WTH happened with coronavirus testing? Behind the epic testing screw-up

Episode #39 | March 31, 2020 | Danielle Pletka, Marc Thiessen, and Alec Stapp

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, do I really need to ask you what the hell is going on? Is there any other answer than…

Marc Thiessen: Coronavirus.

Danielle Pletka: Of course not.

Marc Thiessen: We have managed to jimmy the lock and break into the American Enterprise Institute to get back to our studio, and so we are able to record podcasts again. Just so you know, we're going to be doing these podcasts probably in a little more of an irregular basis. So if you don't get it on the exact day you're used to, we're going to be trying to do more of them in covering this crisis, and we've got a great one today.

Marc Thiessen: Americans have been absolutely flummoxed at the inability of our country to get it right when it comes to testing. We're watching South Korea and Taiwan and Singapore and all these other countries have been able to flatten the curve of this pandemic quickly without the mass lockdowns that we're having, and the reason is because they were able to do testing, but somehow we have not been able to get the testing going. What the hell, Dany?

Danielle Pletka: It's an absolute travesty. It really is. I don't think enough people understand. We who, in Washington, see everything through a political prism have gotten into this sort of "Should Donald Trump have said that? Should Donald Trump have said this?" I've seen team Obama leaking that they, "briefed the president during the transition on just this eventuality." I'm sorry, shut the you-know-what up, guys, because, A, no one expected a pandemic, and B, when you look at the response, I've got to say, the guy who comes off not too bad is actually Donald Trump. He finally got-

Marc Thiessen: Oh, wait-

Danielle Pletka: Wait, wait, wait-

Marc Thiessen: Say it again. Say it again, Dany.

Danielle Pletka: Look, I think at the beginning of this, Donald Trump behaved like his usual silly self, and he quickly got serious about it. All of us who have been waiting for the president

to be that guy, to grow in office, have finally actually seen him and his ability to grow in office over the last month, so I'm delighted to see that. What we haven't seen is our federal bureaucracy respond in the same way. One of the things that we're going to talk about today is the absolute embarrassment... I'm looking for a word that's more extreme... the humiliation that we should feel, as the world's richest, most powerful, most innovative nation, that South Korea can manage the outbreak of a pandemic, not just better than us, but light years ahead of us.

Marc Thiessen: We got the first confirmed case of coronavirus in this country on January 21st, and we are now, just now-

Danielle Pletka: On March 25th.

Marc Thiessen: We are just now at the point where we are testing on a wide scale. It is-

Danielle Pletka: And still not a wide-enough scale to actually match the numbers that we're seeing, for example, the ratio per million people, that we see in South Korea.

Marc Thiessen: Because we're a bigger country, it takes us longer to ramp it up. We had a six-week delay from the moment that we had the first case to where the FDA allowed all hands on deck, private sector, private labs, academic labs, everybody, let's put everything in play to try and get testing ramped up. They actually stopped private labs who were trying to develop tests quickly, because the private sector responds quickly, they stopped them and then they tried to do it just through the CDC. Then the CDC test failed, and only then, after all the academic labs and the private sector labs begged them publicly in a public letter, did they finally allow the private sector and the academic labs to go out and do testing.

Danielle Pletka: Look, you and I have talked about this incessantly on the podcast over the last month, and one of the things that we've emphasized, and that you've done extraordinarily well in your writings, and I've tried to write about as well, is what's happened in China, is the fact that this breakout occurred in China in the first week of December. Because we have eyes and are able to read the newspaper, that the United States should've understood this was coming, certainly by New Year, beginning of January, and yet what we see is this unbelievably tortoise like ramp-up by both the FDA and the CDC. These organizations are so sacrosanct in our eyes, they're so highly respected, that when they screw up, and this has been an absolutely colossal screwup on both the part of the CDC and the FDA, no one wants to admit it.

Marc Thiessen: Well, the government did respond because Secretary Azar, on January 31st, declared a public health emergency.

Danielle Pletka: A month later.

Marc Thiessen: Okay. The first confirmed case in the US was on the 21st. 10 days later, we declared a public health emergency, which was supposed to unleash all the powers of the FDA and the CDC and others. Instead, it had the opposite effect. It clamped down on testing. It had the effect of shutting down labs that were trying to respond because, like you say, they read the newspapers. They saw the news that this virus was coming. Smart, entrepreneurial private labs, academic labs started developing tests, and the government basically told them, "Stop. You have to apply to us for

permission."

Marc Thiessen: The story of the applications... One lab technician told Reuters that he sent in his application to the FDA by email and was told that he had to also send in a paper copy and burn it onto a CD. Like anyone burns anything onto a CD anymore.

Danielle Pletka: That's staggering. Then, of course, they told labs that... When they finally gave permission, they told labs that they had to test their protocols on SARS and on MERS, two other-

Marc Thiessen: This was the FDA that told them this.

Danielle Pletka: The FDA told them this. Then the CDC refused to provide the samples.

Marc Thiessen: Because they were too contagious.

Danielle Pletka: It's like Keystone Cops.

Marc Thiessen: It is Keystone Cops. We're laughing, but it's not funny, because lives are being lost here.

Marc Thiessen: Anyway, so there's a great researcher who did an article for The Dispatch in which he did the tick-tock of all this. He dug down to find out, why are we so behind everybody else in testing? He's done a timeline with the details of exactly how this happened, who is to blame. You will hear this story, and you will be infuriated as you listen to what he has to say.

Danielle Pletka: We'll post the story when we post the transcript, and I really do encourage everybody to read it. Alec Stapp is the author of this piece in The Dispatch. He's the director of technology policy at the Progressive Policy Institute. He writes a lot about technology. He writes about antitrust. He's actually an economist by training, and that prepared him, I think, perfectly to do this kind of analysis. We're really lucky to have gotten him on the show.

Marc Thiessen: Alec, welcome to the podcast.

Alec Stapp: Hey, thanks for having me.

Marc Thiessen: You've done a great piece in The Dispatch explaining the delays with the coronavirus testing. First of all, can you tell us why is testing so critical to our response, and why was it so damaging that we had this delay to begin with?

Alec Stapp: Definitely, yeah. From a public health perspective, public health researchers think about this in terms of surveillance, the idea of being able to monitor how a virus is moving throughout a population, how widespread is it at any given point in time, which areas need to be quarantined, where do you need to redirect your healthcare resources. Right now, obviously, we're seeing the largest outbreak in the New York region, and so they need more ventilators than other regions do. They need more healthcare resources. That's the reason that you want to monitor these things, is if you don't know where the problem is, you can't fight it effectively. Conversely, we've seen that the most effective countries in East Asia, like South Korea,

Singapore, etc., have pursued what's known as a trace, "test, and treat" strategy for combating the coronavirus, and so-

Danielle Pletka: Explain what that is for a second, because we keep hearing about how great the South Koreans have done, and I think that the numbers prove that. But explain how that works.

Alec Stapp: Yeah, that's a great question. What South Korea has done is, one, they've tried to make testing as easy as possible and as convenient as possible. They have what's called drive-through testing, where literally you can pull up in your vehicle to a remote clinic and someone in full protective gear will swab your nose to get a sample, and then it's tested onsite in less than four hours, usually. They've got very rapid testing. Then if you're confirmed as a positive case of coronavirus, then you're immediately isolated and sent to quarantine.

Alec Stapp: South Korea has already got very quickly up to doing about 20,000 tests per day, and for their country, that's more than 5,000 per one million people. For comparison, the US is doing about 100 tests per day, as recently as last week, per one million people, so they're doing 50x the number of tests per capita that the US is doing, because they made it so convenient and the turnaround was so quick-

Marc Thiessen: Alec, so they were able to contain the virus without having mass lockdowns, right?

Alec Stapp: Right. If you're testing a significant portion of the population and very quickly isolating those who test positive, and then furthermore, you're doing what's known as contact tracing, so once you have a positive case, you ask that person for their recent whereabouts, who their family members are, who they've been in contact with, and then you immediately test those people as well, so you're really trying to isolate anyone they could've infected with the virus very quickly to prevent it from spreading to other people. South Korea and other countries are using things like collecting cell phone location data, as well, to know exactly where the people have been recently, and so there's also an interesting trade-off between individual privacy and protecting society from a massive public health concern, as well.

Danielle Pletka: Right. The funny thing is... My daughter came back from Italy. Somebody in her program got coronavirus. They told the school, the school told everybody, the school told our county where we lived, the Virginia Department of Health got in touch with us, and that actually worked. What I don't understand is why that worked in one discrete situation and yet we were incapable of doing that more broadly. Is that a systemic breakdown, in your opinion, Alec, or is that something that just Americans would not tolerate?

Alec Stapp: I think it's a little bit of both. I think definitely our culture, in particular, contrasted with East Asian cultures, we have much more an individualist culture relative to their collectivist approach to things, and so the idea of sacrificing individual privacy for some collective or greater good comes less naturally, I think, to Americans than to East Asian cultures. But like you said, in Europe, they're making these trade-offs, as well. When push comes to shove, I think most people, even in the US, would agree that stopping the coronavirus is more important than protecting everyone's individual privacy to an extreme degree in this moment in time.

Alec Stapp: So I think partly it's cultural, but then at the end of the day, it's also a matter of national strategy. Is there a group of people at the federal level who's coordinating

how we're testing people, how we're isolating them, setting up drive-through centers, what a quarantine policy looks like? If it's not going to be set at the federal level, then by definition it won't be consistent. You can still have a good policy if all the local actors are doing what they need to do, but you're probably going to get some gaps where people fall through in terms of following best practices.

Marc Thiessen: In Hong Kong, Singapore, Taiwan, South Korea, they've had this "trace, test, and treat" strategy, which has avoided mass lockdowns, allowed them to isolate the people who are sick. In the US, we haven't had that, not just because of a cultural reason, but because we lost six weeks in our ability to test. Everyone is wondering, why can South Korea test, and America, the most innovative, strongest economy in the world, we can't test and we lost so much time? You did this great article walking us through what happened. Tell us why we lost six weeks in this fight.

Alec Stapp: Yeah. That was a question that really fascinated me, as well. The reason I decided to research and write this article is because I think it was the most critical component of our failure to combat the coronavirus to date. Without testing, the rest of the strategy we've been discussing kind of falls apart. It's the linchpin and the first necessary step to containing the coronavirus.

Alec Stapp: I looked into this, and my conclusion, in short, was that really the fault lies with the FDA, in particular, a few sets of regulations, and regulators who were unwilling throughout the six-week period from early February to mid-March to waver from those regulations and grant exemptions. Primarily, the number one reason is what's known as an Emergency Use Authorization.

Alec Stapp: This is a case where, on January 31st, the Secretary of Health and Human Services, Alex Azar, declared a national public health emergency, and what that triggers is that any lab that's developing a coronavirus test at that point in time, once there's a public health emergency, is required to seek from the FDA what's known as an Emergency Use Authorization to get cleared to use their test-

Marc Thiessen: Which is supposed to expedite the process, right?

Alec Stapp: Right.

Danielle Pletka: Well, only theoretically is it supposed to, but in fact-

Marc Thiessen: That's why it was created.

Danielle Pletka: You explained it well. It's supposed to expedite, but in fact, it has the reverse effect. Walk everybody through that.

Alec Stapp: Exactly, yeah. If people think about the normal FDA process for approving a new diagnostic device or approving a new therapeutic drug, that process can usually take up to a decade or more at the FDA.

Marc Thiessen: Which is insane.

Alec Stapp: Which is already insane, right? But when you hear the phrase Emergency Use Authorization and the FDA tells you this is a faster expedited process, everyone thinks, "Okay, this is actually helping us cut through the red tape or create a faster

process." What you need to know is that the context for a laboratory-developed test, like what we've been doing with coronavirus prior to the national public health emergency, and what the CDC developed on its own, is that kind of test was actually not regulated by the normal process anyway, and if you were already certified to be a public health lab, you already had the authorization to run these kind of tests on your own and develop your own testing protocol.

Alec Stapp: Many hospital clinical labs and public health labs were already doing tests and already knew what they were doing because the coronavirus, it's a novel virus, but identifying a contagious virus is not so different that you come up with a whole new protocol. You can do things like what we've learned when we had the SARS outbreak or the MERS outbreak. It's what's known as a PCR test, or polymerase chain reaction test. It's basically just identifying the RNA and DNA of the virus itself.

Alec Stapp: So the process is known. Labs already had the capability to do it. Prior to there being a public health emergency, they were legally allowed to do it. But then on January 31st, that process stopped, and they now needed to go to the bureaucracy of the FDA and get permission.

Alec Stapp: The FDA made what I think is the gravest strategic error in the whole process by deciding that, on February 4th, they would only grant an Emergency Use Authorization to the CDC. The CDC developed its own protocol and had a plan to ship its testing protocol, its testing kits, to its partner labs around the country, about 200 labs at the county and state level, and they would control this whole process. What happened there is basically the FDA created a single point of failure. If anything went wrong with that testing kit, we were going to be out of luck and lose weeks-

Marc Thiessen: And it failed.

Alec Stapp: ... and unfortunately that's exactly what... Yeah, and it failed. Unfortunately, that's exactly what happened. The exact cause of why these testing kits failed is still under investigation, but researchers suspect that it's a faulty reagent; one of the solutions that you would mix in the testing kit wasn't working. For almost four weeks after those testing kits were shipped out on February 5th, and they very quickly realized that they weren't working when they tried to validate them, the FDA said, "We'll try to fix it. We'll work with our manufacturing partners to get the reagent solution corrected."

Alec Stapp: They keep failing, keep failing, keep failing, and it's not until a coalition of state and public health labs send a letter to the FDA towards the end of February begging for an exemption, that the FDA can use enforcement discretion to exempt them from the requirement to seek an Emergency Use Authorization, that the FDA finally relents. It takes a few days even after they send this letter begging for enforcement discretion, but eventually the FDA relents and says, "Okay, if you're a certified public health lab for high complexity testing, you can go ahead and start testing now, and we'll give you a 15-day grace period before you actually need to have the Emergency Use Authorization. You can go ahead and get started."

Alec Stapp: Then, concurrently, they also gave the state of New York the ability to regulate its own labs, and so they could even have more flexibility within New York to roll out lab-developed tests. That was some breathing room. Then they realized in the next two weeks that even that wasn't enough and we weren't getting the scale we

needed, and so in the middle of March, they expanded that exemption to all labs, regardless of their certification status, and devolved that regulatory oversight power to the states. Each state was then responsible for overseeing the labs in its region.

Alec Stapp: Then, finally, they also said that they were going to grant this to commercial manufacturers as well. This is when the big national lab chains came online, Quest, LabCorp. If you've ever had your blood drawn, you've probably been to your local outlet of a LabCorp or a Quest. Once those big players came online and had actual capacity, that's when we actually started to really fight the problem of inadequate testing in the United States.

Alec Stapp: Then furthermore, up to this point, during that whole six-week process, we were only doing manual lab-developed tests, but big healthcare giants like Roche, Thermo Fisher, Abbott Labs, they sell very advanced, highly automated machines that can do this process automatically and can run thousands of tests per day per machine. When they got Emergency Use Authorization in mid-March, they also came online and helped us massively increase our testing capabilities.

Danielle Pletka: Oh, awesome. That's so impressive for the most powerful country in the world with the largest economy in the world, that eventually we will be up to speed.

Danielle Pletka: Here's a real question for you to dig in and understand. Now, I think that the FDA has had a good reputation heretofore. We've got Scott Gottlieb here at AEI, who was the former head of the FDA. Scott really worked to streamline a lot of the FDA's bureaucratic processes. Yet normally when you ask people who are of a conservative or libertarian bent, "Would you like the Post Office running our national health service? Would you like Amtrak running the national health service?" people would say, "No, I'd much rather this was in the hands of private individuals." Help us understand why it is that the FDA made one epically bad decision after another.

Alec Stapp: I think that really gets to the title of my piece that I wrote. The title was “The Regulations and Regulators That Delayed Coronavirus Testing in the United States.” Really, that comes down to… We've been discussing rules on the books that prevented testing from happening at the earliest stages and ended up delaying testing by as much as six weeks in the US, but at the end of the day, the regulators made the right choice in mid-March to waive many of these regulations-

Danielle Pletka: But why not in January? Frankly, why not in December, when the news about this was filtering out?

Alec Stapp: Exactly. I'm optimistic that if you would've had a Scott Gottlieb still in the administration, still running the FDA, we would've had a different outcome, because that's what it comes down to. Enforcement discretion means that the person in charge gets to decide when those waivers are made and when those exemptions are granted.

Alec Stapp: I've been following Scott's work very closely in the last few months. He was writing op-eds in the Wall Street Journal in January talking about how this was a potential pandemic and how we needed to be scaling up. He explicitly mentioned in one piece that private companies with large capacity and technical expertise need to be coordinated with and partnered with on this task, and that's not the approach the FDA took. Unfortunately, Scott wasn't in a position to make that decision at that point in time.

Alec Stapp: Then one other thing I'll just mention, because you said that the FDA is so widely respected, at least among the average American, I think that is also very true for the CDC. I think this is actually part of what caused this problem in the first place.

Alec Stapp: One of the most common responses to my piece has been, "Why didn't we just use the World Health Organization's testing kit?" People have seen in the news that this has been distributed to dozens of countries worldwide. It's been used millions of times at this point, seems mostly effective. Why didn't we just use the World Health Organization testing kit?

Alec Stapp: I think it's exactly the fact that the CDC and the FDA are so widely respected, and they have this tradition of always developing their own protocols and it's mostly worked well in the past, that they felt confident to pursue this, what I would call a risky strategy, of placing all of your eggs in one basket by only granting an Emergency Use Authorization for the CDC, because they had what I would say is a hubristic approach and believed too much in themselves that nothing would go wrong.

Marc Thiessen: What we've learned from this experience is that we're only getting to where we need to be once the private sector has been unleashed, right? The private labs are the ones who can do this by machine testing. They're doing more efficient testing.

Marc Thiessen: We've just had this long debate in the Democratic primaries about Medicare for All and having government have a bigger role in our healthcare system. Isn't this a cautionary tale, the fact that when the private sector was brought in, that they did a much more efficient job? Do we want the same bureaucrats who made these decisions to be making all of our healthcare decisions?

Alec Stapp: I think it definitely depends. I think at least the one big takeaway from my research on this topic taught me is that it's, at least, context dependent. Even some regulations that might make sense in ordinary circumstances become completely nonsensical in an emergency setting.

Alec Stapp: Especially with a highly contagious disease like the coronavirus, or any other virus that we see an outbreak, what happens is that speed becomes much more important than perfection. Your average regulator or your average bureaucrat, they care most about checking the boxes and making sure that people are adhering to the rules in a very narrow and strict manner, and that becomes the opposite of what you want to do in a crisis.

Alec Stapp: You want to be able to move quickly. You want to have a diversified, decentralized, distributed approach that brings in a lot of different players, lets people try different things. It, at least, tells me that in emergency settings, this is definitely not what you want to be doing. You want to be bringing in the private sector and letting private companies experiment, innovate, and roll out their products as quickly as possible.

Marc Thiessen: I'll give you another example that relates to this. I wrote a book with Darcy Olsen on the right-to-try movement, which is basically people who have run out of options and have terminal diseases, they should have the right to try experimental drugs that have passed FDA Phase 1 testing, which means they've been proven safe. They have no other options, and they're close to death; they should be able to get these from drug companies and try something experimental to try and save their life.

Marc Thiessen: The FDA response to this for years was, "We don't need that because we have an emergency protocol at the FDA where you can essentially apply to the government for the right to try. You just have to send us an application and we'll approve it, and then they can give you the drug." It turned out that it required 100 hours of paperwork from the doctor in order to apply for it, and so the emergency protocol actually slowed down the process.

Marc Thiessen: It took the exposure of this and the right-to-try movement to get the FDA to eliminate the 100-hour requirement. People were literally dying because the FDA required a doctor to be willing to stop everything they're doing and spend 100 hours filing out paperwork justifying why they needed that. So this is not just one isolated case at the FDA. This is something about the culture at the FDA.

Danielle Pletka: It's systemic.

Marc Thiessen: It's systemic.

Alec Stapp: Yeah, I agree with that assessment. I think that case you mentioned is really telling about the problems in this area. I think as far as combating the coronavirus, this is not over. What we've discussed here today is just about diagnostic testing, but these same issues will come up as we talk about developing vaccines and therapies for people who do contract the coronavirus.

Alec Stapp: I know that Eli Dourado, who's a fellow at the Center for Growth and Opportunity, he published a paper with the Mercatus Center here in D.C. this week talking about how there should be a right to try for coronavirus vaccines, as well, as we roll them out, because we're being told it will be 12 to 18 months before there is an FDA-approved vaccine. In the meantime, people who are potentially on their deathbed might need to have some kind of exemption and a right to try those vaccines.

Alec Stapp: This is an ongoing issue. There are many regulations that are still slowing down our response to the coronavirus, but at least for the meantime we've waived the ones that are relevant to diagnostic testing.

Danielle Pletka: Alec, you detail all of this. It seems pretty clear that there are still problems in the process. One of the things that I ask myself, and as you researched this piece I wonder if you saw, obviously politics overtakes everything in Washington, but is there a recognition inside the FDA and the CDC of the epic scale of their screwup, or do you think that they're still "We did the right thing. Just a couple of little errors slowed us down"?

Alec Stapp: Unfortunately, I have to say the answer is no, based on what I've seen in the news. In particular, I've seen that Dr. Fauci, who is widely respected as an epidemiologist and a public healthcare expert, I think he's been doing a great job responding to the crisis, but when he was asked directly, “Who is to blame for the long delay in coronavirus testing in the United States?” he said, "No one is to blame, no individual. There was a technical glitch that no one could have foreseen," basically saying that accidents happen and we're just doing the best we can now.

Alec Stapp: Though I respect him for his public health expertise, I think in terms of cost-benefit and risk mitigation strategy, that's just completely incorrect. You may not be able to know that a particular reagent will be faulty before you ship out the testing kit, but

what you can do as someone running one of these programs or directing the national response to the coronavirus, you can say, "We're actually going to pursue a decentralized distributive approach that partners with large private companies ahead of time, guarantees there'll be demand for their products so that they're willing to invest in developing them, and waive all relevant regulations, or at least grant them temporary exemptions while they have time to fill out the paperwork and develop the test."

Alec Stapp: You could've done that ahead of time. You wouldn't know what mistakes or accidents will happen, but your approach would be much more resilient to any potential failures. I think, in contrast, the approach the FDA pursued by only granting an Emergency Use Authorization to the CDC was a brittle approach that fell apart when they hit the first roadblock.

Marc Thiessen: Well, you see this cultural problem in the White House briefing the other day where Trump was promoting this treatment of-

Danielle Pletka: Hydroxychloroquine.

Marc Thiessen: Hydroxychloroquine combined with azithromycin, I think it is, the antibiotic. That there are doctors out there saying they're basically using it off-label, which doctors do all the time. They take drugs that the FDA has approved for one purpose, and find it works on another purpose and they use it, and they can do that.

Marc Thiessen: Trump was saying there's a lot of hope in this, and everybody started attacking him. Dr. Fauci's response was "Well, yes, there's hope, but we have to have scientific proof." But it's like, when you're in a crisis and people are dying, somebody dying on their deathbed doesn't have time for the FDA to do a double-blind, placebo-controlled trial before we try something. You've got doctors out there who are trying to treat patients and save lives, and the FDA's response is "We've got to prove it." I just think we need to be more flexible in moments like this.

Alec Stapp: I agree we need to be more flexible, but I would advocate following a middle-ground approach. I've seen President Trump speak about this. He doesn't add, I think, the kind of caveats and warnings that I would like to see a healthcare provider or a public health official mentioning when discussing these potential treatments that could be revolutionary, could happen much quicker than the 12-to-18-month timetable that we've been told for a vaccine.

Alec Stapp: I think the key is that if there's any kind of right-to-try law or any kind of exemption for people to try these treatments out early, there should just be the appropriate warnings and disclosures and full transparency-

Marc Thiessen: Medical supervision.

Alec Stapp: Yeah, what data we have. I think that's the right approach, something that's kind of a middle ground between the Dr. Fauci approach or the President Trump approach.

Marc Thiessen: The culture at the FDA is that you don't get rewarded for speed. You get rewarded for caution, right? The person who discovered the horrible effects of this drug that had been approved, there's an award in her name, because your job is to stop bad drugs from getting onto the market that can hurt people. There's no award for the

person who approves a safe and effective drug quicker. That's why it takes an average, as you pointed out in your article, 10 years to get a lot of drugs onto the market.

Marc Thiessen: We need to speed up that process. Once you've passed a health and safety trial, Phase 1, then there's no reason why you can't have more flexibility in testing those drugs and using them. The FDA is not just testing for safety. We all want safe drugs. They won't let people use it until it's been proven effective in at least 20% of cases, which is just insane.

Alec Stapp: Yeah, I agree. My training is as an economist, not as a public health expert. But as an economist, I look at these issues and I think of cost and benefit. I think the public health approach has always been to minimize cost. Any big problem or potential damage to patients is magnified, and foregone benefits omitted from the calculation. If you can keep any potentially unsafe product off the market, that's a win from a public health perspective.

Alec Stapp: What they aren't counting are the lost benefits of radical effective treatments for people who are really facing life-or-death questions in terms of whether to get treatment or not. I think we've missed out on a lot of innovation over the decades because of this approach by the FDA.

Danielle Pletka: No, I think that's totally right. But I will say, one of the things that has amazed me over recent years is that tort reform used to be a big issue for conservatives, and it has ceased to be one. I think we fail to appreciate how much the litigation that our society engages in at the drop of the hat, "My coffee is too hot. I'm going to sue you," has shaped attitudes and regulatory behavior, because basically, if you are a company, and you are going to get sued in the way that, say, Purdue Pharma has gotten sued, although obviously there are some rights to that case, but there are also some wrongs, if you're a company that's going to get sued, you're doing a cost-benefit analysis and it may simply not be worth it. Of course, who loses out? The individual.

Danielle Pletka: I suspect that the FDA and the CDC have the exact same attitude, which is, “We can't risk a single person dying from this in order for the rest of the society to benefit.” In Australia, they've already rolled out trials of the hydroxychloroquine. They've already rolled out trials. I'm betting that we have not.

Alec Stapp: Yeah, I think that shows that we are definitely moving too slowly in this area. It's the wrong approach, in my mind. I think that they need more flexibility and a willingness to waive these kind of regulations because, yeah, like we said, in an emergency, it makes sense to move quickly, accept some kind of imperfections.

Alec Stapp: To your point about tort reform, I've also read anecdotally that companies who aren't traditionally in this space, and this is in terms of diagnostic testing, vaccines, but also producing things like personal protective equipment, face masks, gowns, gloves, that sort of thing, they're worried about moving into this space and ramping up production to meet the 100x demand that is normally there for these products, because if they create a faulty product, they're worried they'll be sued into bankruptcy. Another potential area for the government to improve the response would be to have some kind of liability protection, liability shield, if the company can meet some kind of basic standard, that it would lose liability for these products, because right now a lot of capacity is sitting on the sidelines because they're worried

about potential liability of these goods.

Marc Thiessen: One of the lessons that we learn with these crises is that it takes a 9/11 in order to shake up the system. This is a public health 9/11 in a lot of ways, and we're probably going to, at the end of this, have a 9/11 commission that's going to look back, and I think your piece, quite frankly, will be the roadmap for the investigation of how the FDA messed up.

Marc Thiessen: Exit question. We now have finally, after a six-week delay, we've gotten to the point where we have the private sector into testing. We're testing at a higher rate, as you said. President Trump just said he wants to get the country back to normal by Easter, which is probably overly optimistic, but people are looking for a light at the end of the tunnel of when we can come out of this. Do you think that now that we've got the testing up, this will allow us to transition from total lockdown strategy that we're in right now to more of the South Korea, Taiwan, Singapore approach of trace, test, and treat and then isolate the patients, but let everybody else who's not sick or not exposed go back to work and get our economy going again?

Alec Stapp: Yeah, I think that's exactly the right approach, and I think there is light at the end of the tunnel, that the testing is a necessary, but not sufficient, condition for getting us back out of a lockdown and back towards a relatively normal economy. You need to have massive wide-scale testing available, but then you need to pursue the rest of those prongs. You need to isolate people very quickly, do contact tracing to make sure we've tested everyone they've been in contact with over the previous two weeks, and then treat them appropriately. Hopefully, the healthcare system is not over capacity at that point in time.

Alec Stapp: You can do this to where certain regions are declared green zones or red zones. If the region hasn't had a case within the last few weeks, it's now a green zone, where people can move about pretty freely. But in the red zones, you're still controlling movement, doing a lot more testing, tracing, and treating. I think we could have a path towards being back.

Alec Stapp: I agree, I think President Trump's timeline is overly optimistic, but I also don't think we'll be in lockdown for a year or more, as some of the more pessimistic people think. We can follow the approach that South Korea has pursued. It just requires massive wide-scale testing.

Alec Stapp: I'll just mention one more regulation that the FDA still needs to waive. They clarified their guidance to say that Emergency Use Authorization does not apply to at-home testing, to where even if you just collect the sample in your home by yourself, you receive a testing kit in the mail, you swab yourself, and then send that off to an FDA-certified lab for testing. Many private companies swarmed into this space in the last few weeks to offer these kind of testing kits for at-home testing, and the FDA said no, these companies do need to still go through the normal process-

Danielle Pletka: Unbelievable. Absolutely unbelievable.

Alec Stapp: … and they've withdrawn. It's unbelievable also because this is probably going to lead to more contagion, because people then are forced to go to hospitals or clinics where other people are sick, and potentially they themselves are sick and spread it around. I think there's a very strong case for allowing at-home testing, for allowing these companies to let people swab themselves and then mail it to a certified lab. So

there are other regulations we need to waive, but if we can do those sort of things, I'm optimistic that we can pursue the South Korea strategy as opposed to the Italy approach.

Danielle Pletka: One thing that we've proven today is that there is no cure still for overzealous, stupid bureaucracy.

Marc Thiessen: You've done a great public service in exposing that. This is some of the best reporting that's happened in the course of this whole pandemic. Thank you for your hard work and for joining us today.

Danielle Pletka: Take care.

Alec Stapp: Thank you very much. Thanks for having me.

Danielle Pletka: Marc, I really liked your 9/11 analogy in the sense that this is really the kind of crisis that concentrates the mind, and what we will need to do after this is have a really hardcore scrub of everything that the United States government did in reaction to the outbreak of the coronavirus. My biggest fear is that people will look at this and say we need more government, not less.

Marc Thiessen: That's exactly right. Look, 9/11, a virulent ideology came and attacked us here at home. Now it's an actual virus, but the effect is the same. This is a crisis on the scale of 9/11. This is a crisis on the scale of Pearl Harbor. We have never had a situation like this where the federal government, for the first time in American history, has intentionally put the American economy into a recession. That's never happened before. We have ordered businesses to stop functioning-

Danielle Pletka: Well, you forget the Carter administration.

Marc Thiessen: Well, of course. That is awesome.

Danielle Pletka: But I digress.

Marc Thiessen: But you digress. Exactly. But we have, literally, intentionally put the economy into a recession and told people, "You can't work." We're very lucky that we can telework, that we can come in and do a podcast, and we can write our articles and we can do our work remotely. There are people in this country who don't know how they're going to pay their bills because of this.

Marc Thiessen: You're damn right we're going to have a 9/11 commission after this to find out what happened. What I fear is, one, you're right, that we're going to say the answer is more government. If anything, this story today is a cautionary tale about too much government in the healthcare system.

Danielle Pletka: Absolutely right.

Marc Thiessen: And two, that it's all going to be an exercise in trying to blame Trump-

Danielle Pletka: As everybody who listens to this podcast knows, I'm totally down with the notion that you blame Trump for certain things. This reaction was not his fault. We have a

medical bureaucracy in place that is absolutely pathetic.

Marc Thiessen: What this exposes, what this particular story with the FDA and testing exposes, is our lack of pandemic preparedness. Despite the fact that we've already gone through SARS, despite the bird flu, despite the MERS crisis, despite Ebola, we are still not ready. In each of those cases, we dodged a bullet. It didn't come here in the scale that we wanted-

Danielle Pletka: It wasn't because we prevented it.

Marc Thiessen: No. We dodged a bullet. We got lucky. This one, as bad as it is, is not nearly as bad as, let's say, a bioweapons attack using smallpox or some kind of virus that has a much higher lethality rate than this, and look at what it's doing to our economy. We need to fix this. We need to figure out, how do we surge testing? Why do we not have a stockpile enough of surgical masks and ventilators and all the rest of this? We've had so many warnings about this for so long. It's just an absolute outrage that our government is not ready, and we've got to fix it.

Danielle Pletka: On that extremely solid and agreeable note, because you're right, thanks for listening, guys. Hope you're all staying safe, socially distancing, washing your hands repeatedly. I'm so sick of-

Marc Thiessen: But not washing your hands of this podcast.

Danielle Pletka: But don't wash your hands of us. We love having you. Thanks for listening.