WTH is going on with a COVID vaccine? Operation Warp Speed director Dr. Slaoui on the coronavirus endgame

Episode #66 | August 6, 2020 | Danielle Pletka, Marc Thiessen, and Dr. Moncef Slaoui

Danielle Pletka: Hi, I'm Danielle Pletka.

Marc Thiessen: I'm Marc Thiessen.

Danielle Pletka: Welcome to our podcast, "What the Hell Is Going On?" Marc, what the hell is going on?

Marc Thiessen: Well, what the hell is going on first is we're going on hiatus. It is August, it is hot, and it is time for a little bit of a break. We've been doing a lot of podcasts in the past few weeks. We even doubled up for a while for twice a week. So we hope you don't mind if we take a little bit of time off in August, but we'll be back in September to cover all the vital events leading up to the most important election in American history.

Marc Thiessen: And that is probably true no matter what your view on the election is, whether you're for or against the President. And two, we have a really, really exciting podcast for you right now because we have somebody who doesn't do a lot of podcasts — doesn't do a lot of interviews, period. His name is Dr. Moncef Slaoui and he is running Operation Warp Speed, which is the effort that President Trump launched in May 15th, 2020 to get a vaccine for the coronavirus in record time. And it is moving at warp speed. We may have a vaccine passing Phase 3 clinical trials by October, November, December of this year, which would be the fastest that a vaccine has ever been developed in human history. And we got the guy who's leading the effort to talk to us today.

Danielle Pletka: It's a great get, thank you. You guys are going to love this. He was really, really frank. He was very generous with his time. So Marc and I are going to keep our intro a little brief today so that you can listen to him, but this is what's on everybody's minds. Look, I mean, Marc, you've been writing about this. For those of us who have kids, kids were in school, now they're not going to be in school. For those of us who are involved with universities, kids were going to be at university, now they're not going to be at university. We are just being whipsawed left, right, and center and the politics around it is just disgusting.

Marc Thiessen: Yes, I agree. The politics is disgusting. It's all about blame game. It's not about the country pulling together. But the reality is our lives have been upended like nothing that's ever happened before. My mom had COVID and she was in the hospital and then a rehabilitation center. I couldn't visit her for three months. I

couldn't see her. You've had people who had their parents and grandparents die and they couldn't even be with them when they passed away. You've got kids who were pulled out of school, parents who can't go to work, tens of millions of people lost their jobs. And the amazing thing is that by this time next year, that could all be a distant memory. We could be at a situation where the most vulnerable people to this virus have been largely immunized from it. We will no longer be running around wearing masks everywhere. We will no longer have to social distance as strictly as we are today. Schools will be open. Nursing homes will be open. Business will be humming. And it's because of Operation Warp Speed, if that happens.

Danielle Pletka: It's really been an unprecedented effort. And you're right. We all came together in the beginning and our politicians behaved with some self-control, and now it's all about figuring out who can screw who faster and not in a good way.

Marc Thiessen: No, you're right, Dany. Here's the thing — you get the sense that there are some people in this country who are really worried that we might get a vaccine before October because they don't want Donald Trump to be able to go into the Rose Garden and announced two weeks or three weeks before the election, "Ladies and gentlemen, my fellow Americans, we did it. We beat the China virus. We've got a vaccine that is proving effective and safe and we've launched a massive effort to mass produce this vaccine and logistical effort to distribute it. And by January, February, all the vulnerable people in this country are going to be getting a chance to immunize themselves." Because there are people in this country who care more about defeating Donald Trump than they care about the virus. They don't want to get a corona relief bill because it might help Donald Trump. We should all be hoping to get this vaccine as fast as possible, regardless of how it's going to affect the November elections.

Danielle Pletka: I completely agree. Now I will say this: Donald Trump, as is his usual wont, doesn't ever make things better on Twitter or anywhere else. I will add that those who have suspicions that there is some political aspect to this are often encouraged by the way that he approaches this. But I think that what they forget is that while Donald Trump may have predilections that drive us all crazy, make us suspicious, make us hate him, make us vote one way or another in November, the people around him are people with integrity, particularly the people who are working on a solution to this virus, people who are working on vaccines. These are not people who joined because they're Republicans or because they're Democrats, they're people who joined up, who gave up, in many cases, very successful careers and are trying to do something for the good of our country. To suggest that somehow everybody around Donald Trump is besmirched by or infected by, to use the theme of the moment, his attitude towards things I think is terribly unjust. And that's where, for example, this gross playing with Dr. Fauci on the one hand by the President and playing with Dr. Birx on the other hand by Speaker Pelosi just seems to me to be the most unacceptable, juvenile way of approaching a national crisis.

Marc Thiessen: Oh, I couldn't agree more. And also the politicization of the resurgence of the virus, there was a big story in — I can't remember if it was the Washington Post or the New York Times the other day, this weekend — about how San Francisco, despite having done everything right, there's a huge surge of virus in San

Francisco area. Everybody wants to blame the fact that they, "Oh, well, we reopened too quickly, and so therefore we brought back the virus." But then, we're finding out the countries — we've had podcasts talking about how well Taiwan did and how some of these South Asian countries did. They're now, many of them, experiencing a resurgence of virus, the countries that did everything right. It's all politicized. It's all about, "Well, we've got to find a way to blame Trump for the resurgence of the virus."

Marc Thiessen: And here's the irony, Dany. And I'm going to do a column on this — that the resurgence of the virus, which everyone's blaming Trump for, could actually be what makes it possible to get the vaccine done by October. The Wall Street Journal had a fascinating article the other day that says basically the problem with a lot of vaccine development is that the pandemic abates before you can test the vaccine, and you don't have enough test cases. If you're going to test the vaccine, what you do is you put people in an area where there's an outbreak and you give some people the vaccine and some people not and see whether it protects those people. And so it's actually the fact that we have outbreaks in Texas and Florida and other states that are allowing the pharmaceutical companies to surge testing areas into those areas, and we may get the answer faster because of the resurgence of the virus.

Danielle Pletka: So I'm not going to celebrate the virus' resurgence, I have to say.... Just looking at what's happening in my native land of Australia, it's been devastating. And they, of course, have had a minuscule number of deaths compared to our own. What you're talking about, Marc, though, is this desire to somehow suggest that red states are more deserving of the outbreak's resurgence than the beautiful people of San Francisco or Manhattan, and that's utterly repulsive. The virus is going to come back and slap all these people in the face and make fools of them, frankly. There's nothing we can do about that, that's the point that we've sunk to in our politics at this moment. All we can do is try to share actual information with people.

Marc Thiessen: That's what we're going to do today because we've got somebody who has not a political bone in his body when it comes to this, he is an accomplished scientist who's been behind the development of more than a dozen vaccines that have probably changed your life and you don't even know it. And he's leading this effort and he's joining us today.

Danielle Pletka: Dr. Moncef Slaoui is our guest. He's the chief advisor to Operation Warp Speed. And I'm not going to read his entire bio because it would take the rest of the podcast, but he spent 30 years at GlaxoSmithKline. He's been a vaccine innovator. He was honored as one of Fortune's 50 Greatest World Leaders for his work in under researched diseases common in the developing world. He's really, first of all, let me just say, having spent a little time with him, a very little time with him, he seems like an amazing person, the Trump administration and our nation, we're so lucky to get him. You're going to love our conversation.

Marc Thiessen: Well, Dr. Slaoui, welcome to the podcast.

Dr. Slaoui: Thank you for having me.

Marc Thiessen: Oh, good. So you are leading an effort called Operation Warp Speed, which is designed to give us a vaccine for the COVID-19 virus in record time. Tell us about Operation Warp Speed and what the goals are.

Dr. Slaoui: Operation Warp Speed actually is really aimed at accelerating development of vaccines, therapeutics, and diagnostics to help control this pandemic. And it's a partnership between various institutes within the Human Health Services, NIH, BARDA, the CDC, GMS, and with also the Department of Defense and a number of private companies that are the sponsors of vaccine programs or therapeutic medicine programs. And the objective is really to significantly enable acceleration of the program. So it's not about discovering a vaccine, but it's about selecting candidate vaccines, if I focus now the conversation around vaccines, and enabling, accelerating their clinical development in animal studies and in tubes, accelerating their development in clinical trials, accelerating the setup of their manufacturing processes, build up of the manufacturing facilities or their refurbishing, and then the manufacturing and stockpiling of vaccine doses. And also prepare by integrating all the information generated through these processes for the companies to file VLAs for approval with the FDA, which will independently review, of course, the performance of these vaccines from all standpoints and either issue an emergency use authorization, depending on data, and how quickly they are available or a VLA formal approval.

Dr. Slaoui: And then the operation is also working closely with the CDC to discuss the allocation of vaccine doses to various sub-populations at risk of acquiring the COVID infection. And also to study the what's called "the pharmacovigilance" to study the safety of these vaccines beyond the clinical trials in which they are currently used.

Danielle Pletka: So Dr. Slaoui, in the military, they always prioritize B-L-U-F, bottom line up front. So let me ask you a bottom line up front question: how optimistic are you about being able to deliver a usable vaccine to just the American public, and we can talk about the world afterwards, to the American public by the end of the year?

Dr. Slaoui: I am, frankly, very optimistic. Based on what we see in animal models with the current vaccines, based on, I would say, the natural history of infection with the coronavirus, SARS-2 virus in depth. Majority of people are able, actually, to control this infection and are either asymptomatic or recover from their infection. I'm optimistic because I think this is a virus that if you are equipped with a little bit of immunity against it, it gives you an advantage of speed, of your immune response countering the virus before too much of the virus has multiplied inside your body. Then you avoid the fact that when your immune response finally mounts, a little bit later than usual. In diseased patients what happens is they get the virus, the virus multiplies too fast and too much before the immune response comes to destroy the virus, but then it destroys the virus and the body at the same time. And that's really most of what the early clinical disease is. So if we accelerate the immune response, we will be able to have a vaccine. And the vaccines that are in development achieve that with two mechanisms. One, we make antibodies that neutralize the virus. So a good fraction of the virus that people receive when they are exposed, somebody who is infected, will be immediately eliminated with those antibodies.

Dr. Slaoui: And the second arm of the immune system that's being stimulated with these vaccines is what's called the cellular response of key leukocytes. You can hear about them now even in lay news where those cells are endowed with the capacity to eliminate the cells that are already infected with the virus and kill the virus inside them and kill those cells at the same time. If there are only a few of them that are infected, you do that, and you don't feel it, or you have a little sneeze or a little cough, or you have mucus and that's the end of it. And I am optimistic too, very optimistic, that we will have a vaccine that's protective and just based, unfortunately, on the current levels of transmission of coronavirus, that's happening in the US, I think the clinical trials will allow us to demonstrate efficacy before the end of the year.

Marc Thiessen: Talk a little bit about that because the Wall Street Journal just had a story saying that until recently, researchers thought it would take many months to get enough COVID cases among study subjects to yield answers because the lockdown measures had slowed the virus. But now with the resurgence, it could shave weeks, if not months off of the results of the clinical trial, the Phase 3 clinical trials, is that correct?

Dr. Slaoui: That's absolutely correct. And what we are doing is we are optimizing the geographic location of the sites in which we run the clinical trials, where through recruitment of volunteers as you... We are, on a daily basis, looking at where the epidemiology is taking place, where transmission is happening on a per zip code basis, and activating clinical trial sites in those areas where transmission is starting to happen. What's important to realize is immunization takes a while. The current vaccines that are being tested are tested after immunizing subjects with two doses of vaccine, a first dose, and then a second dose, either three or four weeks later and then you have to wait another one week to two weeks before you're fully immunized.

Dr. Slaoui: So we start to count the cases for the clinical trial after five to seven weeks or eight weeks after starting to immunize individuals. So what we need is identify sites that are not necessarily at the peak of transmission today, but they are starting to get to go towards the peak so that within four or five, six, seven, eight weeks, there will be more cases still coming into that particular site, in that particular region. We can see that we need between, I'm going to say 70 and 150 cases in the clinical trial to be able to conclude, okay, now we can look at the trial and did it work or not? We believe that that may happen in the period between six weeks and 12 weeks from completing recruitment of the trials. So that puts these dates somewhere between November and December.

Danielle Pletka: So at the very beginning of the COVID pandemic, we were lucky enough to have our colleague, Scott Gottlieb, the former head of the FDA, on the podcast. And he talked about something you've talked about as well. You mentioned in one of the stories that I read, that you've never seen something go through Phase 1 to Phase 4, from humans to acceptance in less than four years. But Scott underscored the reason for that time is in order to check on the adverse impact of any vaccine. How do we get away from those fears that there's going to be some adverse impact that we won't simply have had the time to see?

Dr. Slaoui: So actually the reasons for that time are not uniquely related to the adverse

impact, we are going to come back to the adverse impact in a second. The reason this is going so fast are many. The first one is that over the last 15 years, I would say since actually the SARS 1 outbreak and the MERS outbreak that also happened about 10 years ago, we have learned how to use certain technologies to immunize against respiratory viruses that look like the SARS 2 Coronavirus. So we're not starting from scratch wondering what would it take to immunize against this virus. So the discovery process very early on has been very rapid and have benefited from experience from SARS 1 as well as from the development of what's called platform technologies that are similar from one vaccine, can be used for many different vaccines. There are 90% or 99% the same from one vaccine to the other.

Dr. Slaoui: Why is that important? It is because for those platform technologies, we know their toxicology requirements. They have been studied already in animals and in clinical trials and some of them are being used in commercial vaccines. So we have long experience. This is not true for all of them, but for some of them. We know how they behave for manufacturing. I'm going to use an example. It's like, if you take a Volkswagen or a Bentley, it's actually the same car underneath. It's the same platform, same kind of engine, same suspension. It's just shinier outside in one case and way more expensive in the other. To manufacture them, you can use the same manufacturing site. What's happening here is that we have those platform technologies. We used it to do SARS 1 or MERS or Ebola or Zika vaccines and now we're using them and adapting them to the SARS 2.

Dr. Slaoui: So we can go much faster from a technical standpoint. We know much more about their behavior in toxicology and animal studies. We know much more about their behavior in clinical trials. We know much more about their behavior on how to scale up manufacturing and be able to make millions of doses. This is the number one reason why we're going much faster. We know much more how to work and the operation has selected specifically platform technologies for which a balance between amount of knowledge of the technology and speed of development was…

Dr. Slaoui: The second reason why we're going very fast is that we are taking significant financial risk, not safety risk, not efficacy risk, financial risk by running all elements of development of a vaccine in parallel, rather than wait sequentially. We are running the preclinical work. So the work in animals at the same time as we are preparing for the clinical trials. We're running the clinical trials — as soon as we start the first clinical trials, we already are preparing the sites for the Phase 3 trials at risk. At the same time, we're also investing in the manufacturing facilities, in the manufacturing technology, and what's called scaling up the technologies so that by the time, frankly, we're starting Phase 3 trial, we are already have a refurbished or halfway through refurbishing the manufacturing sites and techniques that are needed to manufacture and we will be stockpiling these vaccines from a manufacturing perspective already before completion of the Phase 3 trial.

Dr. Slaoui: It's a financial risk because those are very expensive processes, but at the same time, what we are able to do is eliminate or condense dramatically the lead time between each step and running very fast. The key point, the key point, is that the FDA will independently review the full data clinical, technical, manufacturing, independently assess the benefits/risk of the vaccines and independently makes

its decision and approval.

Dr. Slaoui: Now, the one thing that's different, the one thing that's different is how much follow-up time we have after people are immunized. By definition in this case, right, within four months or six months from immunizing people in the trials, we will have the data from the trial and because there is such an outbreak and such a pandemic, we may decide who to immunize. And there, we don't know the long-term safety of some of these vaccines. It's true. We have no reason to believe there is anything wrong with them. But for some of them, we simply don't have clinical experience and there the key is going to be what's the benefit-risk to the population. If you have a risk of acquiring COVID-19 and dying from it, as is the case for individuals who are over 75 and have co-morbidities, et cetera, having a theoretical risk over a period of three years or 10 years that something could happen versus your current risk of having an infection that can be deadly in 15-20% of those subjects, I think it's a very important question that the regulators, but also the CDC, will opine upon.

Dr. Slaoui: Personally, I would take those vaccines because it's a risk now versus a theoretical risk in the long-term. Some of the platform technologies we use are going to be available early, and they are not very well known in terms of their long-term safety, so they have the benefit of being here now. Some of the other platforms that we are using are going to be available in a few months later, several months later, and we know more how the platform performs with other vaccines. And I think again, we in the operation have created a portfolio of vaccines that will allow us to make the best choices for the right set population in terms of benefits.

Marc Thiessen: So you could use different vaccines. You have multiple vaccines being developed at the same time, and you could target different vaccines depending on how the clinical trials work at different populations?

Dr. Slaoui: Exactly, exactly. The risk-

Marc Thiessen: It might be better for the older people, might be better for younger people, it might be better for middle-aged or people with certain comorbidities?

Dr. Slaoui: That's exactly the point. We are testing the vaccines in a diversity of population that is representative of the at risk populations. All of them, of course, age population, the co-morbid population, the various ethnicities in the population. As we know, unfortunately, this virus is having a higher morbidity, more impact in a number of ethnicities and socioeconomic status. All of that is being tested in the clinical trials and is going to be done, for sure, for six vaccines. There's two more that may be further be elected into the organization's portfolio. And the data will inform us. The science will inform how to best use these vaccines.

Marc Thiessen: How effective do you expect the vaccine to be? So the FDA standard is 50%. You said in an interview recently, you thought it could be 90%. Ninety-four I think, is the height of any vaccine with mumps, I think, is very high. But do you really think we can have a 90% effective vaccine?

Dr. Slaoui: Well, let me correct that first, because I was one of the inventors of a vaccine

against shingles that is 97.2% against shingles in individuals, including those who are over 80 years of age.

Marc Thiessen: Wow.

Dr. Slaoui: So vaccines can be very effective and they can be effective over — that particular vaccine, without citing its name, is effective over a period of, at least when I retired from GSK —it was over a period of five years, and it was three years ago. And it's probably still the same. So vaccines can be very highly efficacious. And what you need to understand and people need to understand is when we say a vaccine is 90% effective or 80% or 50%, that's what's called the point estimate. But there is a statistical window around that point estimate that is where the real number is. It could be, let's say, if you say my vaccine is 80% efficacious, and there is a window around that 80%, that says it could be a hundred percent or it could be 60%.

Dr. Slaoui: That's what's called the confidence interval around that point estimate. When a vaccine achieves, for instance, 90% efficacy, the real number may be 100%, or it may be 70% or 65% or 85%. We will know what that interval is. It is not exceptional to have a 90% efficacious vaccine. What's very important is I talk about efficacy against a moderate disease. Frankly, an ideal vaccine would be a vaccine that's going to eliminate this virus from the face of the earth. I don't think we're going to have that because that would be a vaccine that eliminates any infection. But we already know 80 to 90% of people who get infected are asymptomatic. What we may achieve is that, I hope, 90%, maybe more, of people who get infected are either asymptomatic and shed less virus so they're less infectious, or if they were going to get sick, are not sick. So they may have what's called mild disease. They may sneeze for two days. They may shed virus a little bit for a day or a week, but they will not be very sick, they will not have fever, they will not go to the hospital, they will not die. Because that will, frankly, change the impact of this pandemic. And most vaccines actually work that way. And we just don't know whether we got infected or not. You wake up some morning and you say, "Well, I'm tired today, I had to sneeze. Maybe I was cold, I had an allergy and I moved on." It could be an allergy, it could be COVID-19, but now you're not sick out of it. So that's what the 90% is for. Not for infection, infection is going to be lower and less sustainable.

Danielle Pletka: So this effort that you're spearheading for the United States, we are seeing this go on in a lot of countries. We're seeing it happen in Europe, there's been a lot of talk about work done at Oxford. Obviously the Chinese, being the epicenter of this coronavirus, are working on it. How much are you all working together and how much are you working in competition? And if you don't mind, let me add a little bit of a tail to that question as well, which is, one of the problems that we discovered at the outbreak of this pandemic was that countries that you relied on for PPE, for example, for personal protective equipment or for swabs, wanted to supply themselves before they wanted to supply us. How big a factor is that in some of these issues?

Dr. Slaoui: So, first of all, we only will be able to control this pandemic on a worldwide basis because the world is global, the way this pandemic came like thunder is because the world is global and we are experiencing all the challenges because the world

is not global anymore now. So the solution has to be global. And I think there will be many different vaccines developed in many countries. As far as what the operation is looking at, we are, we set our self an objective that the vaccine that we will support will be vaccines that are manufactured in the US. They don't have to be discovered in the US, they don't have to belong to a company that is exclusively based in the US. And in fact, as you know, if I take the AstraZeneca Oxford University vaccine, which is one of the vaccines in our portfolio, it's been developed in the UK, it's been developed by AstraZeneca independently from us in a number of countries. Trials are running in the UK, in Brazil, in South Africa.

Dr. Slaoui: But we also took this vaccine and we are developing its manufacturing in a US facility and we are running phase three trial that should be starting within the next two weeks or so also here in the US, be able to fully document, according to the FDA, highest possible standards, its efficacy, and its manufacturability. I take the Johnson's vaccine, J&J, it's a US company, but its vaccine capabilities are based in Europe. Again, it's a vaccine that's being developed for the world, but we are, we took on its development for the US and its first Phase 3 trial will be happening in the US starting early in September. If I take the Novavax vaccine its first trials have taken place in Australia and Novavax had an agreement with the CEPI, which is a specific organization that I was involved in the inception of, that is really geared towards helping the world, and developing countries in particular, fight pandemics.

Dr. Slaoui: CEPI has an agreement with Novavax to develop the vaccine outside of the US, we are developing vaccine for the US. So there's a lot of collaboration, there's a lot of data exchange with friendly countries and companies that are seeking to develop vaccines. We have no specific collaboration yet with a Chinese company, this may happen if there was an amazing scientific breakthrough that is coming from there. We should strive to find the solution. And I think the President had said on May 15, that if we had enough doses of vaccine, once the need in the US are satisfied, our vaccines can go anywhere in the world to help with the pandemic

Danielle Pletka: Dr. Slaoui, you mentioned the Chinese. One of the things that I found interesting was that you had spearheaded the opening of a GlaxoSmithKline research facility in Shanghai, which then closed. I wonder if — obviously there's a lot of suspicion in the United States about the way the Chinese government and the way that the Chinese epidemiologists have handles this virus. Did you have a negative experience then? Or was that simply an economic decision?

Dr. Slaoui: I think it was a mix of both. So in 2007 or 2008, I wanted to create more diversity of creativity and discovery of medicines in our GSK, GlaxoSmithKline, research activities as I was heading all the research activity in the corporation, and looked where patent application were actually have being filed in the world. Of course, the majority's in the US and in Western Europe, but there are countries, of which China was an important point, that are creating a lot of innovation and patents. So we decided to go and create a global discovery center in Shanghai and populated it with great scientists that were Chinese scientists trained. And some of them are professors in US universities or European universities. It was partially populated with those scientists, I would say world-class scientists, as well as local scientists from China. The center grew very well and had about four or 500

scientists.

Dr. Slaoui: However, and this is the challenge, at some point the cultural approach to hierarchy in China was such that we found situations where the pressure of the expectation of the leadership of the labs or the experiment to be run and expecting it to be positive that some of the scientists on the bench, we couldn't be fully trusting of the day to day generate. And that was the beginning of the end, frankly, and we decided, ultimately, to close also based on economic reasons and reasons that had to do with GSK history in China, which I'm sure you're aware of. We decided to close that center. I would say my personal assessment, there's excellent science happening, however, it's trust and verify and super verify, given the experience. One shouldn't be looking the other way, I think that would be a mistake.

Marc Thiessen: It's a perfect segue to my next question, which is, there's… Pfizer has said that they are expecting to have their Phase 3 trials done by October and seek FDA approval. I think Moderna has said November, December, and Dr. Fauci said it might even be earlier than that, which would put the announcement before the November election. Some people have started speculating that there's political pressure here in the US to put a positive result before November. First of all, it would be great if we had a vaccine in October, regardless of politics. So could you tell us if that's possible and two, is there any political pressure on you to get this done before November?

Dr. Slaoui: So the reason I took this role was A, because I humbly thought I can help this country and the world develop faster vaccines against COVID-19 because this is killing thousands of people here and in the world. And therefore, every day counts, the reason has never, ever been and I am sure I'm talking for the thousands of people involved in all the work being done between all the HHS community and the Department of Defense and the other communities and the companies that are working incredibly hard, the reason is every day in the US 1,000 or more, unfortunately, people die and thousands are morbid because of this infection. It has nothing to do with the election. That's number one, the engine of this is that. The second, I would say, is the approach is 100% based on facts and data and nothing else. And we're running clinical trials, we're going as fast as we can appropriately, with vaccine composition that is well-told true, that has shown efficacy in animals, that has shown good Phase 1 studies, that's shown good immunogenicity, that is running very, very large trials to document the safety and the efficacy.

Dr. Slaoui: We're running very large trials because they allow us to reach efficacy faster, not because there's an election, because there's thousands of people dying every day. And the data will be defined by the number of cases. There is no date. It's impossible to give you a date. I have been asked about dates, and I didn't feel any pressure whatsoever to say data will define the date. When we have the number of cases required and then we have an independent data safety monitoring board independently look into the data and says we need to continue, we need to stop because this is not working, or we need to stop because this is working too well, it's unethical to continue, we now need to start to give the vaccine to the placebo arm in the trial and to other people to consider, then that will be the end. So the end of the trials is completely

independent of the operation or anybody involved in the operation. It's actually great academic experts, whose names are unknown to the public who are looking into that data. And this is how all clinical trials are always done. That is how clinical trials are done.

Dr. Slaoui: So the data will dictate, the facts will dictate. We may have the end point in October. We may have it in November 4th, who knows? We may have it in December 15th. That's the answer, and to be honest, on a personal basis, I would resign instantly if I was forced to do something that I thought would be inappropriate.

Danielle Pletka: That's great to hear. Let me ask you if I may, and you've been super generous with your time. Thank you for that. I want to ask you a little of a personal question, but first I want to tell you what I think, so you're not offended by it. There's been criticism of you for your unwillingness to divest certain of your holdings prior to taking on this position at Operation Warp Speed. My view of these things is that if you want the best people, you should not have to force them to bankrupt themselves in order to take on a job that could save hundreds of thousands or millions of lives. But other people have a different perspective. I'd love to hear how you approach this.

Dr. Slaoui: Yes. This has been, frankly, something that really hurts and where I learned the lesson that I'm naive, that politics are more important than ethics and values. I know my values, I know my ethics. I have done things for the last 33 years. I have been fortunate to never have to ask for something because I wanted more money. I always asked for something because I wanted to have impact, people's lives. I obviously had some impact on people's life, which was beneficial to the corporation I was working for. And that allowed me to have a very comfortable financial situation, which by the way, I have never acquired shares. I gained shares as part of my income in GSK, I gained shares as part of my income, by being on the board of various companies. I realized there was a conflict of interest and I offered, was not asked, to divest my Moderna shares.

Dr. Slaoui: Of course, I should divest my Moderna shares and resign from that board. Of course, I should resign from any board, from any company, that has something to do with COVID and also divest my shares. But on GSK, I'm not on the board and GSK's my retirement. So what I said, "This is my retirement," and I am not a financial freak. Tell you, I am like a grand grandfather of financial people. I want to have the dividend paid to me from those shares because it allows me to have a comfortable life and not having to make decisions depending on financial dimensions, because that's taken care of through my GSK shares. So what I said is I will A, divest everything that is a clear conflict, and B, for GSK, I won't leave those shares because that's my retirement. However, any accretion in value of those shares between the day I take the role and the day I leave the role, I'm happy to give that value, whatever it is, to fundamental research. So I can tell you mathematically, it's impossible for me to make any money from this.

Dr. Slaoui: And frankly, if somebody can demonstrate that some money has been made because I was in this role, I'll be happy at the end to give that money. But not my retirement. Why would I try to help the world and forego my 30 years of work? I don't understand it. And why would somebody write that I'm doing this to help

my former colleagues enrich themselves? I mean, I find that really insulting. I don't know these people. And I can tell you something, they don't know me.

Dr. Slaoui: Here's my message to the people if you do that, I say, I know what I've been doing the last 10 or 11 weeks now. I know what I've been doing 24 hours a day. I'm asking them, what have you been doing? I've been working with a thousand other people to try to accelerate vaccines, and therapeutics, and diagnostics day and night. And we're going very fast. I don't know whether they will work or not, but if we didn't try, it wouldn't happen. So, that's my answer. I'm sorry. It gets emotional around it because it really frustrates me. And it taught me a lesson, which is, frankly, there's a number of publications, or newspaper, or media that I was hearing and listening to actively before. I'm not trusting them anymore because we told them information that they specifically omitted from the publication. And, to me, that crosses a red line on ethics. And I disagree with it. So, that's my opinion.

Danielle Pletka: I appreciate your frankness. Thank you for that.

Marc Thiessen: Well, we're very blessed, as Americans, that you're helping to lead this effort. Exit question. How soon do you think we can go back to normal life? What's the timeline for the average American, looking at this effort, hoping that at some point... I mean, we'll never go back to the way we were before perfectly, but when can we hug our grandparents? When can we send our kids to school without worrying? When can we go out in the world and not wear masks everywhere? What's your timeline? Or what's your thought on that?

Dr. Slaoui: I hope we will have enough doses of vaccines in the first two months of 2021 to immunize the at risk populations in the US, vaccines that could have shown efficacy and approved independently by the FDA. And I'm talking about maybe the 30 to 40 million most susceptible people in the US across maybe December, January, February.

Dr. Slaoui: And then — and I think that should decrease dramatically the burden of this disease on society in general. Because, as you know, most of the burden of the disease is on a high risk population. Plus the secondary effect of overwhelming the hospital systems, et cetera, which has an impact on other populations for other reasons. And I think, from there on, it's going to be a gradual process that will be a balance between the benefits/risks that the vaccines will have shown and the risk of particular subpopulation.

Dr. Slaoui: For instance, frankly, immunizing the pediatric population, toddlers, et cetera, will be something that should be really far because they have 70 or 80 years to live. And we need probably there to use platform technologies that are well understood in the long range, such as protein based vaccines, et cetera. We are fortunate that mostly in that population the disease burden is very, very low. And so, I think there will be a gradient of views. But probably between the first quarter and the second quarter of 2021, the most at risk populations will have been, I hope, immunized. And life, I would expect... I hope next summer I can have a vacation, normal vacation.

Danielle Pletka: We hope that for you too. Can I take advantage of you for 30 seconds and just

ask that follow-up question I know people want to know? We all want to make sure our parents, and our teachers, and our populations are first in line, but who's going to be deciding who gets what? You mentioned your shingles vaccine. I still haven't been able to get that because my doctor didn't get a dose. So, how are you going to manage that distribution and that prioritization? And who is going to make those decisions? And then, I'm done.

Dr. Slaoui: Super important question. It's a critical question. And I can tell you first, we decided who should not do it. That's very important. I think this should not be politically motivated. This should be scientifically, ethically, epidemiologically motivated. So, the first thing that we thought we should do, which I discussed with the board that oversees the operation and then with my colleague Francis Collins, who heads the NIH, was to say, "We should organize an independent, scientific summit that will discuss in concept, outside of having the data with the vaccines, because then, the pressure is enormous, discuss just in concept how to best introduce new vaccines, who to immunize first, what kind of performance of vaccine is best suited to what kind of population with what we know."

Dr. Slaoui: Francis suggested that we contact the American Academy of Science and Medicine, who is organizing, long story short, this Friday in an ongoing basis, ethical, epidemiology, and virological vaccinologist discussions around how to best serve the population, with all its diversity, with a new vaccine or new vaccines against COVID-19. And this summit will create a scientific framework of thoughts that has been generated outside of data, outside of data in the sense of, "Oh, this vaccine works, or that vaccines works." But no pressure yet, just the science. That framework will, I'm sure, be very useful to inform the very important decisions that the ACIP and the CDC will need to make based on facts and data, when we have the performance of the vaccine.

Dr. Slaoui: And also, based on how many doses we have. So, we were acutely aware. We don't think we need to do it in the operation. But we are helping to generate the independent information to inform, and the science to inform those important decisions.

Danielle Pletka: Fantastic. Thank you so much.

Marc Thiessen: Thank you. Thank you for what you're doing.

Dr. Slaoui: Thank you.

Marc Thiessen: For our country and for the world and the sacrifices you're making. And thank you for joining us here today.

Marc Thiessen: Dany, first of all, I'm so glad that Dr. Slaoui agreed to do this podcast. And I'm so glad that he's leading this effort, despite the fact that people are just shamelessly attacking him for no good reason. Here's a man who is not a politician, not even a Republican, who has given up time from his life to work 24 hours a day on getting this vaccine to us as soon as possible. And the thanks that he gets is people speculating on his ethics. Why would anybody want to join the government and serve their country and serve humanity with that kind of reward?

Danielle Pletka: Well, remember what Harry Truman said, and that was more than half a century ago: "If you want a friend in Washington, get a dog."

Marc Thiessen: Yep.

Danielle Pletka: That is the ultimate. It was sad to see how disillusioned Dr. Slaoui has become, because so many people view everything through the prism of politics. But, hey, I think we're used to that. I'm just encouraged that he had some — what I thought was pretty good news. He seemed very optimistic. He seemed very bullish on the idea we could actually get something by the end of the year. I got to say, I thought we would be out of this by May, which shows you how much I know. So, if it's by the end of the year, I know we'll all heave a collective sigh of relief.

Marc Thiessen: Here's the thing. And this is why I get frustrated with like the anti-mask people. It's like, this is going to end. Okay? We're not going to be wearing masks for the rest of our lives. We're not going to have to social distance for the rest of our lives. We're going to get a vaccine. We're going to get multiple vaccines. We're going to get therapeutics to treat it. And we're going to be able to go back to our lives.

Marc Thiessen: We just need people to take a few selfless steps for a brief period of time to get us over the finish line. And that finish line, as we just heard from Dr. Slaoui, it's in sight. As he said, if we can immunize the most vulnerable people in January, February of next year, we're out of the woods. We're not completely gone. It's not over. It's going to take a little time to get everybody protected. But we will have taken care of the vast bulk of the problem. And we'll be heading back to normal. And so, just stick it out for a few more months, people. We can do it.

Danielle Pletka: We can do it. We know you out there can do it. If Marc and I can wander around with masks on our faces, as much as we hate this, everybody else can do it too. It really does make a difference. And I think that we've seen pretty persuasive science about that.

Danielle Pletka: Guys, wanted to remind you, we are going to be taking off for a couple of weeks. Please listen to old podcasts. Go back and re-listen to your favorites. Send Marc critical emails about all the things he said wrong. And brace yourselves, because what did Bette Davis say? Was it about the fall election? She said, "We're in for a bumpy ride."

Marc Thiessen: We'll see you guys in September.