations. Whether it be a very simple approach that represents a bridge from one industry to another, or the complex.
>> Glenn Scimonelli: Wonderful. We have a caller on the line from the New York Times. Good afternoon New York Times, what's your question? Hello, New York Times, are you there?
>> Hi, this is Susan havey from Reuters.
>> Glenn Scimonelli: Go ahead with your question.
>> Thank you Dr. Shuren for taking our call yesterday we heard fou the FDA is evaluating medical devices and getting innovative there. Is this sort of a follow-on to his remarks yesterday and can you address that a little bit?
>> The effort we're announcing today is consistent with the President's remark to the chamber of commerce the other day. In fostering innovation, but doing so in the right way to balance innovation with safety.
>> So in terms of the times would you say that this is sort of following on the heels with his proposal and his promises yesterday to get more in step with the business community?
>> Well, the proposal we put out today has been in the works for some time. But this entire focus on innovation has been a consideration by the administration for some time, and is all part of an effort I think by several agencies in the government to promote innovation.
But to do so in striking the right balance.
>> Thank you.
>> Glenn Scimonelli: Thank you, Reuters, and we have a phone call now from Dow Jones. Good afternoon Dow Jones
>> Hi, this is Jennifer. First question I have, I wonder if you can explain to me how, without this pathway, how you would handle if DARPA came to you to try to get approval of upper prosthetics, how is this process going to be different than the current process?
>> Well, currently a company would engage us much later in the device development process. What's different in this case is we're front loading our resources, we're assigning a review team very early on in the development phase. Around the time that you're developing the device prototype, and you're at the point where you'll begin assessing that technology.
What's also different is the review team will be reporting back to this new center science council of our senior managers and expert staff, who will be able to engage early and assure that important scientific questions are addressed quickly, and if there's a need for additional outside expertise, we identify that early.
We're also going to be engaging in far more intense interaction with the sponsor, so we're not just communicating about our needs, we're actually working with them in designing the appropriate clinical trial to assess their technology. All of these efforts to engage early on can help expedite the process.
>> Glenn Scimonelli: Thank you very much Dow Jones.
We now have a call from the gray sheet. Good afternoon, gray sheet, you're on the air.
>> Hi yes this is David with the gray sheet I guess I was curious it does seem -- what are the resources -- I mean, that you'll be looking for in the future? I'm particularly looking with regard to the user fee program, to get a sense of how this type of new type of priority review program in particular would be incorporated into the user fees and performance

goals that will need to be rasterized in 2012.
>> Well it's certainly an issue we can bring to our issues in the user fee program, to have a dialogue about whether or not the pathway we're proposing today in some of the other actions make sense, and whether it's worth making additional investments in promoting that pathway. We'll have those discussions certainly with the public for our open docket and the public meeting we'll be holding in March and it can absolutely be a topic of conversation during user fee reauthorization.
>> Glenn Scimonelli: Thank you, gray sheet. And now we have a call from Steven Greer, good afternoon Steven, what's your question
>> Apologize for the technical difficulties, but I believe you're starting a new way to expedite innovative medical devices, now, those would be seem to be things that by definition would not have predicates and so forth. So are we talking about a new way to expedite clinical human trial requirements?
>> So we're not going to change the requirements that we have in place. But you're absolutely correct that this is a way that we can expedite the assessment and the review of these truly break-through technologies that would not have a predicate on the market, generally. They're more likely to be the higher risk technologies that could come under a premarket approval application, or they might be some of the more moderate risk devices that could come under the de novo is pathway.
>> Could you make maybe an analysis to the drug side, where they have fast track, and so forth?
>> So fast track looks at having a surrogate marker that is likely to correlate with a clinical outcome, and then showing -- validating that link thereafter.
Here, there's always the opportunity for looking at surrogate markers, and that would be available for many of the devices that we currently look at.
What's different in this case is the level of inter action that we have with the manufacturer, and at the time that we engage, and the extent of senior level personnel involvement. In the case of device, what's so different from drug, is that you can identify problems and you can fix them in the technology. Whereas in the drug, the active ingredient is the active ingredient. You start to learn more about it through additional testing. And there, you want to fail smart, you want to fail early, and if it doesn't work move on to a new active ingredient.
With a device when you fail smart you identify a problem, but you can fix it. We're looking to work with manufacturers to fail smart through the process that we're laying out.
>> Okay.
>> Thank you, Jeff. Thank you, Steven. And now we have Walter ice ner on the phone. Hello Walter, what's your question?
>> Hi, thanks. Any good quality program has some ways to measure success. How are you planning on measuring the success of the innovation initiative, what are the metrics? Time involved in getting new products to the market, cost, the number of approvals? Thanks.
>> The most important measures that we'll be using will be on performance. As you laid out, time will be very important. For example, one of the commitments we make is when we accept a product into the pathway, over the course of 120 days, we're going to develop a memorandum with the sponsor that lays out what the critical scientific

questions are, what they need to do, and that timeline for further development and assessment. That is a critical milestone that we're looking to measure at, and we're going to get our first experience with it with the technology that we talked about today.
What won't be a metric is the number of approvals under the pathway. Because our standards remain the same.
None of that is going to change. But our performance will be different.
>> Thank you very much, Walter. Now on the line is aunt Minnie.com, good afternoon, aunt Minnie
>> This is kait from aunt Minnie we're a medical imaging site, thank you. I'm wondering, how will device manufacturers determine whether ne apply for this pathway or the 510, or the PMA, how are they different, how do folks figure out which one to use?
>> Well, that's a very good question. So the pathways like PMA and 5 10-K, go to the risk of the device, and to whether or not there's a predicate on the market.
And we allow for companies to come in and talk to us in advance to try to figure that out, if they have questions.
For certain devices that are truly the break-through technologies that are going to be better than what's out on the market, or there's no alternative out there for patients who have life-threatening or irreversibly debilitating diseases, they may qualify for this pathway.
Now, if you're supposed to be under a PMA, you'll still have to submit a PMA. What changes is the level of engagement from the Center, and certain commitments to action that we will take to help expedite both the development and the assessment of the technology. Where in the past, we focused a lot more on simply the assessment and review.
>> Thank you.
>> Glenn Scimonelli: Thank you. Now on the line is medical device daily. Good afternoon, medical device daily, you're on the air. Hello, medical device daily. Oh, we lost them. Trends in medicine. Good afternoon, trends in medicine, you're on the air.
>> Hi, thank you. Do you have some estimate of how many applications under this program you would expect in the first few years? Would you expect to be flooded with them, or would you expect this to be 1 or two a year, do you have some sense of it?
>> Well, we're hoping there will be a lot of interest in the program, but we're only going to be able to handle a small number, and we don't have an exact number, but it probably is more along the line of one or two or something thereabouts that we'll be able to handle in any given year.
Recall that this process will go on for a period of time. And it's going to be important that if we were to accept a device into the pathway, we probably couldn't accept many that involve the same reviewers, because there's other work in that product line that we need to get done and that we're going to continue our commitments to performance for the other devices. So we think the numbers will be small.
And much of it will depend upon available resources that we have at the time.
>> Thank you.
>> Glenn Scimonelli: Thank you so much, and sorry we had a technical difficulty with medical device daily but we have them back on the line. Good afternoon medical device daily.
>> Hi Dr. Shuren, this is mark McRarey with medical device daily thank you for taking

my call, regarding the parallel review -- I'm sorry not parallel review, but third party review program has not exactly taken off like a rocket, and I'm wondering if you're intending to beef up the program and help the application, given that it will demand more resources.
>> We actually from our perspective have seen extensive use of the third party review program. There's a lot of interest from industry and we have many applications that come through there. We have as one of the 25 actions we plan to take in the coming year, take certain actions to strengthen that particular program, including better training and oversight of the third party reviewers.
We have had some challenges with our third party inspection program that we've put out there where there has not been a lot of interest on the part of industry for having third parties conduct their routine surveillance inspections.
>> Glenn Scimonelli: Thank you so much. And we have AP on the line, good afternoon AP.
>> Hi guys thanks for answering our questions. Just a clarifying point. I'm so used to writing about accelerated approval from the drug side but I just want to make sure, this is the first accelerated approval for devices, there hasn't ever been any kind of accelerated PMA or 510-K process or anything like that.
>> There is an expedited PMA process. So for other medical products they've had their priority review processes, we've had ours, as well.
Under expedited review, we put more attention to those devices -- and this is for expedited PMA, than we do for standard PMA. But what's different, and what we're doing now is again where we engage in the development process, and how we engage. This is a radically different kind of approach than we've used in our other accelerated pathways.
>> I see. So the other accelerated pathway just has to do with timeline, dates, for target review completion, and this is more -- even before the device is submitted, that you're talking to the companies?
>> That's exactly correct.
>> All right, thanks.
>> Thank you, AP. On the line now with FDA news, good afternoon FDA news.
>> Hi, thank you so much for taking my question.
When a similar program was suggested back last June during innovative workshops I think they used the term novel device, there was that concern of possible abuse or a lot of people saying well I have a novel device so I should go through a special kind of pathway.
Can you talk about what kind of safeguards might be put in place so that people can't abuse the program?
>> What's going to be important here is that it's an agreement not only by the sponsor, it's also by the agency.
And having out very set criteria by which we will judge what an appropriate technology would be to come into that pathway.
We've proposed a set of criteria that we would use, but we're very interested to get public reaction and feedback on those criteria, and whether or not we should make changes to them.
>> Thank you.

>>
>> Glenn Scimonelli: Thank you, FDA news. We have a question here for colonel Ling, colonel Ling they're asking how can the FDA help with the development of this prosthetic aim? I'm sorry, the prosthetic arm.
>> Dr. Geoffrey Ling: That's okay.
>> Bad spelling
>> Dr. Geoffrey Ling: I think it was articulated by Dr. Shuren and Dr. Sackner-Bernstein, that is this is still a research and development, we're not a research, we're the army. We're on the development track of this arm and the interface between the brain and the arm itself, so having early involvement of the key regulatory agency, that is the FDA a. is actually critical because it allows us to officially design the appropriate clinical trials to officially respond to the findings of these clinical trials, that is, how do we have to make adaptations to the existing platforms, how do we change the prototype, and such, so that really, this government-sponsored effort will move along not only in a expeditious manner but very critically also in an efficient manner, that is we will not be wasting the tax payer's moneys going down pathway that is -- and potentially dele terius. Having the regulators working with us is critical.
And I would like to point out this is a good example of what would happen when government agencies come together.
The Veterans Administration is involved in this effort, as well as the national institutes of health, as well as the national institute standards. This is all very critical because it is a way of as I believe our good friends at the FDA are trying to point out, is to try to not circumvent at all the critical aspects of regulation, but really how do we Marshall the resources, the innovative resources that are available across government agencies to come up with a very important new technology that will revolutionnize clinical care but doing it in an efficient and deaddition -- expeditious manner. And this is what I really want the listeners to walk away with.
>> Colonel, how far away are we from clinical trials, patient trials?
>> Dr. Geoffrey Ling: Months. Months. We expect that the implantation of the chip into the first patients will be within six months. And that arm is ready to go.
>> Thank you, currently. We have a call from the gray sheet, again. Good afternoon, gray sheet.
>> Hi, yeah, thanks for taking another one from me, appreciate it.
A big emphasis of this program Dr. Shuren is resource engagement much earlier in the process but there are already obviously some early process activities that go on preIVE meetings I know that the center has encouraged and discussions about clinical trial and end points and cloud designs and I think the industry has expressed some concerns about the change in standards as the process moves forward to the submission.

Is there some sort of preIDE or earlier trial design and end point discussions what kind of assurances do companies have with regards to particularly with regard to this priority review program?
>> Well, we will allow for the opportunity to engage in binding commitments on the part of both the company and of the agency, and we will leave that as an option for the manufacturer to choose to engage in or not.
So the program will have flexibility, and if the manufacturer would like to enter into

more of a binding agreement, in terms of clinical trial design, for example, then we will go ahead and do so.
>> Glenn Scimonelli: Thank you so much for your calls, that's about it for today's program. If you'd like more information about FDA's medical device innovation initiative, please go to our website.
Www.Fda.Gov/deviceinnovation Here you can find a description of the initiative, the white paper outlining more details, information on the public meeting, and other important resources.
Media can cleck FDA's flick are site or contract Karen Reilly directly for pictures, and video of today's presentation.
We do apologize for those on the phone who didn't hear the beginning of this webcast, we will have a recording posted on the device innovation website shortly.
I want to thank today's guests commissioner Hamburg, Dr. Jeffrey Shuren, Dr. Sackner-Bernstein and colonel Ling for, and for their insides into FDA's medical device innovation initiative. And for the FDA, I'm Glenn Scimonelli. Have a good day