The Economic Club of New York

114th Year
621st Meeting

Scott Gottlieb, MD
Senior Fellow, American Enterprise Institute
23rd Commissioner of the Food & Drug Administration

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Webinar

Moderator: Becky Quick
Co-Host, CNBC Squawk Box

President Barbara Van Allen: Good morning. Thank you for joining us today. It's Barbara Van Allen. We will get started in 30 seconds. Thank you.

Introduction

Chairman John C. Williams

Good afternoon and welcome to the 621st meeting of The Economic Club of New York, and this is our 114th year. I'm John Williams. I'm the Chair of the Club and I'm the President and CEO of the Federal Reserve Bank of New York. As many of you know, The Economic Club of New York is the nation's leading nonpartisan forum for discussions on economic, social and political issues, and our mission is as important today as ever as we continue to bring people together as a catalyst for conversation and innovation. A special welcome to members of the ECNY 2021 Class of Fellows – a select group of diverse, rising next-gen business thought leaders and welcome to the graduate students of the City University of New York Graduate Center and Columbia University.

Now it's a pleasure for me now to welcome back our special guest today, Dr. Scott Gottlieb. Scott is a resident fellow of the American Enterprise Institute and a physician, medical policy expert and public health advocate. He previously served as the FDA's Deputy Commissioner for medical and scientific affairs, and before that was senior

adviser to the FDA commissioner.

In 2013, Scott was appointed by the Senate to serve on the Federal Health Information Technology Policy Committee, which advises the Department of Health and Human Services on healthcare information technology. Scott has a new book coming out in September. It's titled, *Uncontrolled Spread: Why Covid-19 Crushed Us and How Can We Defeat the Next Pandemic.*

Today's program will be a conversation, and we're very fortunate to have my fellow ECNY Board Trustee and CNBC's Squawk Box co-anchor, Becky Quick, as our moderator. We'll end promptly at 12:45, and as a reminder, this conversation is on the record as we do have media on the line. So without further ado, Becky, I'll hand the mike to you.

Conversation with Dr. Scott Gottlieb

BECKY QUICK: Hey, John, thank you very much. I really appreciate it, and I want to welcome Scott as well. Dr. Gottlieb has been such an incredible voice through this entire pandemic. I've been fortunate enough to have him on our program daily for a long time during the pandemic and now several times a week still as we continue to monitor what happens with this. And I have to say when it comes to the intersection of science

and public policy, there is nobody better to really tell us where things stand, what's evolving, what we're doing right and what we're not doing right. And he's been a voice that I've trusted and asked all of my own personal questions about what to do with my family along the way so I want to thank him very much for being here.

Dr. Gottlieb let's start by just kind of laying out where things stand right now. We thought we'd kind of made it through to easier times and then the Delta variant has snuck up on us and seems to be everywhere right now. How bad are things and where do you think we're headed?

DR. SCOTT GOTTLIEB: I think we're probably heading for the peak of the Delta wave right now. This is sort of the end game, assuming that we don't have a new variant that comes along that reinfects people who have been previously infected in a host-cell fashion or pierces the immunity offered by the vaccines, and so far we haven't seen such a variant emerge. There's one variant that doesn't seem to have a competitive advantage. It seems to be able to defeat the vaccines but it's not spreading. There's another variant, 619, that's being found in South Korea that again, the vaccines seem less effective against. But these new variants don't seem to have a competitive advantage.

So assuming that nothing unexpected emerges, you know, the final end game here was

always going to be one last wave of infection that occurred against the backdrop of a public that was largely exhausted, unwilling really to engage in host-cell mitigation, unwilling to engage in host-cell mask wearing, and it was just going to end up infecting people who had previously evaded infection and had been unwilling to get vaccinated. We thought that that sort of final wave and that end game would play out in the fall when people went back to work and school, that it would be B.117, and it would be against a backdrop of a population that was more vaccinated than the current population. It's happening earlier with a much more contagion variant against the backdrop of a population that hasn't quite reached 60%, the population covered with vaccines, so it's more vulnerable. So, you know, we're seeing a bigger wave play out.

Right now if you look at what's happening in the south, it seems to be starting to peak in some of the outbreak states. The RT, the rate of transfer, is still above 1 meaning you still have an expanding epidemic, but it's falling. So it means that the rate of expansion is slowing in states like Florida, Missouri, Louisiana. In some states like Tennessee it's already fallen below 1, so you have a contracting epidemic. I think it's going to continue to fall. It's usually directional. It doesn't really sawtooth, the RT.

And you can go to covidestim.org and it gives you sort of estimates of the RT over time. That's maintained by the Harvard Chan School. It's a pretty good website for modeling the epidemic, but you see in most of the southern states that the RT is starting to fall.

It's rising in the north so I think that what you're going to see is an epidemic wave that starts to peak and fall in the south, but you do see some growth in cases in the north and the northeast.

And we're not impervious here in the northeast to a wave of infection from Delta. It's probably not going to be as severe as what we saw in some of the southern states because there's more prior infection here. There's more high rates of vaccination. But you still have a sizable vulnerable population so you're still going to see some infection spread through northern states.

And, you know, this isn't going to hit, like every other wave this isn't going to hit the country at a single time. It's going to sort of spread across the country at different points in time. And so as the south is coming out of this, other parts of the nation could be increasing really as we sort of collide with back to school. But I think on the whole, we're probably closer to the end of this than the beginning and it always feels worse right at the point of peak infection.

By my estimate, we're infecting probably at least a million people a day. You and I have talked about that. Most of the infections are occurring in people who've either been vaccinated or younger so they're less likely to get severe symptoms that would cause them to present for testing. A lot of the testing that's being done is being done outside of

labs so it's not getting recorded. A lot of people are doing antigen testing at home or at point of care. There's far less routine surveillance screening going on so we're not picking up a lot of the mild and asymptomatic infections. And so if we're turning over 100,000 infections a day, probably the true rate of infection is 10X that. Ascertainment has got to be around 1 in 10, maybe even lower than that. So I think that there's a lot more infection than we think.

And so if you think about it – and I'll sort of pause here – but if you think about the fact that there's about 90 million eligible Americans for vaccination who haven't been vaccinated yet, probably about 40 million of them have previously had Covid in the other waves of infection and we've probably infected about 15 million people with Delta since we've been in this wave. That may even be a low estimate. There's not that many people left to infect.

And so, you know, after we get through perhaps another 15 million infections, and it sounds like an awful lot, but another 10 or 15 million people, you're just going to be at a point where this epidemic is going to have run its course. Once 85%, 90% of the population has some form of immunity, either through vaccination or prior infection, the rate of transfer is just going to slow significantly. And then it's going to look like what happened in India and the U.K. where it just, it peaked and collapsed as quickly as it rose. And I think that that's what the curves in the south are going to look like.

BECKY QUICK: So basically there's nothing we can do to change the trajectory at this point. We're too far down that path?

DR. SCOTT GOTTLIEB: Well, getting vaccination rates up is helpful obviously and it's going to make us more impervious to a more prolonged epidemic, but the reality is that anyone who goes out and gets vaccinated right now is only going to have partial immunity and it's going to take two or three weeks to acquire partial immunity. A single-dose of the mRNA vaccines and, as you know, I'm on the board of Pfizer, is about 30% protective against Delta so you really need both doses to have really robust protection.

And what you typically see after vaccination, you see a small spike up in infection in the vaccinated population and a lot of people who are sort of critical of the vaccines or anti-vax say, aha, the vaccine causes the infection. What ends up actually happening is people's behavior changes. I think they overestimate how much immunity they have from that first dose and end up going out and doing things that they might not have done so they end up getting infected in the period between the first dose and the second dose.

So even after a first dose of vaccine, you're still vulnerable to Delta. So we're pretty deep into this Delta wave. That's not to say that it's not worth getting vaccinated. It is. And it's not to say that getting vaccinated now isn't going to help you sort of weather this

Delta wave, but it's going to help you on the tail end of it probably.

BECKY QUICK: I know people have a lot of questions. Just today the mayor, Mayor De Blasio said that he's not going to mandate that people have to start wearing masks indoors, but he strongly recommends it. And I guess that kind of gets back to your point of the idea that the public is kind of exasperated with all of these social distancing requirements and things that have come along the way. Is that the right move for somebody like the mayor to be doing this? What should people be doing in their workplaces? What should employers be doing at this point?

DR. SCOTT GOTTLIEB: Well, look, masks certainly help, and I think local officials need to have discretion to take measures. You know, you look at some parts of the south where you have very dense outbreaks and healthcare systems that are getting overrun and I think that some of those local regions need to implement mask mandates. But nationally, you know, this is going to affect the nation with a different level of severity and different points in time. So I don't think we should be doing anything at a federal level.

Whether or not New York at this point needs to implement something that's more consistent, it's unclear to me. I think, you know, New York, has a pretty high rate of vaccination and also a pretty high rate of pre-exposure to Covid through the two

successive waves of infection. It's not to say that they're impervious to Delta, but there's probably a small portion of the overall population that is vulnerable at this point. In absolute numbers, there's still a lot of people, but on a percentage basis, it's probably fairly small, certainly relative to the south.

You know, the one thing with the masks I would just say is that people should be mindful of the quality of the mask. When B.117 was becoming pervasive in the spring, we started talking about double masking because it was a more contagious variant. This is even a more contagious variant than B.117 and so the idea that you're going to drive a lot of personal protection from a simple cloth mask or from a dust mask or a Level 1 procedure mask, you're probably not. It'll cut down on the rate of transmission because it will reduce your ability to transmit large droplets, but if you want to derive a measure of protection you really should be wearing a higher quality mask, particularly with this strain.

And to the extent that, you know, if you're going to inconvenience yourself by wearing a mask, my theory is wear the best mask that you can get your hands on. So wearing a KN95 mask or an N95 mask for two or three weeks while this sort of courses through this region, I think could be prudent, especially for people who are at higher risk from infection, including people who have been vaccinated who aren't impervious to infection and also run the risk of becoming mildly or asymptomatically infected and transferring

the virus to others.

If you look at the Israeli data, they've done a good job of looking at secondary infection among vaccinated people and they showed that the overall rate of secondary infection from people who were vaccinated who become infected is actually quite low, which suggests that people who are vaccinated are less likely to spread the virus probably because they have a shorter period in which they're contagious and which they're shedding virus. That's what some of the data has shown.

But if you look at that data, Israel excluded household contacts because the vaccinated people did go on to infect people within the household, people who were very close contacts. And so, you know, even if you're vaccinated, you do run the risk of bringing the infection into your household if you become mildly or asymptomatically infected.

BECKY QUICK: On that point, correct me if I'm wrong but my understanding of it is that people who have been vaccinated probably are more likely to infect other people very early on before you even necessarily show symptoms or anything else along the lines. So you may not even realize that you're bringing it home to other people.

DR. SCOTT GOTTLIEB: Well, the risk is that if you're vaccinated and you become infected, you may develop a mild illness or you're going to be asymptomatic and a lot of

vaccinated people, because they've been vaccinated wouldn't presume that a minor cold could be Covid. And so that's why I think we're underestimating how much actual Delta spread there is right now because people aren't seeking testing. To the extent that a lot of the spread is happening in people who are younger and who have been vaccinated and they're developing milder symptoms, they're not going out, unless they lose their sense of taste or smell, they're not going out and seeking testing.

The data that the CDC surfaced that led them to say that maybe vaccinated people should be wearing masks after all was an outbreak that they observed in Massachusetts after July 4th, where what they did was they went in and it was an outbreak among a largely vaccinated population, people who were in close proximity to each other. So they were having parties around July 4th, both indoors and outdoors.

But what caught the CDC's attention and what caused them to change their stance on masks and vaccinated people was that when they did nasopharyngeal swabs on the infected population, and these were people who were largely vaccinated, they found that the viral titers that people had in their upper airways was about the same level as those who were unvaccinated. So vaccinated people, on the nasopharyngeal swabs, had as much virus as people who were unvaccinated. So that suggests that they have the same ability to transmit the infection.

Now that's not necessarily a great proxy because what you really want to measure is virus in the lower airways. And it's possible that you have a non-sterilizing, what we call a non-sterilizing mucosal immunity, so you have immunity, better immunity at the level of the lower airways because that's where the aerosols get generated that you transfer that ends up infecting other people. It's not virus from your upper airways, your nasopharyngeal passageway that really causes infection. It's virus in the lower airways.

So, first of all, the nasopharyngeal swabs aren't a perfect proxy for your infectivity, but there was also another study that came out last week that also looked at virus levels in people who were vaccinated and unvaccinated. It showed something similar in terms of high viral titers early in infection among vaccinated and unvaccinated people, fairly consistent viral titers., But what it showed is that those viral titers dropped very quickly in the vaccinated people. So they fought off the infection very quickly and their overall virus burden dropped very quickly. So what it suggests is that someone who is vaccinated maybe early in the course of the infection is equally infectious but the period of time in which they remain infectious is much shorter. And so overall they're less likely to spread the virus.

And that's why when you look at the transmission studies, which is what the Israelis did, they show that vaccinated people are actually less likely to transmit the virus. There might be a very short window in which they're pretty infectious and as likely to transmit

the virus and then it drops off pretty quickly. That's all speculation, but it's speculation from a variety of studies that have come out in the last week.

BECKY QUICK: Okay, so let's do a little news you can use. And this is just, you know, based on my questions and people I know who have questions along these lines. You are somebody who, I think, has been pretty safe through all of this, but also pretty practical about how you go about your business. For people who don't know, you have kids, and your kids aren't vaccinated yet. Is that correct? They're younger.

DR. SCOTT GOTTLIEB: That's right.

BECKY QUICK: So just like I do, you have kids who are unvaccinated. You're cautious, but you're still doing things like traveling from time to time. How do you do that safely and how do you check when you get home?

DR. SCOTT GOTTLIEB: Well, my kids are under 12 so they're not eligible to be vaccinated right now. They're away at camp. If they were home, I'd probably be exercising different behavior. But, you know, when I go out now I do wear a mask. Even when I go into stores locally, I'll wear a KN95 mask. I'm not eating in restaurants indoors. So I am being more cautious. Four weeks ago I wasn't doing that. You know, four weeks ago I wasn't wearing a mask. I put one back on. I'm wearing a KN95 mask

because it's a little bit more comfortable. Probably not quite as good as an N95 mask, but I feel like it's a reasonable accommodation because it's more convenient to slip a KN95 mask on and off.

I'm going to travel on an airplane. I'll wear an N95 mask through the whole trip. So I will be careful. If my kids were home, I'd probably be taking more precautions because I'd be more concerned about developing a mild illness or an asymptomatic infection, bringing it back into the home and putting them at risk. So I would be more cautious if they were home.

I don't think that this wave is going to last that long. I think, you know, this is going to be sort of a period of time where here in the northeast probably it's going to play out over the next three weeks, maybe four weeks at the most, that this is going to course through. We have a sense here in the northeast that Delta, we kind of are deriving our sense of where we are in this epidemic wave based on what's happening in the south. I think we need to recognize that we're going to be on a different trajectory and a different time frame than the south. The south is going to be coming out of this and the north is probably going to be picking up in infection.

You know, it's not like the U.K. where the U.K. epidemic really turns on what happens in London. What ends up happening here is you have much more regionalized epidemics,

partly as a result of regional policy differences, partly as a result of the different experience that this country's had with the infection.

BECKY QUICK: I spoke with Governor Phil Murphy from New Jersey just under two weeks ago. It was about a week and a half ago. And at that point, I asked him what they'd be recommending for schools in New Jersey for kids who are under 12 who have not been vaccinated. At that point he said that the recommendation from the State Health Department was not going to be that kids needed to be masked, even if they were unvaccinated, that they'd leave that up to the discretion of the local school areas.

Two weeks later, every county but one in New Jersey is at least at moderate risk of transmission because the rates have increased so rapidly. What would you be recommending to those boards, not just in New Jersey but in other states around this area where the Delta transmission has gone up, the transmission has gone up? We've got the Delta variant and, as you mentioned, it's probably going to be peaking in the next several weeks as school starts to get started.

DR. SCOTT GOTTLIEB: Yes, look, I think what you heard from Governor Murphy is what's likely to happen around the country. I've talked to a number of governors in both blue and red states and they seem to be very reluctant to implement mandates at a state level. They feel politically they don't really have the support to do it and so they're

kicking these decisions to local districts.

I think different local school districts have different levels of risk based on what the infrastructure is, how much they can de-densify classrooms, how good their air filtration is, how vaccinated their population of teachers is, and also what the background risk for the local community is. If you're in a community that has a high vaccination rate, the risk that you have an outbreak in the school is substantially reduced.

But we saw it in every country really where vaccines were introduced is once you can control the level of spread among the adult population, you effectively control the spread among children. We've seen some instances where the schools became sources of community transmission. That's probably what happened in Michigan when they had the very dense outbreak of B.117. They reopened their schools and the schools became sources of community transmission. But if you can control the infection in the adult population, you can control the infection probably within the schools.

Different schools are going to do different things. I think if we do end up starting the school year in masks, it's probably going to be a short period of time that we need to do it. Most schools in the northeast reopen around September. We might be at the point in time where we're coming down, where the risk is substantially reduced at that point. Four weeks is a long period of time. I think this is going to play out over the next couple

of weeks. And so by the time September rolls around, we might be at a point where infection levels are starting to come down and it feels a little safer to reopen the schools without masks.

But, you know, I don't think if we do start the school year with masks that it's going to be for a long period of time. So it seems to be the prudent thing that you would start the school year and just message that you're going to take this two weeks at a time. A lot of parents don't want their kids in masks in perpetuity in the school, and I think if people understand, you know, that the masks are a temporary measure while infection levels remain high and they're going to be withdrawn as soon as the infection level comes down, I think that they'll be more likely to be accommodating to it. So that's how I would be messaging it if I was running a local school district, saying we're going to look at this two weeks at a time even if we start the school year with masks, and we're going to base it on local prevalence.

BECKY QUICK: Would you let your kids play indoor sports this fall?

DR. SCOTT GOTTLIEB: My kids played indoor sports in the spring when B.117 was still receding. So, you know, we limited the activity but we let them each do what was important to them, and we let them see friends but we tightened the circle. So I think you have to be, I told you a while ago you have to be a nervous Bayesian. You know,

you sort of have to judge risks in a cumulative way. I think some people sort of judge risks in a binary way and they say if I'm going to do one thing, then I'll do everything.

And I think you need to think of the risk in a cumulative fashion over the course of the day and to the extent that there are certain things that are important that you're going to allow, maybe there's certain things that you don't do to try to reduce the overall risk. Because the risk is really cumulative. It's not binary. And so my kids will do, one of my girls does gymnastics. She'll continue to do gymnastics. They wore masks, but it's probably of negligible value, wearing masks when you're doing a close contact sport like that. So I don't think that you're deriving a whole lot of protection from that.

BECKY QUICK: The booster shots, this is something that we know Israel is already offering to people ages 60 and up. We're now looking at Britain and Germany getting ready to start offering for individuals who I think are 65 and older. If you're somebody who got a shot, if you're 65 or older, you got a shot, let's say December or January, should you be kind of looking to see what comes from a third shot, from a booster shot?

DR. SCOTT GOTTLIEB: Well, look, I need to be a little careful what I say, sitting on the board of Pfizer and being a former FDA commissioner. I've said before, I think we should be boosting the older population. Pfizer's got a trial ongoing. They've submitted some of that data to the FDA. They're going to seek approval for a third dose from the

agency. The data so far looks good. We're going to get a lot of data out of Israel. Israel started administering third doses to their population 60 and above, I think yesterday.

And Israel is on a similar timeline to us in terms of when they vaccinated their older population. They're actually a little bit, they were a little bit behind us. And so a lot of our older population actually has vaccines that are probably, are older than the Israeli population. So if immunity is declining, and I think it is over time in that population, it's probably more pronounced here. And you've seen that in enough data that even if public health authorities question the magnitude of the decline in immunity over time, particularly in an older population, I don't think anyone questions directionally what we're seeing.

I think the debate is around what the magnitude of the decline is. I think most people accept at this point that there is some decline over time. And given the fact that the most vulnerable people were vaccinated here in this country in December and January, I think we should be strongly considering administering boosters, trying to keep overall protection from infection above 50%.

The protection from severe disease is still quite robust, even in an older population, even in the outbreaks that we see in the nursing homes, but you don't want protection against infection to fall really below 50% in a vulnerable population because you're

going to start to see some bad outcomes. And you also don't know whether or not the continued decline is going to be linear or at some point you're going to see an acceleration in the decline in immunity. It could be that with a third dose you could get a much more durable immunity. It might not be the case that you have to have a booster every six months. So after a third dose, you could get a more durable response.

Pneumovax, which is another Pfizer vaccine for pneumonia in older populations, you receive three doses of that. It could be that if you space apart the first two doses and you have a longer interval between the first two doses, you get a more durable response as well. And that's something we're going to have to look at in the future.

Initially, when we were administering the vaccines here in the U.S. we tried to give it, we tried to have the duration be as short as possible to try to get the trials done as quickly as possible and try to get immunity into the population as quickly as possible because we were in the setting of a raging epidemic. So we weren't looking to maximize the long-term durability of the immune response. We were looking to maximize the speed at which we can get robust immunity into the population. That's how we came up with three and four weeks.

But a lot of other vaccines, Shingrix, which is a shingles vaccine by GSK, the second dose is administered after two months. Pneumovax, the second dose is administered

after two to six months. And so with most vaccines where you administer two doses, you typically have a longer interval between the two doses. And that's because you get more priming of the immune system by stretching out the interval between the two doses. So there's a lot we don't know and I think people who sort of conclude that, you know, the vaccines don't seem to work real well or don't seem to provide durable protection and we're going to be in this endless cycle of having to re-vaccinate the population, that may not be the case. It may be that we're going to learn a lot about how to dose these in a way that provide a more durable response.

And it may be the case that this ends up as an annual vaccine. Initially, we thought it would end up being an annual vaccine and I think then when we saw how effective the vaccines were, people started to change their thinking around that. But we also initially thought that we'd have to reformulate these vaccines every couple of years because the coronavirus would drift over time and you'd have to tailor the vaccines to the current prevailing strain. That's probably still going to be the case, looking at the rate of mutation of this coronavirus.

BECKY QUICK: So, Scott, let's talk a little bit about your book and some of the lessons that you delve into. First of all, why Covid-19 crushed us. What happened? I mean this is something we should have known was coming. George W. Bush talked about it and warned about it as far back as I think 2005. You had people like Bill Gates talking about

it in TED Talks. Why did this come as such a surprise and seemed to sneak up on us?

DR. SCOTT GOTTLIEB: You know a lot of the book is focused on things that went wrong at the CDC really. I tried to focus less on some of the political shortcomings, which I think a lot of other people have covered and look at the more systemic problems with the structure of our response. And I think that the reality is we don't have an agency capable of having an operational response to a crisis, a public health crisis of this magnitude.

Everyone thought the CDC could handle this, but the reality is CDC isn't an agency that can operationalize a response to something like this. They can handle small outbreaks of the disease, but it's a high science organization that has a very retrospective mindset. It doesn't have a prospective mindset and it doesn't have an operational capability. And so the testing was a perfect example of where we lacked the capability and should never have assumed CDC could develop and manufacture diagnostic tests at the scale that was needed.

I mean CDC typically will develop a diagnostic test for influenza each season, but they only provide it to state public health labs. There's about 100 state public health labs that each could perform probably up to 100 tests a day. So they perform enough testing to do disease surveillance but not wholesale screening of a population and certainly not

testing on an order of magnitude that was required in this epidemic. And so we should never have turned to CDC to develop a diagnostic test. We should have always contracted that out to a commercial manufacturer, but we didn't do that. I think it was very naive to think that CDC was going to be able to do that.

Then when CDC stumbled in their ability to develop that diagnostic test, we went really six weeks without a diagnostic, the country was getting very heavily seeded. And so by the time we finally determined that there was a lot of spread in the U.S., it was too late. The epidemic was widespread. And then without a diagnostic test, we didn't know where it was and wasn't spreading so we weren't able to tailor our mitigation and that's when you ended up with the 14 days to slow the spread and ultimately six weeks of a national shutdown.

We didn't need to shut down the whole country. We needed to shut down New York, New Orleans, Chicago, San Francisco. Certain parts of the country were heavily seeded, but other parts of the country didn't have a lot of spread at that point. But we didn't know. We were situationally blind and so we had a national mandate to close businesses. And then when the spread eventually emerged in places like Florida and Texas, a lot of people there said, look, we've already shut down, we're not doing this again. We already closed our businesses for a month. And so we weren't able to tailor the mitigation.

And the pandemic planning that we had in place, the playbook that we had developed for trying to counter a pandemic flu always envisioned that if you were going to use mitigation, you would use it in targeted fashion. You would only use mitigation, closures of businesses, schools, in places where there was active spread. But the pandemic playbook always assumed that we would have tests for influenza because we could operationalize a test for influenza fairly quickly so we would know where it was and wasn't spreading.

In this case, in the absence of a diagnostic test, CDC relied on the Influenza-like Illness Surveillance System. Basically a system that looks for people presenting with symptoms of flu. They thought that would be a precise way to look for Covid spread. It turned out not to be the case because so much of the Covid spread was through asymptomatic transmission and through symptoms that didn't necessarily present like flu. So by the time they actually picked it up on their Influenza-like Illness Surveillance System, it was too late. The first phone call that the CDC director made to the Commissioner of Health in New York was in early March. I called him up and said, I think you have a problem. By early March, the virus was widespread in New York. We just didn't know it.

Ultimately the way we ended up getting a diagnostic test was through a company called IDT. The CDC finally turned to a contract manufacturer, being pushed very hard by FDA to do that, and IDT really filled the testing void for months in this country. The millions of

tests that eventually flowed to state and private labs were not from CDC. People think CDC finally figured out how to develop and distribute their tests. It was actually from IDT. And IDT was making those tests as a research tool, and when FDA found out that IDT had figured out how to develop a test that was being used for research purposes, they called them up and asked them to start manufacturing it for commercial use, for patient use. And so they were the ones who filled the void.

Another sort of anecdote here is CDC very jealously guards their intellectual property around tests they develop. This sort of stems from a legacy where they felt aggrieved that they had helped develop a test for hepatitis C and it had been licensed by a commercial manufacturer and CDC had never gotten royalties off that and didn't get sort of a stake in how the test ultimately got commercialized and used. And so when they develop tests now they maintain intellectual property over it and they require companies that want to use their test design to actually license the intellectual property from the CDC.

Those IP discussions discourage commercial manufacturers from getting into this game. They extended the negotiation period between CDC and some of the commercial manufacturers that had the capacity to develop tests and it really froze a lot of people out of the market because on the one hand, CDC wasn't distributing virus samples to commercial manufacturers so they were unable to develop their own test designs. They

really were dependent upon the CDC for a test design. On the other hand, when they went to CDC to try to license the CDC test design to start manufacturing these tests at a commercial capacity, CDC didn't readily give them the intellectual property.

At one point, and I talk about this in the book, at one point CDC wouldn't share the validation protocol that they had developed on how you can validate a test after you developed it off of the CDC's test. And New York State wanted to go ahead and put into the field a test that they had developed in their own lab off the CDC design, in the Wadsworth lab, the New York State public health lab. So CDC wouldn't give New York State the protocol because New York State hadn't finished negotiating the agreement with them and FDA just went ahead and gave it to New York State without seeking the CDC's permission. So, you know, the whole sort of structure of how we go about deploying a diagnostic test is flawed. I think it's sort of one example of where we really didn't have an operational capability.

The final point I'll just make quickly is I think we need to look at public health preparedness through a lens of national security. And when you look at that, when you look at it through that kind of a lens you think about trying to build different kinds of capacities and have them available in a different way, and you also think differently about how you deploy some of your national security agencies, including your clandestine agencies and doing surveillance around the world. We are unique in this

country in that we don't involve our foreign intelligence services in this mission.

Traditionally, it's been the CDC that does surveillance around the world. I think that needs to change going forward. We're going to have to rely – at least in part – on our tools of national security to do surveillance around the world and information gathering. There was information to be had in China much earlier than when we first learned some of the truths around this virus that could have given us at least a couple of week head start on knowing that there was asymptomatic transmission, knowing that there was person-to-person transmission, and maybe even earlier than that. I mean some of the first sequencing that was being done in China was mid-December. If we could have gotten our hands on some of those early sequences, we would have known that this was a SARS-like virus that was unique and that certainly would have alerted us very differently.

BECKY QUICK: Scott, if you look at the problems that you just laid out from our own – I don't want to say incompetence, but our lack of preparation, our lack of ability to kind of pivot and turn – do you think we wouldn't be where we are today? Do you think fewer people would have died; fewer people would have been hospitalized if we had been better prepared to go after this?

DR. SCOTT GOTTLIEB: Potentially. Look, if we had been able to field a diagnostic test

earlier, two things would have happened. We wouldn't have been as heavily seeded in the initial wave of infection, and we would have preserved more political capital for local officials to implement mitigation in successive waves of infection. I think both of those things could have saved lives. When you look around the world, even countries that did this well ended up having a lot of spread, but they had less spread overall.

So South Korea did this well. South Korea deployed a diagnostic test early at scale and was able to really mitigate the first wave of infection. Now they're having a wave of infection right now, but at each successive wave of infection they've been able to control it better. And I think we would have bought ourselves more time to get to a vaccine and ultimately been able to use the vaccine as a tool to get immunity into the population, infecting fewer people along the way. So I think we would have been able to potentially preserve more lives. The fact that we were so heavily seeded and so situationally blind early on in this epidemic set us back in a way that we never really got out from under that.

BECKY QUICK: You know we look at things from an economic perspective. You never quite get the same downturn. You never quite get the same recession, but they rhyme, and you can look at patterns and you can pick things up. And I think it's probably the same when you start talking about a pandemic. You may not get the same pandemic next time around, but if you set things up structurally, you can go after it better.

But you're also somebody who knows Washington well. You know the halls of power well. And you know that as focused as we can be in the midst of the crisis, as soon as that crisis passes our attention span tends to wane too. Do you think the types of things that you've laid out, structural changes to try and make us better prepared to deal with this, is there going to be a willing audience that listens to this in Washington? Do you think some of these changes will be implemented?

DR. SCOTT GOTTLIEB: I think the changes will be implemented. The question is what's the sustainability? You know, in the early 2000s, 2003, 2004, and I was at FDA at the time, we put in place a lot of planning for a pandemic with flu. We were worried that H5N1 would start to spread, would cause a global pandemic, and we put in place a lot of operational capability to try to mitigate the impact of a pandemic flu that was expected. It never came. H1N1 was a pandemic flu, but it wasn't as severe as what we had anticipated if H5N1 had made a jump to humans. The problem is we just didn't stick with it. A lot of the planning atrophied. A lot of the operational capability that we had put in place, we sort of moth-balled and didn't keep it as a hot base of preparedness.

Emergent is an example of that. Emergent was a facility that was built to have some reserve capacity to produce vaccine in the event of a pandemic flu. And you saw when we turned to that for help in manufacturing the J&J vaccine, the facility wasn't ready. The facility wasn't kept up to date in a way and resourced in a way that it was available.

So I think that we're going to end up making structural changes. The question is what's the sustainability of that. You know from a CDC standpoint, I think we need to think about how we have much more of an operational capability, much more of an agency that's less focused on long-term science and more focused on near-term exercise of preparedness and protection. Sort of like, you know, we need a JSOC for public health preparedness, not the Harvard School of Public Health, which is what, you know, is how CDC typically operates.

And so we're going to build that capability somewhere. I think it should be housed within CDC, but the question is are we going to continue to resource it for, in perpetuity? Or are we going to let it atrophy when nothing happens for the next ten years? You know I also think, from a CDC standpoint, we need to think about splitting out the prevention work that CDC does, maybe putting it with the NIH or a new agency within HHS and focusing CDC on disease control and so taking some of the prevention features of their mission out of the agency.

That's how it was originally incepted and I think we have to go back to sort of the core capabilities that we wanted that agency to have. So will those structural changes happen? I think they're going to happen. I just don't know that we're going to stick with it long enough for the kind of preparedness we need to be in place for the next pandemic.

And just finally, what we need to be worried about as sort of a category is viruses that replicate through RNA that spread through aerosols or are spread through respiratory disease, because a virus that replicates through RNA has the ability to mutate very quickly and a virus that spreads through aerosols or droplets has the ability to spread very easily. And so that's what we need to worry about as a sort of broad category. We can't just worry about flu or a specific strain of flu or a coronavirus. We should be worried about the whole category of RNA viruses, viruses that replicate through RNA and are spread through droplets or aerosols. And that's pretty broad. That's a much broader category of threats than just, you know, operationalizing preparedness for H5N1 flu, which is basically what we had done.

BECKY QUICK: One of the things you point out in your book is that this pandemic really kind of hit home about the problems and the limitations with our supply chain. It's something that we've seen in business across the way with automobile production when it comes to chip shortages and other things. But it's much more dramatic when you start looking at did we have the personal protective equipment? Did we have the ventilators? Did we have the testing capabilities and even the small components that go into some of those testing capabilities? Your suggestion is that we need to make sure that we are manufacturing the stuff right here in the United States because immediately there was a shutdown, kind of a lockdown, where everybody held on to their own components, every nation.

DR. SCOTT GOTTLIEB: Right. We never anticipated that there would be a global run on the components that we would need to combat a pandemic. And if ask me to predict where the shortage is going to occur in any complicated healthcare supply chain, I can probably find it, having been at FDA. It's going to be the lowest commodity product, lowest margin product within the supply chain. What did we run out of in the testing supply chain? The reagents and the swabs that we used to collect the samples. Because being a low margin product, you have consolidated manufacturing. Typically it's been moved overseas to try to capture lower labor costs so you don't even have it domestically and you can't scale it on your own. And if there's a global run on it, typically it's been underinvested in so it's going to be hard to expand manufacturing quickly.

You know, in certain of these areas we're going to just have to invest in a domestic capability, particularly around, I think, complex biologics manufacturing. We didn't have the capacity to produce the antibody drugs in scale even though that was entirely predictable, that antibody drugs would be the first line of defense against any viral pandemic. We didn't have the ability to quickly scale production of vaccines either.

So one anecdote that I come back to and I talk about in the book is after the hurricane devastated Puerto Rico in 2017, Puerto Rico is responsible for 10% of the drug production in the United States, so 10% of all drugs consumed in the United States are

manufactured in Puerto Rico. Every plant was offline. I had called around to the CEOs and visited the island. They were all offline. There was only one plant that was really fully operational. It was Amgen's facility, which was in a pretty remote part of the island. They had substantial generator capacity and fuel on hand to continue operating that facility really uninterrupted.

And I asked the CEO, Bob Bradway, why he had invested in building such a hardened facility and his answer, he said, was that we had made a guarantee to the federal government that there would never be an interruption in the supply of Neupogen. And the reason why they had made that guarantee and the federal government paid them for that guarantee is that Neupogen is a drug used to reconstitute bone marrow after chemotherapy typically, but it's also a drug that you would use after a radiological attack. People whose bone marrow is poisoned by radiation would need Neupogen to rescue them. And so there was a strategic priority that we always have a supply of Neupogen on hand.

But it's a biologic. It's not something that has a long shelf life. You can't just buy a whole bunch of it and stick it in a warehouse, which is our typical mentality in guarding against these kinds of threats. And so what we did was we paid Amgen to build distributed sites and harden them to make sure that those sites could continue operations, that there would always be a supply of Neupogen available.

And we have what's called provider-managed inventory or manufacturer-managed inventory where Neupogen is kept on site at those manufacturing facilities. And so when a vile of Neupogen comes off the line, it doesn't get immediately shipped out. It gets stored at the manufacturing site and maybe Neupogen that was produced a month ago gets shipped out. So there's always some residual supply available in case you needed to surge supply into the system.

That's the kind of mentality that we're going to have to have across the board. We could pay for some kind of residual capacity when it comes to manufacturing vaccines and biologics and diagnostic testing, but we're going to have to look systematically across the board and find those opportunities and make those investments.

BECKY QUICK: Yay, Amgen, for doing what you said you were going to do. Dr. Gottlieb, I want to thank you very much for being so generous with your time today and for talking us through all of this. And, folks, I just want to remind you, Scott's book is coming out on September 21. Again, it's called *Uncontrolled Spread: Why Covid-19 Crushed Us and How We Can Defeat the Next Pandemic.* I have already pre-ordered my copy on Amazon. You can pre-order yours too. But Dr. Gottlieb, thank you for your time today.

DR. SCOTT GOTTLIEB: Thanks a lot.

BECKY QUICK: We appreciate it. And, John, we're going to turn the microphone back over to you.

CHAIR JOHN C. WILLIAMS: Well, thank you, Becky. Thank you, Scott. That was a fascinating and timely conversation. I really appreciate the opportunity to hear this. And, of course, Scott, I think everyone is looking forward to reading your book when it is released.

So let me, as usual, provide some updates on some future events. Now we are closing our summer session. We have one more event scheduled for later today. And then we'll take a short break until when we come back in September. So at 4 p.m. we have Steve Cadigan, Founder of Cadigan Talent Ventures, who will join us to discuss his new book, *Workquake*. Now, so let me talk about a few events coming up in September. We have Hans Vestberg, Chairman and CEO of Verizon Communications, who will speak on September 13th on the future of telecommunications. And then on September 27, I'm going to be addressing the Club on the economic outlook. So I look forward to that. So if you joined as a guest and would like to become a member, please email the Club at the address on the screen.

Finally, I'd like to take a moment to recognize those of our 337 members of the Centennial Society who are joining us today as their contributions continue to be the

financial backbone of support for the Club and help enable us to offer our wonderful, diverse programming both now and in the future. So thank you again. Stay healthy and safe. We'll see you all again next month.