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Virtual Signature Event

FDA Commissioner Stephen Hahn and Novavax, Inc.'s Stanley Erck

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DAVID M. RUBENSTEIN: Dr. Hahn thank you very much for coming today. Let me give a very brief introduction of your background, if I could. Many people obviously probably already know your background. But Dr. Hahn is a graduate of Rice University and did his medical training at Temple University Medical School. And then he did his residency at the University of California, San Francisco. He is a specialist in radiation oncology, and head of the Radiation Oncology Department at the University of Pennsylvania's Medical School, and later was recruited to head the Radiation Oncology Department at M.D. Anderson Cancer Center, where he later rose up to become the chief medical executive of the – of the Anderson Cancer Center. M.D. Anderson is the largest cancer center in the United States. And he is now the 24th commissioner of the Food and Drug Administration, having taken that position in December of 2019, having been confirmed then.

So, Dr. Hahn, I know you're very busy. I thank you for coming. So let me ask you first, is running FDA harder than running the M.D. Anderson? And do you realize how much more complicated this is? Or do you think it's easier than running M.D. Anderson?

STEPHEN M. HAHN, M.D.: Well, David, first of all, my best to all of your – all of your members. And it's really a pleasure to be here. Thank you for the invitation.

That's a really interesting question. I can tell you that running FDA is a significantly greater challenge than my previous job at M.D. Anderson Cancer Center. There's a lot that's going on in Washington, D.C. I certainly didn't expect to show up as the 24th commissioner of Food and Drugs in the middle of a – or, the beginning of a pandemic. And certainly that has created great challenges for all of the country. But I couldn't be at a better place, from my perspective. The 17,000-plus employees at the FDA are just tremendous and have done remarkable work for the American people. So I'm really proud to be there and working hard alongside them.

MR. RUBENSTEIN: So, you have a different background – radiation oncology – than some people that have become the FDA commissioner. So how do you think you got on the radar screen of the White House? And when they called you and said, would you like to be the FDA commissioner, were you surprised?

DR. HAHN: Well, certainly surprised. I had had a fair amount of administrative experience running large, complex organizations, and through multiple events over my career. So I think that's probably what caught people's radar. I got contacted from the administration and then began the process. And here I am, you know, several months to a year later.

MR. RUBENSTEIN: So you've been accused – or, FDA's been accused, not you personally – but the FDA's been accused of speeding up the vaccine approvals to help with the election. And other people have accused you of – or, FDA – of slowing them down to affect the election. So are you speeding things up to affect the election or are you slowing things down to affect the election? Which is it? You can't be doing both.

DR. HAHN: Right, David, exactly. And it's an interesting position for FDA to be in. Our career scientists and leaders, and those who've been at FDA – I spoke to just a few former

leaders just a little while ago. We find ourselves in the position that we're accused of either going too fast, or too slow, or doing too little, or too much. And I suppose where we'll end up is if we're hearing criticism from both sides, we're probably in the right place because at the end of the day, for us, it's about the risk benefit calculus, particularly during a pandemic like COVID-19. And we do need to call the balls and strikes on medical products. And we do need to use the available data. And sometimes, and particularly in a pandemic, those data sets aren't complete.

Now, we're always willing to revise those decisions, but it does set up for the criticisms that you're describing. What I can tell you is that I am completely confident in the career scientists at FDA. They have made really good decisions based upon the data and science. And I support them 100 percent and have throughout this pandemic.

MR. RUBENSTEIN: So can you explain for the average person what the approval process is? I assume you have to go through phase one, phase two, and phase three, and then after phase three the data goes to the FDA. Is there a committee that decides this at the FDA? Do you personally decide it? Can you overrule the committee? Can you be overruled by the HHS secretary? How does it work?

DR. HAHN: Yeah, really, really important questions. So the authority to FDA, to me as commissioner and then to the FDA as a whole, is delegated, by statute, by law, from the secretary of health and human services. So the secretary delegates that to us. Within the agency, I can talk about that process, but just to be clear, we have not approved or authorized any vaccine. We have not approved – although we have authorized – but we have not approved any therapy for COVID-19 at this point. So we've used what's called emergency use authorization. And the reason that's important is that's different from our standard approval process.

The evidentiary standard – the evidence that we need for an emergency use authorization is that the risks outweigh the benefits. And of course, part of the risk is the urgency of the clinical situation, what the illness looks like, are people dying from it, and then what are the potential benefits from any medical product, versus the risks of that medical product. So for emergency use authorization – not our typical approval process, but with that – those are the standards we typically – those are the standards that are out there.

Now, with respect to vaccines, this is different than other medical products for COVID-19, in that a vaccine is going to go to people who are essentially healthy. They do not have COVID-19. So you can see that the risk-benefit is different in those people than it would be in those who are sick, in the hospital, on a ventilator with COVID-19. So that's an important ground understanding that I think people need to have about where vaccines are.

So, of course, we go through this process in the vaccine world of preclinical or animal testing, followed by phase one, which is a safety assessment, followed by phase two, which is an initial assessment of the efficacy – how well does it illicit an immune response. And then phase three, where we assess both safety and efficacy in a large trial, comparing the vaccine to a placebo, an inactive vaccine. And that gives us the most robust data with respect to determining safety and efficacy.

At the end of the day, the vaccine manufacturers are responsible for conducting all of those studies. We provide technical assistance to guide them. And you may know that in June we actually issued a guidance saying: Here are the data that FDA needs to see with respect to a vaccine regarding safety and efficacy in order for us to make our determination. And two important points on that. One is, we insisted that there be great diversity in these trials so that our decision could represent all of America – so, underrepresented minorities, those with comorbidities, and the elderly are just examples.

And the other important point is that we set as a threshold for efficacy 50 percent. So what we wanted to see was a vaccine that was at least – now, of course, we all want to see a greater efficacy – but at least 50 percent effective in terms of preventing COVID-19 or mitigating the effects of the disease. Essentially, turning something like COVID-19 into a common cold. So those are the clinical end points we wanted to see. And we have been working with the manufacturers as they develop their clinical studies to actually get to those points.

Now, each of these studies, when they get to phase three, will have what's called a data safety monitoring board. And they're, at specified points are allowed to see the data. When the data show a variety of different things, they can make a determination about whether to submit the information to us for an application. So for example, a data safety monitoring board might look at the trial data and say: We have safety concerns. The trial has to stop. It looks like it will not go forward. They may say a futility analysis, which is where they say: No matter how much more we do, this vaccine's not going to work. We have to stop the trial. They may say: We have reached a certain number of events, that is infections. It looks like the vaccine's effective. Let's submit the data to the FDA.

And so all those possibilities could occur. That's on the sponsor. That's on the data safety monitoring board – which is independent. And only then do we receive the data for our application. And then our scientists look at it, they make a determination based upon that data. We provide that information to what's called a vaccine advisory committee, which is outside experts. They give us advice based upon the data that's provided, and a recommendation to us. And that's a public event.

Then the center, ultimately – so, in this case, the Center for Biological Evaluation and Research, led by Dr. Peter Marks – they make the determination. I will be briefed, as the commissioner, all along about this. I will have the opportunity to see the data. I can tell you, throughout this pandemic, throughout my tenure as commissioner, I have not reversed a decision by the career scientists on medical products. And I have no intention of doing that now.

MR. RUBENSTEIN: But you're – legally, you or the secretary of HHS, could you overrule the committee? But you wouldn't, you say. But is it legally possible?

DR. HAHN: There is that authority. But as I said, there's no intent to do that, whatsoever. Again, we don't want to prejudge this. We want to look at the data. And I have complete and absolute confidence in the scientists at FDA, and the decision making that they have here.

MR. RUBENSTEIN: Now, I understand there's a meeting on October the 22nd, where a committee will come together and maybe look at some of the phase three data. Is that a relevant committee meeting for deciding whether you're going to go forward and approve somebody?

DR. HAHN: So that October 22nd meeting, we were required to put that in the Federal Register. What that meeting about – is it's a general meeting about the process and procedures and the approach that we'll use to look at vaccine applications. Now, if we get a vaccine application outside of that timeframe, we will arrange for additional vaccine advisory committee meetings to look at the specific data on that application. So we want to be flexible. We want to be responsive. But we will not cut corners. We will follow our rigorous procedures to assess safety and efficacy.

MR. RUBENSTEIN: Based on your knowledge to date, what would think is the likelihood that a vaccine will be available to the American people? Is it likely to be in October, November, December, January? What is your best guess today?

DR. HAHN: David, I don't have a guess. I don't have a crystal ball. I was a cancer doctor, as you said, before I came here. I told my patients all the time, I don't have a crystal ball, and I don't have a crystal ball here. It would be really inappropriate for me to speculate because, again, we haven't seen the clinical data. That's what's key here. And again, those clinical data re going to come from trials that an independent data safety monitoring board is going to advise a company about, and then we'll receive it. So there's no way that I could possibly know when that's going to come to us. I think everybody in America wants a vaccine as quickly as possible. We want a very effective vaccine. But we also want a vaccine that's safe. And so, again, we're going to make the – we're going to call the balls and strikes on the data, on safety and efficacy. And we're not going to cut corners on that.

MR. RUBENSTEIN: OK. So vaccines that are under development now, they are all ones where you have an injection. Are they typically two injections you get? And how long would the vaccine last for? A year, six months, or it's unclear yet?

DR. HAHN: All of this is unclear. We're going to wait for the data to come in. A number of vaccine candidates are in clinical trials. Some are two vaccines. There's one that's one vaccine. And again, we really have to see the data. Cannot speculate on what the ultimate outcome is and the data would show. We really will, David – and this is our promise to the American people – we really will wait for those data. We will critically look at those data.

MR. RUBENSTEIN: So you're the 24th FDA commissioner. It seems as if the other 23 are often on TV talking about what's going on. Is that a problem, for having all these former FDA commissioners on TV talking about this? Or not a problem?

DR. HAHN: Not a problem. So let me just be clear about this. This is an unprecedented situation, with a pandemic that is, you know, once in hopefully many, many, many years. I personally, and the agency, welcome input from folks outside the agency, particularly those leaders who've had experience within the agency. One thing I've heard from them, and that I can tell you I have relied upon, is that the expertise of the scientists and the career folks at FDA,

they're very, very high – that expertise. And relying upon them has been a staple of my tenure as FDA commissioner.

MR. RUBENSTEIN: Now, Vladimir Putin said that he has a vaccine ready to go, a Sputnik vaccine, or something. If I was offered a chance for that, would that be a good idea to take that vaccine?

DR. HAHN: Well, I'm not your doctor. What I can tell you is that what we've heard is we've heard in press reports. FDA will look at any data that come before us. You know, what I pledge to you is to, to the American people, when we say that a vaccine is safe and effective, that we're putting our stamp of approval behind that. All other vaccines that don't have it, we can't put our stamp of approval behind it.

MR. RUBENSTEIN: OK. So there's been a lot of controversy over hydroxychloroquine. You've probably heard about that. So today, if somebody came to me and said: Why don't you take some hydroxychloroquine to prevent getting this disease, what would you say that I should do? Should I take it or not?

DR. HAHN: I would say you should consult your physician, that this is a decision in the context of a physician-patient relationship. We do know that there are data out there. And we want physicians to understand those data. There are five randomized trials, several of them in the in-patient setting, one of them the recovery trial from the United Kingdom, which demonstrated that there was not a benefit to hydroxychloroquine to inpatients. And there was the suggestion that there might be increased side effects related to the heart. So we want doctors to know those data.

We have a number of other trials that are ongoing, particularly early in the disease. And we are going to wait for those data to make our ultimate determination about hydroxychloroquine. But also to know there are other randomized trials that have been completed earlier in the disease that have also shown no benefit from hydroxychloroquine. So to me, this is a decision that's made between a doctor and a patient. The doctor needs to understand where all the data are, and the concerns about the risks.

MR. RUBENSTEIN: OK. What about convalescent plasma. That is something you've approved. Can you comment on where we are on convalescent plasma now?

DR. HAHN: Yes. So we authorized convalescent plasma because the totality of evidence was in support of that authorization. Now, just like hydroxychloroquine, just like remdesivir, just like all of our decisions we are continuing to collect data. And we very much want data from randomized clinical trials to update. But here are the data we use to make that decision – and, again, this was a decision made by our career scientists at the Center for Biological Evaluation and Research. I support their decision. I think they made a good decision.

First of all, published literature showing that in COVID-19 there was a benefit in at least a dozen studies – now, some studies didn't show a benefit, but there was preponderance of evidence in these published studies. Secondly, there's animal data which support its use, including historical data of using convalescent plasma to treat other infections. Third of all, we

had a really good safety read that this – that convalescent plasma was safe in patients with COVID-19. And then finally, the analyses that we did and others have done of the data from the Mayo Clinic, this very large, expanded access program, demonstrated a promising positive effect.

Now, that could change with additional data. And we're constantly looking at new data. But that totality of evidence is what we use for this authorization. Bottom line, we have kept convalescent plasma around as a potential therapy for doctors to choose if they want to prescribe that. And we thought it was important, given the totality of evidence and the significance of the pandemic, to make that decision. But I want to reassure the American people, we will revisit that decision when we have the data that justify relooking at it.

MR. RUBENSTEIN: OK. So no regrets about that decision?

DR. HAHN: None.

MR. RUBENSTEIN: OK. So let me ask you, what are the side effects likely to be? All of us have gotten polio vaccine injections, I suppose – of our generation. And there's no side effects that I think are really inappropriate. But there's always some side effects for medicine. So are there any side effects that are potentially dangerous from any of the vaccines that are now being worked on?

DR. HAHN: So I can't comment about specific side effects and any information we have at the agency, because it's confidential commercial information. What I can tell you is that we know that from vaccines, and the vaccine approvals we've done, that they are remarkably safe. We do know that some vaccines have some local side effects – like inflammation, things like that, headache, et cetera. However, we don't have the data yet for the COVID-19 vaccines. And we're waiting to collect those data and look at those data. So more information to come.

MR. RUBENSTEIN: OK. So on testing. Does the FDA approve the tests that are used for testing for COVID-19? Do you approve that, or is that CDC?

DR. HAHN: So we do have – we have authorized the tests for COVID-19. Our key here is that we want to look at the data to make sure that they're reliable, and reproduceable, and accurate. And so we have done that throughout the pandemic. And we continue to do that. We have over 500 applications still pending in front of us for additional tests. This has been a great example for a public-private partnership. And we've had a great response to our information that we've given in terms of what we require to see for these tests.

MR. RUBENSTEIN: And do you believe everybody should get a test, or only people that have symptoms should get a test? Because I think the CDC said, if you're asymptomatic don't get a test.

DR. HAHN: Yeah. I think that simplifies what the CDC said. Again, probably best to direct those questions to the CDC. But the purpose of the revisions to the guidance was really to have

there be a public health or physician consequence. And so much what's in there has said: Consult your physician about whether you should get a test.

MR. RUBENSTEIN: OK. Let's suppose you approve somebody – or, the FDA approves some vaccines, one or more. And let's suppose, whatever the date is – let's say it's the end of the year, or January, whenever it's approved. How long will it take before people can actually get them? Or are there enough vaccines that are being manufactured now, so once you give the approval within a month, or two months, or three months, everybody in the United States that wants them can get them?

DR. HAHN: Well, we've been working with manufacturers on the manufacturing process. As you probably know, many of them are manufacturing vaccines at risk. Even though they don't have authorization or approval from FDA, they've been starting that manufacturing process. So getting prepared for the possibility that one will be either approved or authorized. FDA is not responsible for the allocation. That is really CDC, with the Health and Human Services, that is putting out the plan of who would get it and when. We're working very closely, though, with manufacturers to make sure that the quality associated with this manufacturing is what it needs to be, because what we want to make sure is that every lot of vaccine has the highest quality possible for the American people.

MR. RUBENSTEIN: So I assume it would be embarrassing if you got COVID-19, though it's not something impossible. So what do you do to stay healthy yourself? You don't want to be the FDA commission and coming down with COVID-19. So you're wearing masks all the time, are you staying away from people? How are you saying healthy?

DR. HAHN: So our path forward in America, to stay open, to do the things that we want to do before we have a vaccine available, is these commonsense public health measures. And that's what I've been following. Wear a mask. Socially distance. Avoid crowded, particularly inside crowded places, but avoid crowds as much as possible. When you can't socially distance, wear a mask, and protect the vulnerable among us. Following those commonsense public health measures, there is evidence to suggest that that has helped a lot across this country. We strongly recommend that for the American people. And that's what I've done for myself, personally, and my family.

MR. RUBENSTEIN: All right. So are you getting a flu shot? Do you think everybody should get a flu shot?

DR. HAHN: I will be getting a flu shot, and I think you absolutely should follow your doctor's and CDC's recommendations for flu shot administration.

MR. RUBENSTEIN: And do you see any evidence that the virus is receding? Or is it still in a phase where it's going to be growing, and we're going to deal with this for quite some time? In other words, do you see any evidence that social distancing and testing has reduced the number of incidences, or do you think it's still a serious problem?

DR. HAHN: Well, this virus is with us and it's a serious problem, there is no question about that in my mind. But I do think that we have data from the White House Coronavirus Taskforce that shows that these commonsense measures that I'm talking about have in fact mitigated some of these outbreaks. We need to stay diligent. We need to stay – we need to continue to push forward with these – with these commonsense measures.

MR. RUBENSTEIN: And the taskforce is meeting regularly? You're on the White House Coronavirus Taskforce. Does it still meet regularly and give press reports?

DR. HAHN: We are meeting regularly. And we are discussing a variety of topics – such as the guidances, such as testing, such a therapeutics. So we are meeting regularly.

MR. RUBENSTEIN: OK. On a couple other things, other than this main subject. What is the FDA position on the medical efficacy of marijuana?

DR. HAHN: So the agency recognizes – and we recently put out some information this summer on this particular issue – the agency recognizes that medical marijuana and also other marijuana derivatives, such as CBD, cannabinoids, could potentially have some therapeutic benefit. And so we have helped developers in the pathways. We think that the best pathway for therapeutic benefits is our drug pathway. And so trying to make it clear to folks, what are the data we're going to need to see to actually look at the effectiveness and safety of these products for particular medical conditions. So we are certainly open to seeing this. But we also realize that some people are making claims about these products that can't be substantiated by the data. And that is not OK. And we continue to look for ways to enforce against claims that can't be substantiated.

MR. RUBENSTEIN: Is there any evidence we're making progress against the opioid epidemic we have?

DR. HAHN: Well, you know, opioids continue to be a significant problem in the country. And we remain focused on that. This is one of the things that, despite the COVID-19 pandemic, we've stayed laser-focused on. You probably know some of the thing we've done, such as try to enable non-opioid pain medications development. Really working hard with developers, for example, of over-the-counter Naloxone, the reversal agent for narcotics. Also working with other forms of Naloxone to try to mitigate the effects of opioid overdose. And then medical-assisted therapy. So we're working on all cylinders. Our team is very – continues to lean in on this. And we will continue to do that work on the benefit of the American people, in this really difficult epidemic.

MR. RUBENSTEIN: So are you confident that the FDA commissioner has the independence that he or she should have under the law?

DR. HAHN: So what I can assure you and your viewers today, anybody who's listening to this, is that FDA, and me as FDA commissioner, we will independently call the balls and strike on medical products. And at the end of the day, the decisions we make, the decisions that the career

scientists make, will be made based upon the science and the data. And that is an assurance that I can give you right here and now.

MR. RUBENSTEIN: So whenever you retire from this position – and the FDA commissioner job is a tough one. People usually don't last five or six years at this job. It's a job that can burn you out. Whenever you do leave, what would be your advice to your successor about how to be a successful FDA commissioner?

DR. HAHN: Well, one most important one is: Trust the career scientists. Trust the incredible expertise of the career scientists. Listen to their counsel. They have a lot of experience. They've done this a long time. They use very rigorous methods and approaches to make decisions. Trust the career scientists and the career staff at FDA. They are just terrific. And they do unbelievably great work on behalf of the American people.

MR. RUBENSTEIN: So I assume you don't go to cocktail parties and dinners a lot these days, but do you get advice from people coming in all the time in email about solutions that are going to solve this problem? And how do you deal with all these over-the-transom pieces of advice you get from old friends, and so forth?

DR. HAHN: So I'm always open, personally, to advice. I think keeping an open mind about that, not dismissing it, is really important, because for the most part people have really good intentions with giving advice. Now, you know, sitting in the chair as FDA commissioner I have a broader view of what's going on both internally and externally. So I have to factor that into any decision that I make. But I'm always willing to listen to that.

Now, we're hearing every day from people who have potential solutions to COVID-19 – different therapeutics, different tests, et cetera. And we have a mechanism, something called the coronavirus treatment acceleration program, where we prioritize those applications with the highest science, the best science, so that we can move forward with those as expeditiously as possible. So one thing I'm really proud of in the agency is that we have worked with incredible speed to look at these applications and try to get medical products onto the market as quickly as possible, through our authorization process.

And at the same time, we have met all of our other obligations. So you may or may not know this, David, but we are meeting with the same historical pace we have over the last few years, all of our user-fee deadlines for medical product approvals. And that's a remarkable situation, given the fact that our workload has basically doubled over the last nine to 10 months.

MR. RUBENSTEIN: So a final question. Members of The Economic Club of Washington, when you do get a vaccine approved, can we get it first? Members of The Economic Club of Washington, can you do something that makes sure we get in line first? Or who's going to get it first, if it's not Economic Club of Washington members?

DR. HAHN: So, as I mentioned before, the Centers for Disease Control and the National Academy of Medicine are working on a plan right now. They're working with Health and Human Services. And they'll be making the determination about who receives the vaccine, and

in what order. Again, we all feel the urgency of the situation. We all want a vaccine that's effective as possible. But we want a vaccine that's safe. And that's my promise, as FDA commissioner, that we will call the balls and strike with our high rigorous standards of safety and efficacy.

MR. RUBENSTEIN: Dr. Hahn, thank you very much for your time. I know your schedule is very tight. I appreciate your coming by. And good luck on all the things you're working on, OK?

DR. HAHN: Thank you, David.

MR. RUBENSTEIN: I'm now going to have our next guest, Stanley Erck. And let me introduce Stanley Erck. Stanley Erck is the CEO of Novavax. Novavax, as some of you may know, is Gaithersburg company that is now one of the companies that under Operation Warp Speed, has received a fair amount of money from the federal government and is working on a vaccine for the coronavirus. Doctor – or, Mr. Erck is a person who is a native of Southern California. He is a graduate of the University of Illinois, and a graduate of the University of Chicago Business School, Vietnam War veteran, and he's also been the CEO of a number of biotech companies. And he's been the CEO of Novavax since June of – April of 2011. He joined as a director in June of 2009.

So he's coming to us today from Colorado. And you can hear me, Mr. Erck?

STANLEY C. ERCK: I can hear you just fine. Thank you for having me.

MR. RUBENSTEIN: OK. Thank you very much.

So your company was a small company. I can't honestly say it was that well known, even to those of us who live in this area. So all of a sudden you've got an enormous amount of money – billion dollar-plus – from the federal government to help produce a vaccine for coronavirus. How did the government know about you? And what was your company's expertise that enabled the government to feel comfortable giving you a billion dollars-plus to develop a vaccine?

MR. ERCK: Well, it's like the commissioner said. Everything's based upon data that you generate. And since the 10-year period that I've been with the company, we've actually been making vaccines against emerging viruses throughout. This is not our first coronavirus. This is our third coronavirus vaccine. And we've been making influenza vaccines. We just had a pivotal phase three flu vaccine unblinded in March, which showed dramatically better data than the comparative vaccines. We've gone through Ebola vaccines. And so we've been doing this for quite some time, and there hasn't been – and we're maybe not known as well because there hasn't been a pandemic. And so we've been practicing for those for some time.

MR. RUBENSTEIN: All right. Well, before –

MR. ERCK: All of these projects, all of these vaccines that we've made, the beauty of this, is use the same platform. We make – we make a protein in a certain manufacturing system, then we mix it with an adjuvant. And both in flu, and Ebola, and coronavirus. And so we get a lot of base data on efficacy and safety from these vaccines.

MR. RUBENSTEIN: So what can you tell us publicly about the likelihood that your virus vaccine will be ready to be approved by the FDA at some point in the near future? Is it months away, a year away? How long do you think it'll be before your vaccine can be on the market?

MR. ERCK: Well, the first part of your question is maybe what level of confidence we have that the vaccine is going to work. I personally think that the vaccines will work against coronavirus. And so that's a huge statement, because we need – it's going to be a vaccine that's going to stop this pandemic. So what – why do we think that we're progressing on a pathway toward that is everything that we've done is consistent along the pathway of developing the coronavirus vaccine, and consistent with what we've done with the other vaccines. In particularly this phase three flu vaccine was a good predictor of the type of immune response and safety we'll get.

But we go through the steps. You start making – when we got the gene sequence back in January, we made the gene sequence. We put it into mice, which is the standard model to see that it's safe. And then we go into non-human primates. And I think what got the attention of the rest of the scientific world is we got dramatically good neutralizing antibodies. A measure of immune responses in non-human primates that almost always predicts what'll happen in humans. And so that was the first real demonstration. And you can actually challenge these animals with coronavirus and show that your vaccine protects. We've done that. And we've done it in mice. We've done it in non-human primates.

And now we're – it's parlayed into the first human trial. And when we look at our phase one data – against all the other phase one data. You look at immune response, neutralizing response, compared with safety. And then the third thing you have to have is you have to be able to make it. And you have to be able to make it at large scale. So we have a vaccine that's stable, that is – can be distributed at refrigerated temperatures, and has these immunogenic and safety profile that we believe is as good as anybody's.

So when it's going to happen is what your question was targeted toward. We're scaling up now. We're doing – we're about to – from the last two weeks for the next six weeks, we've got six major trials coming on, three of which will be phase three trials, two of which will be phase two trials, in five different countries. And it will get us data later this year, we believe. And so I can't put a timetable on it, because it depends upon in the countries that we pick how much disease is circulating at the time we're doing our clinical trial, therefore how many cases do you collect. And everybody's doing the same trial. You can't predict which date. You try to get to a certain number of cases. You unblind. And then you see what you got.

MR. RUBENSTEIN: Why do you use – why do you do phase three or phase two outside the United States? Is there some advantage of doing it outside the United States?

MR. ERCK: I think so. I think it's – we're dealing with a global problem. We're manufacturing outside the United States. We're testing outside the United States. It's not good enough just to solve the coronavirus problem in the United States. And so you need to have – you need to have product that can be distributed globally, number one. Number two is there are – the virus is circulating at different levels in different countries. And we've started a trial in South Africa because it was predicted that they would have a very high rate of disease.

And the premise here is, is that if there's no virus circulating – if you go into an area where there's no virus circulating, you can't show your vaccine works. And so you go to a place where you predict there's high levels of transmission. South Africa was one. The U.K. was one. The U.S. is clearly one. And we'll be going into India as well. So you pick – it gives you more chances of showing how well your vaccine is working or not working.

MR. RUBENSTEIN: So for a vaccine to be considered effective and to be working, does it have to work 100 percent of the time, 90 percent of the time? Or what are the – typically the side effects that people might have to worry about with any of the vaccines that are now being prepared?

MR. ERCK: Sure. The standard side effects, I think as the commissioner said, is you get – often you have a sore arms, you have malaise or fatigue for some short period of time. Headaches. And that's more typical of the type of side effects you get with vaccination. And what you do is you compare it to people who don't get your vaccine, people who get placebo. Because people who don't get your vaccine and get placebo have malaise, and they have headaches, and you try to see what the difference is between the two. And so – I'm sorry, I missed part – the first part of your question.

MR. RUBENSTEIN: So you're saying that there's likely to be side effects, but they'll be side effects that are more or less tolerable?

MR. ERCK: Right.

MR. RUBENSTEIN: OK. So back on your – for people who are watching, they want to know how you got the grant. You're not as famous as Pfizer, or Merck. Now, Moderna's not as well-known as maybe Merck, or Pfizer, or AstraZeneca. But you're not a very big company. Before you got this grant from the federal government, your market cap was roughly under $100 million. Now it's $4.6 billion. That's a big increase. So how does one go to the federal government and say: Hey, I think I can produce a vaccine, and give me some money. How did you all do that?

MR. ERCK: Data. We have – we showed them the best data. And well-regarded scientific models, non-human primates. We showed the best data. And so everybody looked up and said: Wow, that's better than the data that's been shown by Pfizer or Moderna. We ought – and it's manufacturable. And it's safe. And it's from a platform the company's been working on for a decade. And so it's not just brand new. It's data that shows very – and that's what it is. It's all data-driven.

MR. RUBENSTEIN: So when you get – when you got word that you were likely to get this grant – I don't know how it worked – but obviously it was going to have a dramatic effect on the market value of your company. Your market value's up about 5,000 percent since December. How do you keep that information private until it's publicly announced? How do you avoid people trading on that?

MR. ERCK: Well, I mean, this is – I've been in biotech for 40 years. We always have had the balance between data that you know and data that you announce. And you have to have – you have to use judgement as to what the timing – you know, whether you're confident that the data is material, so therefore you have to announce it. And that's – and we've often, like we did, go out and get peer reviewed analysis of your data. And we've had a couple of New England Journal papers published just in the past few weeks. And so that's the only way you can do it.

MR. RUBENSTEIN: OK. All right, so when your vaccine – let's suppose it is approved. And who decides who's going to get it first? Is it Americans? Is it older people? Who is going to decide who's going to get it first? And do you have to listen to what the federal government says in that, or you can sell it to anybody you want to sell it to?

MR. ERCK: Well, there'll be tension. And one of the reasons we set up a manufacturing – global manufacturing platform is such that we can get product distributed globally. As I mentioned, this is a global problem. It's not a problem just in solving it in high-income countries. It's low-income and middle-income countries. We have seven different manufacturing sites in seven different countries that probably, by next year, can make upwards of 2 billion doses. And it will not be blocked by closing borders.

And so therefore in the U.S., we have product that we have made in the U.S. And we'll rely upon the CDC and the ACIP[1] to help figure out how to distribute product. And the same organizations in Europe. And we work with Gavi, the Global Alliance for Vaccines, which distributes products to 97 different countries – in low- and middle-income countries. We're going to supply product for all of those.

MR. RUBENSTEIN: Your company's based in Maryland. How about giving it first to people who are also living in Maryland? How about that?

MR. ERCK: I'm all for that. But I don't have all those choices.

MR. RUBENSTEIN: And what will it likely cost somebody? Let's suppose your vaccine comes out, and I say I want to get it. What do I have to pay for it?

MR. ERCK: Yeah. It depends on whether you're getting it through the first – I think that, like flu, I think that the ordinary person is not going to be paying for the vaccine for some period of time – certainly not during the pandemic influenza period.

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[1] The Advisory Committee on Immunization Practices is a committee within the Centers for Disease Control and Prevention that provides advice and guidance on effective control of vaccine-preventable diseases in the U.S. civilian population.

MR. RUBENSTEIN: So your company was modestly sized and not that well known in the general public, I would say. Now it's pretty well known. How has your life changed since that time? You have people from high school calling you up, telling you they really like you a lot more, and can you get them the vaccine? How has your life changed?

MR. ERCK: Yeah. Well, there used to be Saturdays and Sundays.

MR. RUBENSTEIN: So now you don't have very much time? All right.

MR. ERCK: Now, that's not true of just me. That's true of my whole company. Look, we're the easiest place to recruit the best people to right now. Everything we've done, all the data that we've shown shows that we have a solution to this pandemic. And this is a once-in-a-lifetime opportunity. We're getting the best of the best scientists – experienced, and not just out of school – coming to work with the company. And so though we got enormous problems in terms of scaling up, in terms of supply chain logistics, getting in seven different manufacturing sites to produce product and distribute it around the globe. We have enormous problems, but we've got great people joining the company. It's all-encompassing.

MR. RUBENSTEIN: OK. Well, a lot of people have been working out of their home because of the COVID situation. But if you're producing a virus for the COVID crisis, do you have to work out of your home as well? So have you been working out of your home? And is that harder to do, or easier to do when you're in your business?

MR. ERCK: No, I have to have people in the lab. We have people – so we've got – we've got basically three different sets of labs. We've got them in Gaithersburg, where they do assays. And people have to physically be there to do assays. So we staggered work times. We have – we just bought a manufacturing site in the Czech Republic. We've got 150 people. There are going to be 200. It's about to start producing at a rate of a billion doses a year. And we have to figure out how to stagger those workers. People have to come to work.

You know, I talked with – you know, in Prague, we talked with the prime minister a couple times and said: Look, we've got to let our people – make sure they can get in country to be – to work there, I can go there. And the same thing in Sweden, where we make – where we make the – [inaudible]. We have to have people. And for those who aren't physically on the production line, we work from home. And so.

MR. RUBENSTEIN: So the information about how your trials are going is obviously very confidential, but also could move your stock dramatically. So how do you make certain that very few people know what the trials are showing so that inappropriate actions are not taken in trading your stock?

MR. ERCK: Well, that's something throughout the history of our company we've dealt with. You know, it's blind your data. So we also do placebo control trials. If you get – if you get great results for immune response, I don't know whether it's from the placebo or not the placebo until we unblind it. And then it's a very defined process of unblinding. You get in a closed

room for a few days, run the statistics. And you get your answer. So nobody knows the true answer until you unblind it.

MR. RUBENSTEIN: Are you also manufacturing a flu vaccine?

MR. ERCK: We are. And we have this great phase three unblinded flu – pivotal flu trial that we got in March, which everybody knows we need a better flu vaccine. We've been working on it for many years. And just coincidentally – I mean, in January, when I was looking for that plant in the Czech Republic, I was looking at it to make flu vaccine. And instead, it's now a COVID vaccine. But we have – we have I think provable phase three flu data. And my frustration is, is that because of all the capacity of manufacturing has been sucked away by COVID, I've got to find a way to do flu. So we're working on it. We'll get there. But COVID makes the project take a little longer.

MR. RUBENSTEIN: So with the polio vaccine, many people watching are probably familiar with that, that vaccine came about by taking a part of a live virus, and kind of making it a little bit inactive or not dangerous. Why is it with this virus that same technique, which worked with polio, doesn't seem to be one that people are using – they're doing different techniques. What's wrong with the technique used in the polio vaccine for the coronavirus problem?

MR. ERCK: Well, it's the beauty of our technology. We don't even work with virus. We never work with virus. So you don't have to build a plant that has all the safety precautions of escaping virus. We never, ever work with a live virus in our manufacturing process. We actually sequence the gene for the protein that we want to make. All we're making is a protein. Remember, you got a virus with RNA, you got proteins on it. Viruses don't live by themselves. That protein – they have to – they have to infect human cells. In the case of coronavirus, it infects it by this spike protein, the S protein.

If you can just take that protein, put it in your arm, and your immune system says: That protein – something's wrong here, there's something that looks like coronavirus, makes antibodies to it, so that you have a plethora of antibodies that when you actually get real virus, it blocks it. And so it blocks it so the virus can't infect your respiratory cells. And that's what – that's what immunization is. So that's the modern technique of not using – you don't have to use virus anymore.

MR. RUBENSTEIN: I see. So let's suppose a number of virus vaccines are approved by the FDA – Merck, Pfizer, AstraZeneca, and Novavax. And I have to go to my doctor. And I say: I want a virus vaccine. And I've got four choices, he would say, let's say. Why would somebody say I'll take one from Novavax, as you're not as well known, as why wouldn't one say I'll take one from Merck, because they've been around longer, they're better known. What's the argument that it doesn't make a difference if you get it from Novavax, or Merck, or AstraZeneca? How do you compete with those well-known companies and say your vaccine's likely to be as good as theirs?

MR. ERCK: So it's a challenge. And it's a challenge for little old Novavax to go up against Merck and Pfizer, and say their vaccine is better. But the beauty is – the beauty is, is the data

will be there. When we get – when we get approved, we will get approved and there will be a dossier, a package of data, which will say: Here are the four or five immune response types, or immune responses we get with each of these vaccines. And they'll say: Here's the data profile of each of these vaccines. And their doctor will help them make that judgement that – you know, so if you don't mind I'll use Novavax as the example.

Say Novavax gets 80 percent efficacy. And we have a really clean safety profile. And somebody else has 65 percent efficacy. Well, if both – you know, so that makes it sort of obvious to pick. But the fact is, is we're going to – we're going to roll out vaccines. And we have to have multiple – [audio break] – vaccine company that doesn't want another vaccine company to be successful at some degree, because there's just not enough capacity to get it out there. But as we get through the pandemic into the more traditional annual vaccine, then people will decide based upon the data that comes out. And it'll be published. All of the data will be published.

MR. RUBENSTEIN: So say somebody has an 80 percent efficacy, that means that 80 percent of the time it works and 20 percent it doesn't. But in that 20 percent it doesn't, does that mean that that they have some really bad side effects? Or it just didn't have any positive effect?

MR. ERCK: No, I don't think it has anything to do with the side effects. It just says they didn't have – their immune response didn't respond as well.

MR. RUBENSTEIN: All right. So let's suppose after the presidential election whoever's the next president – the current one or President Biden – they say: We want to start all over again and prepare for another pandemic – in case another pandemic is coming. And we want to do it better than we did this pandemic. What would you advise the next president of the United States about how vaccines might be better prepared and tested than this particular pandemic? Is there any advice you would have to the next president about how to make things better?

MR. ERCK: Well, I think that I'm probably a good person to ask the question, because my last two companies over 20 years I've been trying to make pandemic vaccines. We started 20 years ago with an H5N1, started to build that up. And H5N1 sort of went away. And there was this lull. Nobody would fund any pandemic vaccine work. And H1N1 came in 2009, big flurry of activity, then went away. And there hasn't been any pandemic funding in the past eight or nine years. And because now we've got the big one. So what'll happen next time? I don't know.

I mean, it may well be that they just don't have the – they continue that process. They go back to – [audio break] – because what you have to do to prepare for a pandemic – one of the things you have to do is you have to build a base of production and keep it warm where no products are coming out of it. And it just depends on whether you have the will to spend – pick a number, $5 or $10 billion a year – just to keep a warm base, and products never come out of that until there is a pandemic.

MR. RUBENSTEIN: I see. So take – with your vaccine, let's suppose it's approved. And I get a shot. And then I guess I need a booster shot, or whatever they call it, a second shot. But how

long does the vaccine last? Does it last for a year, six months, two years, a lifetime? How long do they typically last?

MR. ERCK: The answer is yes. We don't know. It's one of those. It will last one of those. We don't know. It could be an annual shot. It could be a five-year booster. We don't know.

MR. RUBENSTEIN: OK. And if somebody is watching here today, and they say: OK, I've listened to Mr. Erck. And I think he knows what he's talking about. I think his stock is a good buy. I'm going to go buy the stock. Do you think your stock's a good buy at this price, because it might have built in all the great effects you're going to have if you actually get approved?

MR. ERCK: What do you think I'm going to say to that?

MR. RUBENSTEIN: You can't answer that.

MR. ERCK: [Laughs.] It's – you know, of course I think it's a good buy. I think we have not only a lot of pandemic coronavirus vaccine to make over the coming years, we've got almost a perfect flu vaccine that hasn't even gotten to the market yet. And we've got an RSV[2] vaccine, which is probably equally important. So we have a pipeline. This is one example of the pipeline.

MR. RUBENSTEIN: OK. So the main message that, let's say, you would like to convey to all the people that are watching about your company and about the vaccine process, is what? If you were to summarize the main message you would like people to take away from our conversation, what would be the main message you would like people to walk away with?

MR. ERCK: So the platform is making recombinant nanoparticles – [audio break] – makes a very potent, safe vaccine. And there are a variety of major targets. The largest cause of hospitalization of children in the United States and globally is RSV. We have a vaccine for that, that's ready to prove that again in phase three. So we've got flu vaccine, and we've got the capacity to get through this coronavirus situation and build on that. And so call us just a – you know, the best respiratory vaccine company, that's a big market. And that's a big accomplishment. Use that same platform for other viral diseases. So there's lots of, lots of opportunity for –

MR. RUBENSTEIN: OK. All right. Well, I appreciate your coming on. I know you've got a lot of other things you're doing, and I know you're in Colorado at the moment. So I want to thank you for making the time for us. And I'll be waiting to see when the vaccine is ready. And hopefully it will be ready relatively soon, and I can get my vaccine. And you've said you were going to make sure people that lived in Maryland get it first, right?

MR. ERCK: No, I'll get your address and make sure that you have it on the first production line.

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[2] Respiratory syncytial virus, or RSV, is a common respiratory virus that usually causes mild, cold-like symptoms. Most people recover in a week or two, but RSV can be serious, especially for infants and older adults.

MR. RUBENSTEIN: Well, I don't know if I want to be the first, but I'll be early. Somebody else should be first. But OK. But thank you very much for taking the time to be with us, OK?

MR. ERCK: All right. Thank you.

MR. RUBENSTEIN: Thanks a lot. Bye.

So I'd like to remind everybody that this video of what we've just seen today will be on our website as soon as this is completed. I want to thank everybody for tuning in. And again, I want to thank all of our sponsors. And I want to thank Mary Brady and others, and Judy, for organizing all this. And thank you. We're finished today. And our next program, we'll have the postmaster general of the United States in two weeks. Thank you very much.

Stephen M. Hahn, M.D.
Commissioner
Food and Drug Administration

Dr. Stephen M. Hahn was sworn in as the 24th Commissioner of Food and Drugs on December 17, 2019. Dr. Hahn is a physician, scientist and health care leader with an extensive background in patient care, academic research and executive leadership.

Dr. Hahn is a dedicated clinician, having trained in both medical oncology and radiation oncology. In his previous leadership roles, he has always carefully balanced executive management with clinical time to continue to serve oncology patients, his true passion. He specializes in treating both lung cancer and sarcoma.

Throughout his oncology career, Dr. Hahn maintained a keen interest in research, authoring more than 220 peer-reviewed original research articles. His research focuses on the molecular causes of the tumor microenvironment, particularly the study of chemical signals that go awry (known as aberrant signal transduction pathways), and the evaluation of proton therapy as a means of improving the effectiveness of radiation therapy. His experience in medical product development and clinical trials spans drugs, biologics, medical devices, and diagnostics.

Prior to joining the FDA, Dr. Hahn served as the chief medical executive (CME) at The University of Texas MD Anderson Cancer Center, a facility that cares for more than 140,000 patients a year. He has proven executive leadership that spans research, development, clinical trials, patient care, health system management and education. In his role as CME, he was responsible for day-to-day management of the institution, including business, clinical and faculty matters. Under his purview was one of the largest clinical trial groups in the country. Dr. Hahn

joined MD Anderson in 2015 as Division Head, Department Chair and Professor of Radiation Oncology. Before joining MD Anderson, he served as chair of the Radiation Oncology department at the University of Pennsylvania's Perelman School of Medicine from 2005 to 2014.

Dr. Hahn earned the rank of Commander in the U.S. Public Health Service Commissioned Corps while at the National Institute of Health's National Cancer Institute, where he also completed a fellowship in medical oncology and a residency in radiation oncology. He also a completed residency in internal medicine at University of California, San Francisco. He graduated from the Lewis Katz School of Medicine at Temple University in Pennsylvania and received his bachelor's in biology from Rice University in Texas.

Stanley C. Erck
President and Chief Executive Officer
Novavax, Inc.

Stanley Erck was named president and chief executive officer of Novavax in April 2011. He became a Novavax director in June 2009 and served as its executive chairman of the board beginning in February 2010.

From 2000 to 2008, Erck was president and chief executive officer of IOMAI Corporation, leading the company through an initial public offering and a merger with Intercell, an Austrian vaccine company, and through the development of a late-stage infectious disease product candidate.

He previously served as president and chief executive officer at Procept, a publicly traded immunology company, as vice president of corporate development at Integrated Genetics (now Genzyme), and in management positions within Baxter International.

Erck currently sits on the board of directors of MaxCyte, Inc. He received an undergraduate degree from the University of Illinois and a master's degree in business administration from the University of Chicago Booth School of Business.