



WTH is the path out of this nightmare? Scott Gottlieb discusses his plan for a return to normalcy

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Danielle Pletka: Hi, I'm Danielle Pletka.

Marc Thiessen: And I'm Marc Thiessen.

Danielle Pletka: Welcome to our podcast, What the Hell Is Going On. Marc, I laugh every single time, we might as well rename the podcast, What the Hell Is Going On with Coronavirus?

Marc Thiessen: Well, what Americans are wondering is when the hell are we going to come out of this nightmare?

Danielle Pletka: Yeah.

Marc Thiessen: It is just awful. We just got a new jobs report. 6.6 million people lost their jobs in the last week alone. That's on top of 3.3 million, the previous week. So in two weeks, 10 million Americans have lost their jobs. This is unprecedented in what we're doing. The reality is that Americans are willing to hunker down. They're willing to ride this thing out, but they need to see a light at the end of the tunnel, which is why President Trump has been pushing the medical community to say, "When are we going to come out of the wilderness on this? What's our path out of this?"

Marc Thiessen: And like all good things, AEI comes to the rescue. Our colleague, Dr. Scott Gottlieb, along with a team of epidemiologists and former FDA and government officials, has put together what they call a roadmap to reopening, which lays this out in stages. We're in phase one, phase two, phase three and lays out clear benchmarks for how to move from one phase so we can start reopening the country while defeating the virus while mitigating the risk.

Danielle Pletka: I commend it to you. We'll put the report up for everybody so that you can read through it. What I think the valuable thing that Scott and his colleagues did is that they give us sort of a timeline. I'm betting that every single one of our listeners feels exactly the way that you and I, and I know my family and all of our friends do, which is it's not so much the mitigation. It's not so much being trapped at home. It's not any of those things. It's not knowing when it's going to be over. It's that uncertainty. And so Scott does a really good job of laying out what the triggers are that will enable us to move out of this phase right now into the next phase.

- Danielle Pletka: What's going to enable us to move forward again? It's knowing that, understanding that, and being able to kind of check stuff off. On the other hand, I got to say increasingly in my mind is this question, when you're talking about 10 million people who aren't going to have a paycheck next week, that's just our country, we're talking about the same kinds of issues, the world over. You start worrying whether the cure is worse than the disease. I think that almost every day now.
- Marc Thiessen: The president has used that exact phrase. I'm glad you and President Trump are in sync yet again.
- Danielle Pletka: We're so often in sync, the Donald and I.
- Marc Thiessen: More and more so, Dany. But that's a topic for another day. But look, the reality is he's right to ask the question. I think Scott would make the case that, "No, the cure is not worse than the disease." What we've got to do... This is a layman's analogy, not a medical analogy, but right now what we're doing is chemotherapy to the economy. We are going in and we are killing good cells along with bad cells in order to cure the disease. At some point, we need to shift towards a more immunotherapy approach where we have better options for treating the disease without killing the healthy cells, which are people going about their lives and doing their jobs. Scott has essentially laid out a plan to transition to that, which I think is very hopeful.
- Danielle Pletka: So I guess I would make a slightly different analogy. You talk about in your column today in the Washington Post, the analogy to 9/11. Obviously, like so many, it's not a perfect analogy. And you don't ever want to take away from both the suffering that went on then or the challenge that existed.
- Danielle Pletka: But I remember one of the most important phrases in the 9/11 Commission's Report, which was, "Why didn't we know? Why didn't we think this would happen?" It was so obvious that this was coming in retrospect. And the answer was because it was a failure of imagination. I think that that's what we suffer from because it's so outside our ken, we really don't think that it's possible that millions and millions of people could die from this. And so I say to myself every year we got the flu, 60,000 people die. Are more than 60,000 people going to die in the United States? Maybe we're doing the wrong thing. And I guess that's my own failure of imagination, which is that no, actually millions and millions of people could die.
- Marc Thiessen: Well, the difference of course between 9/11 and this and the failure of imagination is that it would take a lot of imagination to anticipate that 19 guys with box cutters would take planes and turn them into missiles and use them to attack us. That was an incredibly novel and unprecedented form of attack. In the case of a pandemic, it didn't take any imagination to know this was coming. We knew it was coming because back in, I mean, 2005 I wrote a speech for President Bush laying out the danger of a pandemic and saying we needed to prepare and President Bush created the national stockpile, and all these other things to prepare for it.
- Danielle Pletka: And we still fell down on the job.
- Marc Thiessen: And we still fell down on the job. This was like a slow motion train wreck. You saw the train coming. It was coming and people said, "Hey, the train is coming. We better get ready. Okay, yeah." And then the train hits and we're not ready.

- Danielle Pletka: Maybe we all need to have the imagination to understand that we're mitigating potential death of millions and millions of people. On the other hand, we just talked to Mike Strain last week about the economy. We talked to Derek Scissors about China and the economy just a week before that. And both of them were pretty optimistic. I got to say, listening to the news every single day, looking at those unemployment numbers, I ask myself whether their optimism is warranted, whether we can really bounce back in the way that people have been hoping, given that this has stretched on for so long.
- Marc Thiessen: Well, the good news is the help is coming because we passed the bill. \$2 trillion in emergency relief. It's not coming out yet because they're going to start doing the small business relief on Friday. So this is just starting. There's a lag between passing the bill and when the relief arrives. And so hopefully, what we are seeing is if this money starts getting injected into the economy, it's going to buy us some time. These numbers are going to go down. We'll flatten the curve of the unemployment curve along with the epidemiological curve, and then we can get back to normal. Let's get to Scott and his plan, because I think it gives me hope that there is a path here.
- Danielle Pletka: Folks who've been listening to our podcast know who Scott Gottlieb is because he's been on with us before, but for those of you who are new to us, Scott Gottlieb's a resident fellow at the American Enterprise Institute. He was the commissioner of the FDA from 2017 to 2019, he is on the board of a number of pharmaceutical companies. He's a doctor himself. He served in the Bush administration as well. He is one of the most cogent and lucid experts on this issue we love having him on.
- Marc Thiessen: Scott, welcome back to the podcast.
- Scott Gottlieb: Thanks for having me.
- Marc Thiessen: All right, so you just released a new plan, a roadmap to reopening. Everybody is wondering when this nightmare is going to be over. Your plan has four phases, the fourth one I want to save to the end because that relates to how we prepare for the next pandemic, but walk us through the three phases and how we get from each to the next.
- Scott Gottlieb: Right, so I wrote the report, thanks for having me, I wrote the report with Mark McClellan who was the commissioner of the Food and Drug Administration and then had run Medicare and Medicaid. Lauren Silvis who is the deputy center director at CDRH, the device center at FDA and then the chief of staff at the agency and has a lot of expertise in diagnostics and surveillance. Caitilin Rivers, who's an epidemiologist at Johns Hopkins. And Crystal Watson, a colleague of hers who's an expert in health security also at Johns Hopkins. And Caitilin had worked with DOD in the past with the army doing epidemiological work. The roadmap as you noted has four phases to it. The first phase is the one we're in right now, which is efforts to try to slow the spread. So that's the mitigation tactics that we're taking right now. Basically population-based mitigation tactics to try to keep people apart, social distancing. You want to separate people.
- Scott Gottlieb: The reason we're doing that is because the epidemic is so large in scope that we've exhausted the ability to do what we call case-based interventions. And those are tactics where instead of targeting the population as a whole, you target individuals with the virus. And so that's what people are used to seeing disease hunters and

folks at CDC doing, where you go in, you figure out who has the infection, you try to isolate them, you put them maybe in quarantine, you may try to find out all the people they've been in contact with and you isolate those individuals as well where you keep close tabs on them. That's case-based interventions. That's targeting individuals with the infection as opposed to what we're doing right now with coronavirus where we're doing population-based interventions.

Marc Thiessen: That's what South Korea did, right?

Scott Gottlieb: South Korea did a combination, so South Korea had a very extensive system in place to do those case-based tactics to try to find people. They did massive screenings so they tried to identify cases and then they at scale, at very large scale, they tried to find those infected individuals and find all the people they had been in contact with so they relied on that. They also did some population-based tactics, but they never had to do the same level of population-based mitigation as we did because they were able to rely more on the case based interventions. We exhausted our ability to do those case-based interventions as soon as there was a large outbreak in an American city. Initially we were doing that, so the initial travelers that had come over from China, we had isolated them and isolated their contacts. But once we had outbreak, so once we had the Seattle outbreak for example, that really exhausted our ability to do those kinds of tactics once there were thousands of cases in the US. So that's really where we are right now.

Scott Gottlieb: We talk about how do you transition to phase two and phase two is really what people would perceive as starting to reopen the country, starting to reopen America. And I think the important thing to keep in mind here is it's not going to be an on and off switch. There's not a moment in time where you can say we've crossed the threshold and now we can go back to doing exactly what we did before, some semblance of it. This is going to be a gradual transition and I think that's the thing that I think some policy makers haven't fully built into some of the policy assumptions. That we're going to need to gradually transition out of these population-based tactics into a different posture. And what we say in the report is once you have a sustained reduction in new cases, so you see a clear downward trend in new cases you have to wait an additional 14 days. And we picked 14 days because that's the length of one replication cycle, the incubation period can be up to 14 days.

Scott Gottlieb: And then once you wait that period of time, then you can start to lift the population-based mitigation, try to substitute in more case-based interventions. And we talk about other things that need to be in place when you do that, you need a very robust screening capacity. So you need to be able to have the capacity to screen the population. Anyone who presents with signs and symptoms of coronavirus and do some background surveillance screening and you also need to have surge capacity in place in the healthcare systems that if you do have another large outbreak or another epidemic you have the capacity to handle it and you want to have those kinds of capacities in place. Now what we tried to do with the report is we tried to do two things.

Scott Gottlieb: One, identify very clear milestones that you can use as a measure for success around which you would pivot to a different posture. And then very clearly spell out how you would pivot away from some of the things you're doing now towards different kinds of inventions. And people can debate whether or not 14 days is too long or too short. They can debate whether or not seeing a sustained reduction is the right

measure. But what we wanted to do is have things that people can react to. We wanted to make the report very specific, very granular. So that way policymakers when they pick it up, can try to make decisions around what we put forward and whether or not we pick the right or the wrong metrics or this kind of decision making.

Danielle Pletka: Right, Scott. Can I interrupt you for a second though? When you talk about the 14 days, first of all it's really commendable that you have this sort of timeline because I think that that's easy for people to grasp, but when you talk about 14 days, 14 days from once we've crested the peak or are you talking about days from what?

Scott Gottlieb: 14 days from when you see a sustained reduction in cases. And so to your point, really crested the peak when you see yourself sort of plateauing and starting to come down, you see a clear steady decline in new cases. And whether you need to see that for four days or eight days in order to have a clear trend, it's going to depend on what the data shows. If you look at Italy for example, I think most people accept Italy's coming down their epidemic curve. But as they were plateauing and as there were sort of indications that they may be plateauing, it bounced around. They had a couple of days where the cases shot up and then a couple more days where it seemed to be on a downward trend. And so there was uncertainty about where that peak was. I think now you see a clear trend.

Scott Gottlieb: There's some indication right now that New York may be approaching a plateau, maybe by next week. That's optimistic, but there's a possibility when you look at some of the data, you start to see a slowing in certain of the measures that people look at to try to discern an indication of whether or not the epidemic's continuing to expand at the same pace. And what you're looking for to try to get a sense of when you're approaching that plateau is the pace of expansion. When the pace starts to slow and when what we call the doubling time expands. And so when instead of taking four days to double the number of cases, it starts taking five days and six days and seven days. Then you know you're starting to approach the peak of your epidemic.

Marc Thiessen: And this is state by state, right? Not a national trend. This is the trend in New York versus Seattle versus Louisiana and so you could have some states where you're seeing that and so you could start lifting, making the transition you describe. Where in other states where it's worse, you'd have to wait, is that correct?

Scott Gottlieb: Right. In the plan we talk about states. The reason we did that is because decisions are largely made by states and they're being made at a state level in the setting of this epidemic. I think in an ideal world you'd really look at this on a regional basis because that's likely to be how the epidemic expands and contracts. It's not going to be New York, it's going to be New York, northern New Jersey, southern Connecticut, Westchester. It's a regional epidemic, same thing with Massachusetts, same thing with the Southeast. So these are likely to be more regional in scope and I think the different regions of the country, and sometimes the region will be defined by a state, sometimes there'll be multiple regions within a state. I think we're likely to see different regions going in and out of epidemic spread at different points. New York is going to be coming out of its epidemic when probably the Southeast is starting to really hit the steep part of its curve.

Marc Thiessen: And how will life change in phase two? So it's not just, "Okay, we can go back to the way we're doing things." Right?

- Scott Gottlieb: Yeah, that's the difficult question that is hard to anticipate, what is life going to look like in June and what is life going to look like in July, August, and September? And I think the big variable here is what technology do we have available? Because if we have a successful therapeutic available by the summer, things start to change dramatically, that could be a real inflection point in our posture. But if we don't have an effective therapeutic, this is going to be a constant threat. This coronavirus is unlikely to go away. It's not going to be like the 1918 pandemic flu where the flu came, actually, twice, there were two waves of the flu, but then it didn't come back, it disappeared. This is likely to come back, this is likely to become a seasonal virus, it's likely to be the case that South America and the Southern Hemisphere becomes epidemic as they go into their winter as we're going into our summer, and this wants to come back in the fall.
- Scott Gottlieb: This is a virus that wants to infect 40% of the population, that would be its sort of innate attack rate. If you look at the characteristics of the virus and if we let it attack 40% of the population, obviously the casualties would be enormous. So we're going to do what it takes to prevent that from happening. So we face the risk that this becomes something that becomes endemic, that wants to come back in the fall and we need a much different posture to prevent large outbreaks from happening.
- Danielle Pletka: Right. So endemic, cyclical, I think all of those things really rest on this question that you lay out in phase two and understanding how to move to phase three, which is a therapeutic, a vaccine. We had a conversation last week with someone, this young fellow named Alec Stapp, who went through and looked at the regulatory failures that really delayed our ability to test, and we're still really not up to speed. Given that, do you think that it's optimistic to think that we're going to have a therapeutic in your phase two that's even going to allow us to move to phase three before, let's say, the summer?
- Scott Gottlieb: Yeah, well, on the surveillance, we're not where we need to be. We're not at the kind of scale we need to be in the setting of the current epidemic, but it's expanding. I think we're going to have very robust screening capacity and it's going to be incumbent upon Congress to legislate a framework where we have really a massive screening system in this country. And I've sort of outlined what that looks like in a recent op-ed in the Wall Street Journal, what I think that should look like. But we'll be at scale with respect to the testing probably within three or four weeks. Now, we should have started that earlier, we'd be at scale now, but we will get the testing in place.
- Scott Gottlieb: The bigger variable is the therapeutic, we have to assume that we're two years away from a vaccine. I think maybe if we get lucky, we'll have one in a year and a half, some people have said a year, I think that's too ambitious and optimistic because this is a very novel vaccine. We're using novel technology to make it, we've never made a vaccine to a coronavirus before. This is a vaccine that you'd put in a large population, you'd basically mass vaccinate the population, so there's going to be a high threshold for safety considerations. But that said, I don't think we need a vaccine to have a much different public health posture with respect to this virus. I think if we had a handful of effective drugs, or even just one very effective drug, coupled to a very robust surveillance system so that you can detect spread when you still have small outbreaks before they become large outbreaks, that dramatically changes the risk profile.

- Scott Gottlieb: This becomes a livable pathogen, it becomes something that people aren't afraid to go out to the restaurant and the theaters and they'll go back into stadiums because they'll know that if there's an outbreak, first of all, there isn't going to be a large outbreak because it's going to be detected. And if there was an outbreak in a city that wasn't detected efficiently, and they happen to get the virus and they get into trouble with it, there's a drug that can either be used as a prophylaxis to prevent them from getting sick or be used as a treatment. Will we have it? I think that we are taking a very deliberate approach with respect to the development of a vaccine, almost like an industrial policy where the government's partnering with companies to try to drive that forward more quickly. We're not doing the same thing when it comes to drugs.
- Scott Gottlieb: I think we need to be, I think we need to be thinking about trying to go in, find the drugs that are showing the most promise and having a very deliberate development approach to how we move those drugs through development, through the regulatory process with the government actively engaged, as ultimately the government's going to be both the gatekeeper and the purchaser here. We're not doing that right now and I think that's something we need to be thinking very carefully about and hopefully, taking up pretty quickly.
- Danielle Pletka: Why aren't we doing it?
- Scott Gottlieb: I don't know, as a matter of policy, I'm not sure why there isn't as much emphasis being placed on the therapies as there is on the vaccines. You always think of a vaccine approach in a setting of something like this where you have a virus that wants to become endemic, and ultimately you want to vanquish it from the population. But the vaccine is going to be years away and a drug could be available as soon as the summer. If you look at some of the drugs that are in development, there are antivirals that are showing, I believe, activity and could be potentially beneficial, could be safe and effective for the indication, especially if they're used early in the course of the disease.
- Scott Gottlieb: I think an antiviral is likely to have more benefit when it's used earlier rather than later. And there's also drug approaches where people are developing recombinant antibodies, they're basically manufacturing the equivalent of the antibodies that people would make when they're exposed to the virus. So when you're exposed to the virus, part of what gives you the immunity to the virus is your body makes antibodies that target the virus. Well, there's biotech strategies for developing those antibodies in big bio-reactors and there's companies working on that.
- Marc Thiessen: Getting back to the timeline, so you think that we're going to be able to get to phase two, as you presented it, April's going to be a tough month, but if we keep the mitigation efforts, we'll be able to start shifting to phase two in May and in June depending on different parts of the country. When and how do you see us moving to phase three and what does that look like?
- Scott Gottlieb: Well, look, I think you're right, I think that April's going to be a difficult month, the next two weeks are going to be very difficult and cases are going to continue to climb, and remember hospitalizations and deaths lag new cases. So even when the cases are peaking, probably sometime in late April, maybe earlier in New York, but probably late April, early May for the rest of the country, hospitalizations and deaths are going to continue to climb. In China, cases peaked about six weeks after they imposed the lockdown on Wuhan and then hospitalizations didn't peak for another

four weeks after that because time to hospitalization is nine to 12 days. Time to death is three to six weeks with this virus, tragically. So-

- Marc Thiessen: Do you believe any numbers you're getting out of China?
- Scott Gottlieb: I believe some of the numbers we're getting out of China. I think China undercounted the number of cases they have had, but I think you need to also appreciate that they faced a circumstance similar to what we're facing in that they didn't have testing capacity when this virus first presented itself and it overwhelmed their system. So they undercounted infection simply because they couldn't test all the people who were infected, and they couldn't even do it posthumously, so they undercounted their deaths as well. We're undercounting our infections now because we don't have testing capacity to keep up with the infection, so there's a lot of infection that's just happening in the community that we're just not going to capture. I think our death statistics will be accurate because we're going to capture all the deaths because they are presenting to the hospital.
- Danielle Pletka: So, phase three, we get out of our bad month in April. We're moving towards not just a therapeutic but maybe some treatments. We're looking toward getting to mass vaccination. Does life go back to normal in phase three?
- Scott Gottlieb: I think there's the potential that life goes back to something that approximates normal enough that we don't remember what life was like before, if that makes any sense. I think that there are certain things that-
- Danielle Pletka: New normal.
- Scott Gottlieb: It's a new normal. I think there's certain things that are just going to change. I don't mean to compare it to 9/11, because... In no way am I comparing this tragedy to that tragedy. But if you think about 9/11, after 9/11 we imposed security features that we just didn't have before 9/11. We didn't have a TSA. We didn't take our shoes off in the airport. We didn't hand an ID in before we went into a building. Now, we just accept that as a way of living. We don't really think about it anymore. I think after this epidemic runs its course, even if we're able to vanquish it with a vaccine or a very effective therapeutic and a surveillance system, there's things we're going to do differently in the future. I think that you're going to see infection control being much more prominent. I think we're going to invest much more into public health infrastructure to do surveillance screening and do diagnostics testing.
- Scott Gottlieb: I think people are going to think much more about hand hygiene. I bet you handshaking and things like that are frowned upon. I don't know that we'll ever start having 5,000-person conferences again. I think crowding people into a room is going to be looked at differently in the future. At least for a time, even while this is still circulating and maybe it's not fully vanquished, but there's therapeutics that are largely mitigating the risk.
- Scott Gottlieb: I think we'll do things differently. People may wear masks more in our society like they do in other societies, especially during flu season. I think people are going to be much more conscious about the spread of viruses generally. And I don't know that we ever fully vanquish this, short of having a very effective vaccine and mass inoculating the population. So, having the equivalent of a vaccine that vanquished measles or polio, which we may get. We may have that in a couple of years. If what

we end up doing in the near-term, in the near-term being the next two years, is having drugs that could very effectively treat it and having a surveillance system that identifies outbreaks and allows us to use those case-based interventions to isolate people who have it, it's still going to be there as a pervasive, low-level threat.

Scott Gottlieb: So, we're willing to go out to restaurants again, we're going to go to theaters, we're going to shop, but we're going to be more careful about hand hygiene and what we do. Shared services. I bet you, you see things like use of ultraviolet light in walkways in airports because it kills viruses, things like that will change. People will start to think about how to build hygiene into the infrastructure.

Danielle Pletka: So, Scott, not to press you on something that's really, really, really hard to answer, but I think the big question that... I know it's on my mind, I bet it's on everybody's minds, is just the when. Okay? Your report says phase three. What do you think is realistic for people to think about, in terms of a return to their new normal?

Scott Gottlieb: So, I'll give you my optimistic realistic scenario. So, I think this is an optimistic scenario, but I think it's certainly within the realm of what could happen. I think that April's a tough month, as we've said and as I've been saying. I think the national epidemic peaks towards the end of April or early May. There might be parts of the country that still haven't peaked by the end of April, but they're peaking certainly as you get into early May.

Scott Gottlieb: I think May is the transition month. We're starting to lift some of these mitigations. Maybe the first thing to go are these shelter-in-place orders, but then there's a mandate that if you go out, you have to wear a mask. And certain things remain heavily regulated. We don't go back to going into sports stadiums or crowding into conference halls. Restaurants have more ordinances imposed on them by local health officials around spacing and things like that. There's temperature checks for people who are preparing food.

Scott Gottlieb: May is a transition month. So, we're starting to lift some of these mitigation tactics. We're starting to go back to elements of our normal life. June is a more rapid transition. So, a lot of these things are changing in June, but the residual that you're going to see are the things that may not go away. So, there's rules on how many people can crowd into an elevator. There's explicit lines for how you line up, so you don't bunch and you don't crowd. So, there's elements that maintain some aspects of social distancing. And that's what you're seeing in China.

Scott Gottlieb: I think then in July and August, maybe life does get back to something close to normal, where people are still worried about this, they haven't forgotten it. This was a national shock and a trauma, but you're not seeing it spreading. There's some isolated reports of outbreaks, but transmission really breaks off. And I think that's going to happen potentially for a couple of reasons. One, is that the epidemic will have run its course, and so transmission will break off. But in South Korea, what you're seeing is you're seeing the epidemic has run its course, but you're still seeing cases reported every day, 80 cases, 50 cases. I think in July and August, the summer, the depth of the summer, the hot humid months could be a backstop against spread.

Scott Gottlieb: Typically, coronas don't spread in the summer. This one is different. It's likely to continue to spread in the summer because it's so novel. People have no cross immunity, so they're very susceptible to it. But that said, between the epidemic

running its course and the depth of the summer in the country, I think that's probably enough, that July and August could be relatively quiescent, relatively comfortable again.

Scott Gottlieb: And that's kind of what happened with H1N1 in 2009. H1N1 was a very novel virus, very contagious. It spread around the country very efficiently, spread all the way into June. Typically, you wouldn't see flu spreading in June, but in July and August, it just collapsed. But what happened with H1N1 was it was back in September, and I think this one might follow that same pattern. So, July and August, we're getting back to our lives. We're going out, we're having small picnics again. We're not going to be crowding on the beach July 4th. We're not going to be going to concerts. We're still going to be nervous, but we're getting back to things.

Scott Gottlieb: And then, what do we do in September? And my hope is by then we have a drug. My hope is that by the summer we might have one or more therapeutics available that really changes the contours of this. I would be putting a lot of emphasis in trying to get that therapeutic, trying to develop a drug in a very timely fashion. There's enough promising agents already in development that we may turn over a couple of cards soon, that show something has substantial enough promise that we should try to accelerate it to the market.

Marc Thiessen: Let's spend a little time talking about the therapeutic and the vaccine development, because you use the phrase, we're using a very "deliberate" approach to vaccine development and that that's better than the approach we're taking towards developing the therapeutic treatment, which is less deliberate. Deliberate is not the word I want to hear. The word I want to hear is Manhattan Project. The word I want to hear is everybody, all hands on deck, let's fix this thing. Is that happening, or are we really not marshaling our resources? And are we having the same bureaucratic delays at the FDA and other places that hamper the testing effort? Are they hampering both our vaccine and our therapeutic development?

Scott Gottlieb: It's not happening. And I wouldn't say that it's a function of bureaucratic delays. I think it's a function of that deliberate leadership that you talk about. Where is the commission? The task force where you're bringing everyone together who's going to have a hand in this? The people who can help fund it? The people who are going to help fund the scale up of manufacturing? The private sector companies that are working on these things?

Scott Gottlieb: And the regulators that are going to be charged with evaluating them, coming together to try to look at a much more deliberate pathway to develop these. We're taking a more traditional approach and this isn't the traditional kind of problem. Now that said, the industry is taking some really extraordinary steps where you see companies meeting on a weekly basis. The heads of R and D of all these companies are coming together to meet every week to share learning, share information, share pre-competitive findings and in some cases share competitive findings. You see companies partnering to do scale-up of manufacturing in ways they've never done before.

Scott Gottlieb: So there is a consortium that's formed of industry participants outside of the government, but in some respects it's formed outside of the government auspices because the government didn't step in to try to bring that group together, bring that kind of collaboration. And that's something I think that we need to be doing. And there's a lot of room for the government to be playing, I think, a stronger role in

trying to accelerate development here and bringing together the relevant elements. Recognizing that at the end of the day, the government's going to be both the funder and the arbiter of what ultimately comes to the market. And so they're an important player here.

- Marc Thiessen: One of your recommendations in phase four is that we need to be able to develop the capability to develop vaccines for novel viruses in months, not years. Right now you're talking about two years to a vaccine and the common cold is a coronavirus and we haven't been able to develop a vaccine for that. Is it possible we won't be able to develop the vaccine?
- Scott Gottlieb: We should be able to develop a vaccine to this, but it might be harder than we think. The reason why we were able to develop a vaccine so quickly in 2009, the H1N1, that virus was discovered April 15th in the United States, although it was circulating before that we just didn't recognize it. The first vaccine was licensed that September, four more were licensed in October and we did mass inoculations by December. The reason we were able to do that is because we made that vaccine on a traditional flu platform. So there wasn't a lot that was novel about that. Here it's highly novel. There is a lot of uncertainty. Now we came up with the vaccines very quickly. So vaccines have already gone into phase one trial, safety testing. We were able to develop the vaccines very quickly, but we were able to do that because we used very novel platforms.
- Scott Gottlieb: Where it was an mRNA approach where you're basically using the genetic sequence of the virus or the genetic sequence of the viral component that you want to develop the antibodies to, and you're putting that into people, to dupe their immune system into developing antibodies against just that component of the virus. (30:43) And that's very novel. We've never used that kind of an approach to develop a vaccine before, but it's a very fast approach. So that creates opportunity. We were able to get vaccines into development very quickly, but it creates uncertainty. We've never done this before. And I will say on the back end of this, I think regulators are going to be cautious. Global regulators are going to be cautious because what you always worry about with medical products is the potential for a low probability, high risk event.
- Scott Gottlieb: So mass casualties. There are very few settings in medicine where you have the potential with a medical product to cause distributed harm, mass casualties. One is if something for example is circulating in the blood supply that you don't recognize because everyone uses blood products on a daily basis. And so if you're not screening the blood supply adequately and have new viruses circulating, there's a potential that the whole population can be infected with it because you didn't detect it. And that's what happened with HIV. HIV circulated in the blood supply undetected. People who got frequent transfusions ended up getting HIV. So a lot of hemophiliacs over that period of time become HIV positive because of the frequent blood transfusions they got. The other area where you have the risk is with certain drugs you have a risk of teratogenicity or carcinoma-
- Marc Thiessen: What does that mean in English?
- Scott Gottlieb: I was going to explain. A risk that a drug could cause birth defects or a risk that a drug can increase your risk of developing cancer. Those are latent side effects. So if you have a new drug and you give it to a population and let's say it increases the risk of developing cancer, you're not going to see that in the first year. It might take two

or three years to see that. Or if a drug causes birth defects, you're not going to see that right away. It takes at least nine months to see it. Right? So, those are latent risks, which means that the drug gets approved and is given to a broad population and it has one of the side effects, you're not going to know it for a period of time. You have the potential for distributed harm. You could have a lot of people exposed to a risk before you know that the risk has manifest.

Scott Gottlieb: So that's another place where you see the potential for broader harm from a medical product. The third place is with vaccines because if you have a new vaccine, you're going to give it to a broad population potentially right out of the gate. And if it has some latent side effect associated with it, meaning a side effect that isn't apparent for many months and many years, and you've just given it to 100 million people, you can cause serious harm over a very large population.

Scott Gottlieb: And that's the uncertainty with a vaccine. That's why vaccine trials end up being so large. And there's so much caution with vaccines, especially when you're giving them to young people, to pediatric patients. This is a vaccine that if it's effective and it's deemed to be safe and it's approved, it's not a vaccine that you're going to give to 10,000 people or 10 million people. It's a vaccine that you're going to give to the entire world. You're going to give it to every American that's willing to take the vaccine ...

Danielle Pletka: Right, like smallpox.

Scott Gottlieb: Like smallpox, like polio, like the measles vaccine. So you're going to want to make sure it's safe. Your regulators are going to want a greater degree of assuredness that this is a safe vaccine, for understandable reasons. And so all of that, the fact that this is a very novel vaccine made on a very novel platform. The fact that we've never made a vaccine to coronavirus before, and there's some theoretical concerns that a vaccine in this setting could actually potentiate coronavirus, actually make you more susceptible to it under certain circumstances. And the fact that we're going to be giving this to a very large population, I think all are going to make it such that regulators want a high degree of assurance around safety.

Danielle Pletka: Of certainty. Right. So Scott, one of the things that ... you've mentioned swine flu a couple of times, people didn't talk about it, certainly not in the same way that we're now talking about coronavirus, but swine flu was out there in 2009. I just pulled up some of the CDC numbers, you know, the estimate was that up to 575,000 people worldwide died from the swine flu. But we didn't do anything at all like what we're doing now to mitigate it. And increasingly what you're hearing from people, even from the President of the United States, is the cure worse than the disease? What do you think?

Scott Gottlieb: Right, we're oddly complacent about the flu every season. So we should just start from that. We should be much more concerned about flu, getting people vaccinated, preventing transmission of flu. But remember, flu ends up killing far too many people in the United States each year. So it might kill tens of thousands of people in a bad year, high tens of thousands, but it also infects tens of millions of people and infects a very large percentage of the population. If we were to let this virus, this coronavirus, infect the population at the same proportion as the flu, the casualties wouldn't be in the tens of thousands, they'd be in the many millions.

- Scott Gottlieb: This is a far more dangerous virus, and even in addition to the death that it causes, the case fatality rate associated with this virus, and we can debate whether it's 0.5% or 1% or 1.5%. In addition to that, this virus causes an extreme amount of morbidity, causes an extreme amount of severe disease that puts people not just in the hospital but in the ICU and on ventilators. People may be surviving this virus, but a large percentage, maybe as many as 10% but certainly 5%, are only surviving this virus after prolonged admissions of critical care, many of which are spent with prolonged stays on a ventilator.
- Scott Gottlieb: If we allowed this virus to spread through a large portion of the population, the healthcare system would be completely overwhelmed. We would just have to accept that we have a nonfunctional healthcare system and hospitals will only be able to take care of COVID patients. If you get an infection or a heart attack or a stroke, you're just not going to be able to get care. The hospitals are going to be overwhelmed and if you go into the hospital, you're going to end up getting coronavirus.
- Scott Gottlieb: That's not a functional country. It's not a functional healthcare system. I think that you couldn't operate the nation against that backdrop, not just because the healthcare system wouldn't function, but people would be scared to go out. The idea that you can have a functional economy with this spreading in the background, with those kinds of images on TV, with the health care system completely overwhelmed, I'm not sure that the consumer is going to be willing to do much.
- Scott Gottlieb: If you look at what's happening in China right now, and this data was convincing to policy makers in thinking about extending these stay at home mandates through April, sure the factories have restarted, but people go to work and they go home. The consumer has not come back in China and China might be able to sustain that because, you guys know better than me, they are largely a manufacturing economy. They're not a consumer driven economy. We're a consumer driven economy. If our consumer doesn't come back, the idea that you're going to have this snapback and the economy is just going to rebound, it's not going to happen.
- Scott Gottlieb: The consumer is still going to be afraid to go to the theater, go to restaurants, go to the mall, go shopping. People are going to be very uncomfortable. So, I don't know that you have a functional economy with this in the background. You have to break the back of this epidemic. You have to cut off this kind of epidemic transmission to give people the confidence to go back and to make sure the healthcare system can function.
- Marc Thiessen: Scott, last question from me. You mentioned 9/11 and you were hesitant to make the comparison. I actually make the comparison in my column in The Post today. In 9/11 we had a series of terrorist attacks that led up to 9/11 that were warning signs. You had the Khobar Towers, the first attack on the World Trade Center, the Khobar Towers, the attacks on the US embassies in Kenya and Tanzania and Cole. We still weren't prepared for 9/11 and we beat ourselves up. We did a lot of investigations as to why we weren't prepared. The situation is the same with this virus. We had SARS outbreak, we had the Avian Flu, we had the Swine Flu, we had MERS, we had Ebola. All of these warning signs. Why weren't we prepared for this?
- Scott Gottlieb: Yeah. I'm hesitant to make the comparison because every tragedy is different, but I think the analogy you draw is apt and it's inexplicable. I don't know why we weren't prepared. We've been talking about the risk of a pandemic flu for years. We've been

doing tabletop exercises for years. There's been multiple reports written. There's been commissions looking at preparedness. We created a strategic stockpile that was supposed to help us prepare for a pandemic and have ventilators and have PPE, personal protective equipment, that doctors would use in the setting of a pandemic. We stockpiled masks. We created vaccine capacity. We did all these things and we were caught unprepared and we didn't have what we needed in the stockpile.

Scott Gottlieb: We didn't have the testing capacity we needed and the public health labs were too small to handle the volume of testing that was required. I think that there's going to need to be a lot of retrospective analysis on what went wrong and what we didn't do right over the course, not just of the last two months, but over the course of many years leading up to this. And I think there's going to be a lot of things that we do differently going forward. Just to give you one example, I don't think states are ever going to rely on a federal stockpile again. I think you're going to see states develop their own strategic stockpile of critical health equipment. I don't think that we can allow manufacturing of critical health components to be fully offshored. It's fine to rely on the grid for your power as long as you have a backup generator. We relied on the international manufacturing system and we relied on offshore manufacturing and just-in-time delivery for critical healthcare components, but we didn't have a backup generator.

Scott Gottlieb: We had no capacity here that we could start or that was mothballed or that was ready to go or could be expanded in a setting like this. We were dependent upon the global supply chain, and you know what happened? That global supply chain didn't just get stretched, it got nationalized. And we knew it would get nationalized because we had seen it happen before in 2009, getting back to the H1N1 example. There was a situation where the vaccine for H1N1 was being manufactured in a foreign facility and the country in which that facility was located made sure that all the vaccine that they needed to satisfy their local need was fulfilled before they allowed shipments to come to the US even though that was a facility that was designed to manufacture for the US. That was our stock.

Danielle Pletka: What country was that?

Scott Gottlieb: Australia.

Marc Thiessen: Dany.

Danielle Pletka: Oh, no.

Marc Thiessen: Crikey.

Danielle Pletka: Crikey. Okay. I'm sorry, because we're going to two exit questions and this, I promise, is the exit for us. What you're saying now sounds like music to someone like Bernie Sanders's ears. It's going to be a huge amount of fuel on the fire for nationalizing healthcare for single-payer, for Medicare for All. Why would that be wrong?

Scott Gottlieb: This isn't about a nationalized health care system and I think we're going to have a better experience than a lot of other countries because of how good our system is at delivering critical care. New York is the best healthcare system in the world and if any city could sustain what's happening in New York right now, it's New York City. I

think you're going to see in the end when you look on a relative basis, when you compare the amount of cases we had and the underlying morbidity, the underlying severity of the disease that we had and how we're able to sustain life, I think we're going to be on the better end of that yardstick. I think what this is an argument for is a better strategic approach to how we deal with health security in a global world.

Scott Gottlieb: How we make sure that we have access to manufacturing capacity here in the United States and don't rely completely on farm manufacturing for critical healthcare components. How do we create incentives to bring manufacturing back to the US? How do we create strategic stockpiles of the right components? How do we recognize the vulnerabilities in the supply chain? The critical vulnerabilities are often the lowest margin products in the supply chain, precisely because they've been offshored, they've been under-invested in, it's consolidated manufacturing so you might have one or two sites. Right now when it comes to testing for coronavirus, one of the things that's in critical shortage and is the bottleneck, is the nasopharyngeal swabs that you use to put in someone's nose to get a sample. You know where most of those are manufactured?

Marc Thiessen: China?

Scott Gottlieb: In a single facility in Northern Italy. That's not an optimal place to be manufacturing right now. Not only is that plant now suspect because of the outbreak in Northern Italy, but the Europeans want access to the same product, and so they're taking stock that was intended for the US so that's in shortage right now. We have to look at those choke points more deliberately and find ways to mitigate the potential risk. We didn't do that, so it's not a question of nationalized health care or the quality of our healthcare delivery. I think we're going to stand up pretty well when it comes to the quality of our healthcare delivery and how our systems handled the actual casualties. It's a question of making sure we have the supplies and the capacity that we need to prop up those doctors, to make sure they have what they need to deliver the care that they want to deliver. That's where we fell flat.

Marc Thiessen: Well, Scott thank you for joining us today and for doing this really, really, really important report. Listening to you today and reading the report, I wish you were in government.

Danielle Pletka: Yeah, me too. Scott, thank you so much for taking the time. We're really grateful.

Scott Gottlieb: Thanks a lot. Yeah. Take care.

Danielle Pletka: So, we ended on a question that is very interesting to me and that I think is, there's going to be a lot of political energy behind. So, the Democratic Convention has been moved to August, and I'm willing to bet that Bernie Sanders and his entire cohort are going to be pressing for nationalized healthcare because of this.

Marc Thiessen: You think? You think?

Danielle Pletka: I do think.

Marc Thiessen: This came up in the Democratic debate a few weeks ago, not that anyone remembers the Democratic debate because it seems like a million years ago. You

know what Joe Biden said to him, "Italy has single-payer healthcare. How are they doing?" You know?

Danielle Pletka: That's 100% true. What about the UK? If we look at all of these places-

Marc Thiessen: The UK has 40,000 ventilators, period. To make that per capita compared to the United States, they don't have even close to the amount of ventilators that they need in order to handle this thing. I mean, it's just ... Every country that has national healthcare, they're not shining in this situation at all.

Danielle Pletka: Right. Well, they're not shining because their death rates are going to end up being much higher, and that's what Scott said. At the end of the day, he said, "yes, we have problems. Yes, we haven't gotten to this, but in terms of the quality of the healthcare that people are getting, it's nothing like you've seen in Italy." I've been in a hospital in Italy, and let me tell you, not during the coronavirus, during the best of times, I wouldn't set foot in a hospital in Italy unless I was forced to do so.

Marc Thiessen: If you just go back and listen to our episode with Alec Stapp about the absolute incompetence of the FDA in dealing with testing and then extrapolate that to every other healthcare decision that could possibly be made in fighting this and generally managing our healthcare, do you trust the people who weren't able to get a test ... who only allowed the CDC to have a test, and then that test failed and only then reached out to the academic labs and the private sector, and oh, by the way, who came into the rescue with the testing? Abbott Labs, all the private companies. They're the ones whose tests we're using because the CDC's test failed.

Danielle Pletka: I think the right line was the one I used in our last podcast, which is if you like the Post Office and you want them to run your healthcare-

Marc Thiessen: Exactly, yeah.

Danielle Pletka: ... that's the right solution.

Marc Thiessen: If anything, this whole situation is an indictment of government healthcare, an indictment of the idea that we should hand over to government bureaucrats because, look, at every stage of this fiasco, it is government bureaucrats who have slowed us down or screwed us up. There was, I mentioned in my post, column today about how we got to this point. George W. Bush in 2005 created the National Strategic Stockpile, the goal of which was to make sure that we had enough masks, enough gowns, enough protective equipment, enough face shields, enough ventilators, enough-

Danielle Pletka: We don't.

Marc Thiessen: We built it up, and guess what happened. CBS news reported in 2009, we depleted it during the swine flu and never gave them the money to replenish it. So, we literally used up all the equipment and then said, "Ah, we don't need to spend money on that," and didn't fill it up, the ventilators. In 2008, the Bush administration launched an initiative to stockpile 40,000 ventilators. They gave a contract to a company. The Obama administration gave a contract to a company to buy, to develop and produce 40,000 ventilators.

- Marc Thiessen: Five years later, the company withdrew without delivering a single ventilator. So, they had to start over. They got another company, this time, a Dutch company, Phillips, to do it, and the FDA took five years to approve the ventilator design. They only approved it in the summer of 2019, and they put the order in in December of 2019, the very month that this pandemic started. So, it took our government a decade to sit around and do nothing when it came to ventilators. That's why we don't have ventilators. These government bureaucrats, we're going to put them in charge of our entire healthcare system. Are you kidding me?
- Danielle Pletka: I think that is probably one of the single best indictments I've heard of government-run healthcare.
- Marc Thiessen: Un-effing-believable.
- Danielle Pletka: There's Marc, not living up to our explicit rating again. Once we move on from what Scott describes as phase one and phase two of the coronavirus, there's going to be a reckoning, and what we need to hear is what you just said. It is absolutely vitally important that once we do the version of the 9/11 Commission about how this pandemic struck the United States so unawares, there are going to be a lot of stupid ideas as there were in the wake of 9/11, stupid ideas that we live with to this day like the Department of Homeland Security, and we are going to need to be very vigilant that we don't make our situation worse rather than better in the future.
- Marc Thiessen: Well, what we will do is, what we always do, is we don't anticipate and then we get hit, and then we ...
- Danielle Pletka: Overcompensate.
- Marc Thiessen: Overcompensate and make things worse sometimes, make things better in other times. I mean, look, after 9/11, for all the flaws of our response, we haven't been hit again in the Homeland, and that's a testament to a lot of things we did, and I hope-
- Danielle Pletka: Although not to the giant government bureaucracy that was created.
- Marc Thiessen: Fair ... Well, that's one element of our response, but we did do a lot of things to make sure we didn't get hit. I guarantee you that we will do a lot of things to make sure that if another pandemic hits, we're going to gold-plate everything. We're going to have the best-
- Danielle Pletka: I want a gold-plated ventilator.
- Marc Thiessen: Exactly, gold-plated ventilators available for everyone. We're going to have ICU beds. We're going to have all this stuff. As Scott suggested, the states are going to take this up, and they're going to have their own stockpile. There's going to be lots of things, so if another pandemic comes, we finally will be prepared, but you know what? Why does it always take a tragedy to make this happen? Why did it take 9/11 for us to take the terrorist threat seriously? Why did it take this? At a cost of 10 million people losing their jobs, not knowing how they're going to pay their rent or feed their families next week. It took that-
- Danielle Pletka: Of course.

Marc Thiessen: ... to take pandemic preparedness seriously.

Danielle Pletka: We're going to wrap up on this, but you know the answer to that, and it is because you can't prove a negative.

Marc Thiessen: Yeah.

Danielle Pletka: No one will believe anything is coming until it does, and then once it does, we spend a lot of time working to lock and bar the barn door from which the horse has just run out. Folks, thank you very much for joining us. We hope that you are all surviving, washing your hands, distancing yourself, especially from the relatives and friends who don't wish to be with-

Marc Thiessen: Don't distance yourself from this podcast.

Danielle Pletka: Don't distance yourself from us. Thanks again for tuning in. Don't hesitate to send us suggestions, emails, anything you'd like. We look forward to hearing from you.

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