Talks at GS
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Recorded: December 6, 2021

Dr. Scott Gottlieb: It's very unusual that a respiratory virus would present only with severe pneumonia, and so it was a clear suggestion that we were seeing the tip of the iceberg. And that got me alarmed.

Sharmin Mossavar-Rahmani: Hello, everyone, and welcome to Talks at GS. My name is Sharmin Mossavar-Rahmani. I am the chief investment officer for the consumer and wealth management division. We're very happy, very pleased really to have you here, Dr. Scott Gottlieb, a leading authority on COVID-19.

Many of you already know Dr. Gottlieb from his various appearances in the news, from his very frequent and insightful tweets for which we're very grateful, and for having actually been on several of our client calls. As you probably already know, Dr. Scott Gottlieb was the commissioner for the FDA between 2017 and 2019. He's on the board of Pfizer, on the board of Illumina, and involved with a venture capital company as well.

Dr. Gottlieb, in addition to all these various things, very early on got focused on COVID. Actually six weeks before the WHO declared it a pandemic, he expressed a significant amount of concern about what was happening. He got very involved with the White House, and he has since published a very interesting book. It is called *Uncontrolled Spread*.

So Dr. Gottlieb, let's start with this new variant. We had a call a few days ago with Dr. Borea [sp?]. It was a client call, and she told us the right way to pronounce it is Omicron. So first of all, how do you pronounce it? And what do we actually know about the transmissibility and the severity of this?

Dr. Scott Gottlieb: Yeah, well, I think nobody's really certain how to pronounce it. Omicron, omicron. We're still figuring out how transmissible this is. The presumption is that it's highly transmissible right now. The ROT, the rate of transfer, is somewhere between 2 and 3. To give you sort of a sense of what that means, the ROT for the Wuhan variant, when it was an epidemic in New York during the beginning of the epidemic before we implemented any mitigation, was about 3.5. The ROT for Delta, for the initial wave of Delta infection in the United States in the South in Florida was about 1.6. This looks to be around 2 to 3 based on the modeling that we're seeing right now. Probably closer to 3.

But part of the challenge right now is that we're sort of in the fog of viral war, and we have imperfect data. And everyone's sort of modeling off of the same data sets. And there's at least some confounding aspects to that data. We've over sampled some of the initial clusters of infection in terms of the sequencing work that was done, so we might have a more narrow view of what the genetic diversity is of this virus. We might have misjudged when it

first made its entry into the human population. We don't have a good estimate of what the prevalence is. The assumption right now is this is representing 90-100% of all infections in the Gauteng Province in South Africa, but that's probably not true.

You know, we could be getting better estimates of that, but we don't really have the tools on the ground. And physicians there are busy providing crisis levels of care and so don't have the time to do the kind of investigation that would be required, just like we didn't have the time in the setting of the New York epidemic. We weren't getting good bottom-line clinical information.

So, you know, I think that there is at least a possibility. If you look at the last sort of 14 days of data, which is what we're really looking at, there was a rapid acceleration in cases, which I think, you know, concerned everyone. We've seen a leveling off over the last four days. Now it's over a weekend when cases would typically come down. There's less reporting. There's less testing. But since we're only looking at 14 days of data, four days is important. And what you've seen is the positivity rate level off, cases come down. So it at least raises the question of whether or not this is the very beginning of an epidemic and we caught the very beginning, or we've sort of captured an epidemic that was underway and we're somewhere along the epidemic curve. And it wasn't detected right away perhaps because it was causing a lot of subclinical illness. Perhaps because there wasn't a lot of testing in place because they had had this devastating Delta wave, and testing really came down. Perhaps because they've been having a very big flu epidemic in South Africa, and this was sort of happening in the backdrop of a flu epidemic.

I don't think that that's sort of a likely case. I think it's

more likely that the conventional wisdom that we sort of caught the beginning of an epidemic with a new variant is probably right. But at least there is a possibility that we're further along in this than we thought. And that would raise different questions about its transmissibility and the kind of threat it poses.

The other thing that we're finding is it's not causing at least yet a lot of hospitalization. Now, again, if you're in the beginning of a new epidemic with a new variant, not a lot of time has passed. It hasn't coursed its way into vulnerable parts of the population. That may be why you're not seeing a lot of hospitalization. Or it's just either less innately virulent or, more likely, it's infecting people who have been previously infected and have some residual immunity. So they're somewhat protected against sever outcomes. We don't know the answers to those questions. I think in the next two weeks we'll start to answer them as we get more bottom-line clinical data. But some of the early data at least has suggested that this is causing less severe illness, perhaps because it's reinfecting people who have been previously infected with Delta.

Sharmin Mossavar-Rahmani: There was an article overnight about some transmission in a Hong Kong hotel where they're quarantining people, and they said there must have been some transmission across two rooms, just from doors opening and closing. Is that a bit of an exaggeration? Is that realistic?

Dr. Scott Gottlieb: No, it's not an exaggeration, but I tend to -- we're going to see anecdotes, reports where there's been significant superspreader events from this. Oslo is one. We saw the person who traveled to the conference in the Javits Center in Minnesota and then went on to infect 15 people from 30 close contacts. The

case in Connecticut that was recently disclosed where a single individual infected two family members.

You know, it feels sort of measles-like when you see these situations where a single introduction, or two introductions in the case of Oslo, caused a very large spreading event. But you don't know the circumstances of what went on inside that setting. And what we don't know also are all the instances where someone who was infected with this went into a congregant setting and there was no forward transmission.

What we're seeing are the cases that got identified because we were able to maybe trace a traveler, turn over the infection, and identify the spread. So it's sort of a skewed window into how the virus is behaving. You're going to identify the superspreader events. You're going to miss the ones that aren't. So I tend to sort of discount them to some degree and try not to draw too many conclusions from that.

I think the more informative data is going to be what comes out of South Africa and looking at the clinical courses. And we're going to have data very soon on whether or not people who were vaccinated are getting the infected. Most people have only had two doses of vaccine in South Africa. Very few people have had three doses or been fully boosted. So we're going to get data on that.

There was some data over the weekend that looked at a single hospital in Tshwane in Pretoria, which is a very hard-hit part of Pretoria in South Africa. And they looked at how all their admissions since this epidemic kind of began, you know, judging this to have begun ten days ago or so. And they had 166 admissions. They found 38 COVID-positive patients. Most were incidental pickups. There were patients who were admitted for a surgical

reason or an obstetrical reason or other medical reason and found to have COVID incidentally but didn't seem to be symptomatic of COVID.

Of the nine patients who were admitted for COVID pneumonia and were there because of the COVID, all were unvaccinated. Now, that could be because most people in South Africa are unvaccinated. It could be because the epidemic seems to have originated in a younger age population initially, and so most of the younger people aren't vaccinated. Most of the older people are. So it could be confounded by a lot of things. And again, it's one data set from one hospital, but that's kind of what we're going on right now.

I think you're going to see more reporting of the experience of patients who've been vaccinated with this infection. The South Africans put out a very good analysis showing that a lot of the infections they've been diagnosing are reinfections of people who were previously infected with Delta. So the Delta immunity doesn't seem to be protective against at least infection. Maybe it seems to be more protective against disease but not infection. I think you're going to see some similar reporting coming out very soon on vaccinated individuals.

But again, this is very early in the epidemic. The epidemic hasn't coursed through the population, so the data is sort of confounded by where the early spread was.

Sharmin Mossavar-Rahmani: The European Union CDC just came out last week and said that, of the people they had evaluated, a large portion were asymptomatic and 50% had mild symptoms. Does that signify anything in terms of the severity of this new variant?

Dr. Scott Gottlieb: Yes. So what they said was of the cases that they've identified outside of South Africa, 50% were asymptomatic, 50% had mild symptoms. You know, there have been reports. I've heard that there have been reports of the CDC of people who had severe disease and people who have died from the virus. Again, that wouldn't be surprising. If this is a COVID virus, it's going to get into vulnerable populations and cause severe outcomes.

So far on the whole, again, it appears to be causing a lot of subclinical illness and less mild illness on the whole. If you look at the just early reporting from physicians in South Africa and also the ex-South African experience, we now have a data set of 60 or so people in Oslo. We have the 15 people in Minnesota. So we have people we're going to be able to follow longitudinally now, but it's going to be very hard to tease apart whether or not this is an innately less virulent strain, which is what some people are sort of concluding. Or whether or not it's just spreading through reinfections.

So people who are getting it may not have good antibody protections, so they get infected. But then they still have cellular immunity. They have memory B cells and T cells that should be largely intact and help them fight off the disease. So you see a high infection rate but a lower rate of disease because of that preexisting immunity, because the cellular immunity should be largely intact even if this virus has a heavily mutated spike protein. The T cells target parts of the virus that haven't really changed. And so that's definitely going on. I mean, it's definitely a function of the people who are getting this virus that previously had COVID so they're protected. Whether or not it's innately less virulent we're not going to know for a while. It's very hard to tease that out. It's going to take a lot more data. And unfortunately, you're going to have wait to see how it

behaves in sort of immune-naive people.

And there's not a lot of pockets, at least in South Africa, of people who haven't been exposed to COVID or haven't been vaccinated. Probably the only preserved population that's large is, unfortunately, children and toddlers because the Delta really coursed its way through South Africa in a devastating way. And the presumption is upwards of 90% of people, at least in the Gauteng Province, have had Delta infections, people who aren't vaccinated.

So it's going to be very hard to find people who are sort of COVID naive and see how it behaves in them. And unfortunately, I mean, you don't want to wait to find that out.

Sharmin Mossavar-Rahmani: By COVID naive, you mean people who are neither infected nor vaccinated?

Dr. Scott Gottlieb: Neither infected nor vaccinated. Again, the only large group that I could think of that is in that cohort would be young children because the vaccine hasn't been rolled out to children in South Africa. By and large, I would presume that they've been more protected from prior infection than adults and older people because parents shelter their children. So that's a vulnerable population.

Now, you've seen rising rates of hospitalizations among kids for COVID, and that's caused a lot of concern. 11% of all the hospitalizations in the province are kids under the age of two. And that's higher than what you would expect. But it's not clear if that data is also being confounded by the flu epidemic because what I'm told is clinically, when children get admitted for a respiratory infection, right now there's a presumption made that they have COVID, even if

they don't initially test positive for COVID. And so there could be some flu admissions happening that there's a presumptive diagnosis made of COVID. And that makes clinical sense that, out of an abundance of caution, you would treat any child as if they have COVID if they're being admitted for a severe respiratory viral illnesses. But that could be confounding some of the data, the fact that there's a flu epidemic happening alongside this.

Sharmin Mossavar-Rahmani: You mentioned memory cells, B cells, and T cells. It's a great segue to the question of boosters. So does everybody need to get boosters? If people have already been double vaccinated, should they wait and see for a more tailored vaccine for this variant? How should they think about it? Should the more vulnerable population only focus on boosters?

Dr. Scott Gottlieb: Yeah, look, this is my conjecture. I'm on the board of Pfizer, as you mentioned. I don't think anybody should wait for a more tailored vaccine. You know, I am still reasonably confident that a properly boosted vaccine is going to offer a meaningful measure of protection here. You may see a significant decline in the protection against any infection, but the protection against probably symptomatic disease and certainly severe disease is going to be retained at some level. And protection against severe disease probably at a meaningful level. That would be my presumption.

And it's based on the fact that we have seen from the boosters that the booster almost behaves like a different product. That when someone gets that third dose, they develop not just more antibodies but they develop a larger complement of antibodies. You get what's called a polyclonal effect where you're getting antibodies against more targets on the surface of the virus. And so even if the

virus mutates the receptive-binding domain, which is the immune-dominant portion of the viral code that we develop our best antibodies against, with a polyclonal response you're developing antibodies to a lot of other targets. And so you retain more protection against the virus. And that's what the third dose does.

The other people who can get a polyclonal response typically are those who have had the infection and then get two doses of vaccine because the infection almost functions as a first dose and, in the subsequent doses, function as boosters. So you also see a very broad antibody response in those individuals.

And so if anything is going to be more protective, it's going to be a properly boosted vaccine. And I think that there's still a reasonable degree of confidence that a properly boosted vaccine is going to be meaningfully protective at least against bad outcomes. If we do end up having to switch to an Omicron-specific vaccine -- I hope I pronounced that right -- I suspect there's reasons why you'd want to stick with the ancestral strain, the current vaccine, as long as possible.

If we do switch, unless we lose the vaccines entirely, unless they don't work -- which I would just be really surprised, I wouldn't expect that outcome -- I think what you would do if the vaccines show that they're less effective is probably switch for some portion of the population. You wouldn't want to convert the entire population to an Omicron vaccine if it's providing good enough protection for people who are otherwise at low risk of a bad outcome from COVID.

But maybe for people who are at significant risk of a bad outcome -- older individuals, immuno-compromised

individuals -- you might give them an Omicron-specific variant vaccine. So I think anyone who thinks that this is going to be widely distributed, it would have to be that the vaccine doesn't work at all or works just marginally for the entire population to be eligible and us to mass produce and switch over all the production to an Omicron vaccine, at least in my estimation.

Because what we've seen in the past -- and again, the data is very limited -- is that when you design a vaccine to a specific variant, it might work very well against that variant but not so well against everything else. So for example, when we developed a vaccine against 1351 -- and Pfizer did this, Moderna did it, too -- the immune response to the vaccine looked very good against 1351 but didn't look so protective against everything else. And what may be happening is that, as the virus mutates in sort of an overly simplistic description -- and if a virologist were listening to this, they'll be sort of offended by this description -- but the virus kind of figures out how to hide parts of its surface so you don't develop an antibody response to all the components of the coronavirus that you might have with the old Wuhan strain. But you just develop a good immune response to the one components that's very specific to that new variant.

So you now have good immunity against the variant but not so good immunity against Delta and Gamma and all the other things. So you can leave the whole population better detected against this new variant but worse protected against everything else. And because this new variant is so heavily mutated, it's almost on a different tree than the other strains of COVID. It's kind of like almost its own virus. It's not a different virus. I don't want to imply it is. But it's had divergent evolution.

And so if you sort of give everyone immunity to this virus and bias everyone's immune system to this virus, you've kind of biased it away from everything else. And everything else is the whole complement of coronaviruses. And so it raises the possibility you could get COVID infected with this and Delta. So I think from a public health standpoint, there would be reluctance to do that, especially if the current vaccines are proving effective enough for most people.

It's a short way of saying, just 10 minutes explaining this, I think that there's going to be a real reluctance to mass inoculate the population with a new variant booster. So anyone who's holding out for that, it may not be coming.

Sharmin Mossavar-Rahmani: As we think about the booster vaccine, you obviously are aware that there are some people who are cautioning against it. Dr. Offit, well-known infectious disease specialist pediatrician, designed a vaccine. Has said that you have to worry about what he calls original antigenic sin.

We had Dr. Richard Hatchett on one of our client calls, and he specifically talked about immunity for the viral vector vaccines like AstraZeneca and J&J. So are there concerns about that, especially if we're going to have to have this vaccine on a regular basis every winter season?

Dr. Scott Gottlieb: Look, there's theoretical concerns. I mean, the original antigenic sin, the notion there is that your immunity is biased towards what you saw first, and so you're not going to develop as good immunity against everything else. And so if you keep repeatedly dosing someone with the ancestral strain, the Wuhan variant, if you have to give them an Omicron-specific vaccine, they're not going to respond as well to it.

But there's no reason to think that the third dose is suddenly going to be the one that biases their immune system versus the first two that you already had, first off. And second off, I again don't think that, if I had to sort of place a bet today, I would say that we're not going to be switching to a new variant vaccine. If we have to, we can and we will. Pfizer and Moderna are both developing the vaccines. They'll move them through development. Pfizer will start manufacturing at risk commercial-scale manufacturing to be ready to go. But it would have to take completely losing these vaccines to switch everyone over to an Omicron-specific vaccine. And if you're not going to do that, then you're potentially entertaining the possibility that a certain population that really needs the most robust protection from this particular strain because it's become epidemic here, maybe it gets apportioned to that population. I think that's an "if" right now and uncertain.

But so far, based on what we've seen over the last week to ten days, the emerging evidence suggests that the vaccines are protective, and it's just going to be a question of determining what level of protection they're affording. We also have a different backdrop immune profile in this country, and I think that also is a big question of: How will this behave in the US?

There are differences. We have higher vaccination rates. We're going to end up having very high prior infection in the population from Delta and the various strains that have circulated here. We have more people that have been infected and vaccinated. And so those people have very robust immunity. And so it's a very different immune composition.

I think the fear is, if you talk to the sort of epidemiologists

who are looking at this data, the fear is, even if this causes only a small percentage of people to have a bad outcome and it's less virulent overall and people who have been exposed to Delta or vaccinated are reasonably well protected, a small percentage of a big number is still a very big number. And if this is highly contagious and moves through the population much more easily, you're going to see bad outcomes. You're going to see the health care systems oppressed because even if some small percentage of people end up being hospitalized, if the attack rate is very high, it ends up being a high number.

Sharmin Mossavar-Rahmani: When people are looking at some of the new alternatives, so we already had some monoclonal antibody treatments. And now there's the Pfizer antiviral pill. So people can say, well, the odds of a severe disease is low, but we also have these other alternatives. How should they think about it?

Dr. Scott Gottlieb: Well, I think what people should recognize is this isn't the spring of 2020. Our toolbox has vastly improved. I mean, we have massive testing in place. We have massive sequencing in place. We're actually using testing, tracking, and tracing to try to control introductions here, so we can better control the scope of the epidemic. We're going to have hopefully orally available drugs. The Pfizer drug, the Merck drug, which I think should be approved. We have the monoclonal antibodies that I think can be used much more aggressively, be used as prophylaxis for people who are at high risk of a bad outcome. We're not using them that way.

By and large, the Vir antibody and the AstraZeneca antibody look preserved even if the Regeneron antibody and the Lilly antibody look like they're not going to be as effective against this new variant. But Regeneron and Lilly

already have second-generation antibodies in development.

We have access to home testing that look like they're all -- the major tests that are on the market look like they can detect these new variant. When you do the sort of epitope mapping, it doesn't look like this new variant has mutated parts of the virus that those tests like the Bionix now targets. So those should be effective.

I would argue from a policy standpoint, I don't think we're making as effective use of our tools as we should be. I think we should be handing out home diagnostics to everyone and not wringing our hands over the fact that some people are going to hoard them, some people who are wealthier are going to get them also. Just give them out. I mean, we should just be subsidizing the delivery of these tests. I think we should be expanding utilization of the antibodies and crashing manufacturing of the Vir and the AZ antibody which we know are preserved against this right now so we can have ample supply of those and using those in a prophylactic fashion for people who are immuno-compromised.

We need to do more to try to vaccine children and boosters. I think the kind of ambivalence about the boosters was hard to unwind. You know, a lot of public health officials spent months saying boosters are unnecessary, and then all of a sudden boosters were necessary. I know who was saying what because I was on the receiving end of some of the, “Why are you saying that?”

Pfizer put out a statement in July that it was going to pursue the authorization for the boosters after they saw the Israeli data showing declining effectiveness of the two doses. They started at that point a 10,000-patient outcome study looking at two doses versus three doses. Made the

initial filing in August. The whole application went into September. The approval was in October. But I remember that July day. It was July 9th because I went on TV and sort of made the case for why I thought this was necessary. Obviously I'd been briefed by people in the company. And there was a lot of criticism from the public health community. And that persisted for months until I think the data sort of firmed up and people became convinced.

But the problem is a virologist can change their opinion quickly. A clinician can based on accruing data. But the public, it's hard, after you've heard a message for three months, it's hard to suddenly change that message. And so I think we're probably still seeing the residual of that, that people are confused about the boosters. And I think it's going to take time.

Omicron seems to be focusing the public a little differently. I think people now recognize that this could be important. And you're seeing rates of vaccination go up a lot in recent days, but that's going to be hard to sort of fully educate the public around boosters.

Sharmin Mossavar-Rahmani: Actually, I think the attendance here is affected by Omicron. There were a lot more people registered to show up in person. And I think we have fewer people showing up because of that. They're on Zoom.

Dr. Scott Gottlieb: I would just say the absolute risk of coming in contact with this virus is exceedingly low right now. It might not stay that way, and it might change very quickly. But there's very little of this circulating in the US. And you can say that confidentially now. When we were saying in January of 2020 or February of 2020 that the absolute risk of getting COVID in the US was exceedingly

low and we relied on flu surveillance to make that statement, that wasn't a reliable statement. I mean, there were tens of thousands of cases, but we weren't detecting them and many of them were here in New York.

Now, given the level of sequencing we're doing and surveillance testing that we're doing, the fact that we can detect this variant on PCR tests and we're not just dependent upon sequencing because of a very tell-tale signature that it leaves on a PCR test, I think we can confidently say that this isn't spreading in the community right now. And the absolute risk of contracting this is exceedingly low, and what we have to deal with is a Delta wave.

Because tragically, the prospect we face is that we continue to see Delta infections mostly around unvaccinated people or people who haven't gone out and gotten the booster. And then those people are just as vulnerable to Omicron infection because the prior infection with Delta doesn't confer enough immunity to protect against an infection with Omicron. I think that would be tragic when you have people sort of successively infected with COVID because each time you get infected, it's a little bit of a roll of the dice even though you have some residual immunity.

So people who are sort of saying, “Well, I'll just get Delta and get it over with,” you're not going to get it over with. And people who are saying, “I'm naturally immune to this because I had a Delta infection,” you may not be. I mean, a prior Delta infection may protect very well against a subsequent Delta infection. Might even protect better against the subsequent Delta infection than the vaccine does, but it's not going to protect against an Omicron infection. We've seen that. That's very clear in the data in South Africa.

And there is some suggestion from the evidence such that it is that a vaccine will be more protective.

Sharmin Mossavar-Rahmani: When you think about the winter we're going into, the Delta you said is still around, prevalent. Omicron less so. What is the winter surge going to look like then, in your view?

Dr. Scott Gottlieb: Yeah, I think that Delta is going to continue to course its way through around the country. The Delta epidemic in the Southeast has subsided in the South. Prevalence levels are very low. Southwest is coming down sharply. The mountain states, the Pacific Northwest has moved through its Delta wave. You know, so Delta is sort of moving around in a regional fashion as we've been predicting for months. Now it's the Great Lakes region, Minnesota, Wisconsin, Michigan, and New England that are really sort of lit up by Delta.

I think the Delta wave here in the Northeast is probably going to be, at least in the tristate area, is probably going to be more subdued relative to what we've seen in other parts of the country. But I still think we're going to see -- and we're seeing -- a pickup of infections. And we've been predicting this for a long time.

I think the risk is that I had said many times Delta will be the last major wave of infection barring something unexpected. And that wasn't just sort of a caveat to leave me wiggle room. There was a presumption that future variants would be within the Delta lineage, and Delta would acquire qualities that gave it partial immunoscope so it would mutate. But Delta immunity would sort of persist.

And so now that we've had so much Delta infection, so

much vaccination, prevalence levels would decline a lot. And that's clearly what we're seeing in the South. Prevalence levels there are, like, six cases per 100,000 per day. We haven't been at levels that low at any point really in this epidemic since it began.

I think the risk now is that parts of the country where you have low vaccination rates, high Delta immunity, and overconfidence where people aren't doing any mitigation because they feel COVID is over, they're going to be very vulnerable to Omicron. And that describes many parts of the South. Now, at what point how will this play out? It's hard to tell, but in January we should see prevalence levels really come down nationally as Delta kind of finishes moving through the population. And the risk is that, if Omicron starts to heavily seed the US and it is as contagious as it appears to be based on the early data, you're going to see a pickup. And what we could see is maybe not another huge wave of infection but, kind of like what we saw in 2021 where we came off that huge surge of infection with the Wuhan variant. And then B117 emerged. And suddenly we were coming down and then we kind of leveled off.

We went up a little bit. And all through the spring we had persistent infections. We started to decline in the summertime as we vaccinated our way out of it and we had a seasonal benefit. And so I think there's a possibility you could see the same thing with Omicron, depending on how contagious it is where you start to see a pickup of infections as we get into maybe February/March. And what should have been a really quiescent spring and summer with COVID ends up being sort of more persistent. And we do get a benefit of a seasonal response. Hopefully the boosted vaccines are effective and more people get the boosters and that provides a backstop.

It's going to depend on what the ROT is in the US population. If the rate of transfer here is 3.0, it's going to be hard to put the brakes on it. If it's 2.0, we can get ahead of it with the benefit of seasonal change and boosted vaccines and people employing some mitigation.

That's why, again, buying time with trying to use tracking and tracing and reduce the number of introductions and testing and putting in place prudent measures on travelers, I don't think we should be putting in place travel bans but requiring people to be tested before they get on a plane and be vaccinated coming to the US is prudent.

Everything we could do to sort of buy ourselves some weeks to get further into the warm months with this is going to help us get the benefit of a potential backstop against another huge epidemic wave, which I don't think we're going to have with this. But the potential is there.

Sharmin Mossavar-Rahmani: What do you suggest people do differently?

Dr. Scott Gottlieb: Right now, nothing. I mean, I think people should be doing what they're doing to try to get through the Delta wave. And most people are taking prudent steps to try to protect themselves and their families from Delta infection. That's really the immediate risk.

Getting boosted. Getting vaccinated if you're not vaccinated. Getting a booster if you haven't had a booster. Everyone over the age of 18 is eligible now. Continuing to employee prudent mitigation. I think mask wearing is important, but wearing a high-quality mask is important. If you're wearing a cloth mask, you're not affording yourself

a measurable level of protection against something that is clearly at this point airborne.

If Omicron, if the data is believable about how this is spreading, it's an airborne virus. Delta is an airborne virus. It's not spreading through droplets. And so if you want to protect yourself against a virus that's airborne, wearing a K95 or an N95 mask becomes more important. Procedure mask is probably 45% protective.

Sharmin Mossavar-Rahmani: Procedure, you mean these surgical masks?

Dr. Scott Gottlieb: Yeah, but a Level 3 procedure mask. You have to wear a proper procedure mask, and not all of them are proper medical masks. You have to look for a Level 3 procedure mask. But a cloth mask isn't going to afford a measurable degree of protection. It'll cut down on droplets. It'll help reduce your likelihood of transmitting the infection if you're infected yourself and you're an asymptomatic carrier.

But I think what's happening is a lot of people are going into congregant settings, high-risk settings, with a cloth mask on thinking that they're impervious, and they're much more vulnerable than they perceive. I wear a K95 mask, but it's FTA listed. So it's been tested. I can just buy it off of Amazon. Most the time I slip on a cloth mask on top of it to get a better fit and also it looks more fashionable.

Sharmin Mossavar-Rahmani: With the new variant, have you adjusted your travel schedule?

Dr. Scott Gottlieb: You know, with the new variant, my travel schedule has adjusted for me. But I'm not, again,

worried about the absolute risk of this new variant. And based on the clinical profile, I'm not any more personally worried about this new variant than I would be about reinfection from Delta, really, so far based on what we know. So it hasn't really changed my thinking.

The one thing I would be mindful of is traveling overseas right now. I think that there is, as this unfolds, we're sort of in an uncertain period. You're seeing countries either react appropriately or overreact. When you see countries closing off all travel and sealing their borders and putting in place 10-day quarantines for people who come in, so these policies are changing so quickly that I wouldn't want to get caught in a quarantine.

And I also would definitely not want to get caught with a COVID diagnosis outside the US because they'll put you in a room and throw away the key potentially. So I'd be mindful about traveling outside the US right now unless you had to, unless it was sort of mission-critical travel, you have to see a family member or something like that. But domestic travel I feel reasonably comfortable.

But again, I wear an N95 mask door to door when I travel. I wear a K95 mask when I have to sort of slip it on and off. So I feel reasonably protected that I'm wearing a high-quality mask appropriately. And I think if you're doing that you have a reasonable degree of protection from an airborne virus.

Sharmin Mossavar-Rahmani: If we could now turn to your book, you talked about what January and February were like. What prompted you to write a book?

Dr. Scott Gottlieb: I felt like a lot of the narrative was around the political shortcomings and the political failures

that led us to be excessively vulnerable to this virus. And I wanted to look at what were some of the more systemic failures, some of the more structural failures of agencies, of our response, of government that left us vulnerable because those are the ones that are going to persist in perpetuity. I mean, political leadership comes and goes. There were clearly political mistakes made in 2020 that stymied our response to this virus.

But there were also a lot of failings at an agency level. And particularly I focus a lot on the CDC and some of the missteps of the CDC. And I thought the book would be coming out at a time that we would be engaging in a very robust political and policy debate about how we make sure this doesn't happen again. That hasn't started yet. And I don't know why it hasn't started yet. I can sort of speculate why we really haven't engaged in that discussion yet, but the book was an attempt to kind of inform that debate. And I thought it would be going on, so I had visions of being handed out at congressional hearings. They'd be all talking about this.

But I think that's going to start. I think it's going to be a hard debate to have in this country because -- I'll sort of pause here. Part of what I sense is happening is our reluctance to engage in that debate somewhat emanates from the fact that we don't have any consensus about what the proper role of public health is in the setting of a crisis. And the role of public health agencies have really been called into question.

If you envision any proper pandemic planning and proper pandemic response, it has to be envisioned based on empowering public health agencies, properly resourcing them, all things I talk about in the book. How do we reform CDC to make it more functional in a setting of a

crisis?

But I think that there's real skepticism about the role of public health authorities and public health officials and public health agencies in this country right now that kind of is an impediment to having that discussion. And it's a right-left debate. It's certainly more on the political right. And I work for a conservative think tank and I hear it from my conservative colleagues. But I think it's a little bit more pervasive than that.

I think there are a lot of people who feel that the advice they got was wrong, was poorly informed, shifted too much, stayed in place too long even as the evidence changed. And so you have a broader degree of the public that are skeptical of how public health agencies function in the setting of this crisis. And we're going to have to get over that. We're going to have to first resolve that skepticism before we have a really I think thoughtful debate about how to empower public health agencies more effectively.

Sharmin Mossavar-Rahmani: You had already left the FDA but got involved very early on. So expressed a lot of concern. Ended up working with the White House on an ad-hoc basis. What actually prompted you in the first place to be so concerned? And how were you so involved in all these discussions when you were no longer at the FDA?

Dr. Scott Gottlieb: Yeah, well, the first phone call I made, so it was the weekend, it was Martin Luther King Day weekend, the holiday weekend. I guess it was sort of mid January. And it was the day that the Chinese government reported that the number of cases in Wuhan had quadrupled from 50 to 200. And all 200 were in the hospital with severe pneumonia.

And so first of all, it was a velocity of the increase in the reporting, and clearly that identified under reporting. But also it was the fact that it was very unusual that a respiratory virus would present only with severe pneumonia. And so it was a clear suggestion that we were seeing the tip of the iceberg. And that got me alarmed.

You know, a sort of SARS-like viruses spreading rapidly in the city of Wuhan causing severe pneumonia. We know of 200 cases and they're hospitalized. There's probably hundreds, if not thousands, more. This looked like an infection that was out of control, an outbreak that was out of control.

So that day, I contacted the head of domestic policy counsel in the White House, who I had worked closely with. He had worked with FDA back during my prior stint at FDA. And basically expressed concern, urged him to get a briefing from CDC. Told him it was going to be important to get CDC and FDA collaborating and that we were going to need diagnostic tests in place here if cases started to spread.

That was with the communications I talk about some of it in the book, and it's been also -- someone gave those communications to the Washington *Post*. It's been reported in the Washington *Post*. I suspect someone in the White House.

So that was the first sort of contact. And then I developed a pretty regular dialogue with him and a few others in the White House at a policy level. Not with the HHS. I didn't talk to the secretary, and I didn't talk to his staff and not with FDA. I was communicating with the White House, trying to give them advice on what they should be doing, which was unusual in and of itself that the White House

was kind of quarterbacking this. Normally, that leadership would come from HHS. A lot of the efforts were coming out of the White House by people who didn't have a public health background.

The head of the DPC, the Domestic Policy Council, did, having worked in the FDA, but a lot of the other people were generalists. But that day was -- that data report, I'd been tracking it. But that report really got me worried enough to reach out and say, "You guys better be focused on this."

And they were aware of it. And the National Security Council had already taken briefings on it. But it was the first time that the domestic policy side of the White House I think had gotten actively engaged. And that was also the day -- so the head of the DPC reached out to HHS to ask for a bring on it that day. And that was also the day that the secretary called the president for the first time to brief him on it. And that was reported in the Washington *Post*, that the president was pulled off the golf course to take a briefing from the secretary. And the read-out to the Washington *Post* was that the president seemed sort of disinterested in it and he'd brought up vaping in that discussion.

But I think that it was the fact that it was sort of abrupt. The president was pulled off a golf course for this briefing on something that he hadn't been previously been briefed on. And that's sort of an abrupt gesture, if you will.

Sharmin Mossavar-Rahmani: In your book, you've been critical of three institutions. First and foremost, I would say local and central government in China. Then WHO. And then the CDC, which you have referred to. Can we go through each of those and highlight some of your concerns,

especially with the local and central government in China?

Dr. Scott Gottlieb: Well, look, there was clearly a lack of information sharing in China early. And I think that initially there was suppression of information at a local level from Chinese authorities in Beijing. And then there was suppression of information from Chinese authorities in Beijing from the rest of the world. They still haven't shared the source strains.

There was clear evidence by mid December, we now know there was clear evidence that this was a novel coronavirus that was circulating, that there was human-to-human transmission. They had evidence of health care workers getting infected, which is evidence of human-to-human transmission. They had evidence that this was a respiratory virus that was spreading through droplets or potentially aerosols. And they had evidence of asymptomatic transmission. The doctors, if you talked to them in China, believed that there was asymptomatic transmission going on.

And so those were sort of key details that, if those had been -- those didn't get firmed up until, like, mid to late January, all the details that I just outlined. If those had been divulged in mid December, a month is a long time. The South Africans were exceedingly forthcoming and look at the punitive actions we took against them to discourage what should be encouraged. But the Chinese government was not.

And in the hands of a competent political apparatus, I think a good response mechanism, a month's a long time. I think if this does start to spread, the fact that the South Africans gave the world such early awareness is going to pay dividends.

That's some of the criticism of what went on in China. There just wasn't information sharing of information that was available, that should have been shared, and that they had an obligation to share under the international health regulations and other commitments that they made to global bodies.

With the WHO, I think there's a lot of issues, but I think we're seeing some of them right now. We don't have an estimate of prevalence in South Africa, which could be obtained. South Africa's sequencing 100 to 200 samples a week, they clearly could benefit from support, but I don't think they're going to ask the US for it after we banned travel. I don't think they're going to then turn around and say, “We need your help.”

But the WHO could be on the ground collecting evidence, helping them sequence samples, parceling them out to labs, providing more on-the-ground sort of assistance, assisting a greater degree, trying to ascertain sort of the clinical data. It's very hard for South African physicians to both provide crisis levels of care and publish articles. And we saw doctors in New York couldn't do it during the crisis. We weren't getting good clinical reporting. So I think that's something the WHO could be doing much more effectively right now instead of just sort of we're all waiting for reporting from South Africa.

Now, they'll say we're on the ground, we have offices there, there's people there. But if it was highly effective, we would have 5,000 sequences in the public database right now, not 250. So there's clearly more that could be done. We would have PCR tests deployed through South Africa that could assay for S gene target failure, which is the tell-tale signature from this new variant as opposed to the sample

that we're using is of about 100 patients, literally. And 90% of them had S gene target failure, and so people are using that as a prevalence estimate. But most hospitals don't have those assays deployed, so we don't have really a distributed assessment right now. So I think there's a lot more that could be done.

You know, and CDC, we only have nine minutes left. I mean, I could talk for the next --

Sharmin Mossavar-Rahmani: Several hours, yes.

Dr. Scott Gottlieb: It's a very high science organization that's very retrospective that is culturally accustomed to being sort of the definitive answer to a question and would much prefer to take four months to be a definitive answer working with their own bespoke data sets than to be an organization that's putting out sort of partial information in a real-time fashion to inform decision making in a current crisis. They don't want to be wrong.

They don't function like a National Security Agency or intelligence agency. An intelligence agency would say, “We assess X based on Y, and we assign this probability to our assessment.” And they don't mind saying, “We only have a 10% level of certainty.” Because they know policymakers need to make decisions in real time, and you're better off with a partial estimate that's 10% predictive or 10% certain than something than the lack of information.

CDC wants to be 100%. And they'll wait three weeks or four weeks if you let them to be 100%. So we didn't have an agency that was able to collect and do real-time analytical work and surface actionable information. We're going to need to create that. Just culturally they weren't able to do it. And if you look at a lot of their analytics and

their analysis, it came out way too late, and it wasn't very practical at many times.

They did one analysis that was by the summer. They were looking at the circumstances that people engaged in before they got infected. So what did you do two weeks before your infection? And what they found was a very high percentage of people, a statistically significant sample of people ate out at a restaurant. And this was in the summer they did this analysis. And so they said, “Clearly eating out at a restaurant is a risk factor for developing COVID.” This was in the summer of 2020.

And in the survey they forgot to ask. “Forgot” may be a generous word. They didn't ask whether you ate indoors or outdoors. That seems to be a very important question, differentiating whether you're in a sort of confined congregant indoor setting or are you eating outdoors, from a clinical standpoint. And in the same survey, they also grouped coffee shops with bars. And I asked them why, and they said, “Well, they're very similar settings where people engage in similar activities.”

The analytics were impractical. And there's multiple examples like that. And the other thing was that they just don't have -- it's institutional but institutionally they're not set up to be able to mount a logistical response. They weren't set up to be able to develop a diagnostic test and mass deploy it, but they were turned to to do it. And so I think it was both a misunderstanding by political officials of what CDC was and wasn't capable of doing, and a lack of CDC's self-awareness to sort of raise their hand and say, “Look, we can't do this. We're not the right agency. We're going to need to pull in other agencies.”

Eventually there was a recognition with the creation of

Operation Warp Speed that you didn't really have a government agency capable of responding, and so you had to bring together different agencies. So to sort of jump start the development of a vaccine, they brought together FDA and the department of defense and elements of FEMA in one sort of new hybrid organization. That was Operation Warp Speed.

I think early on we should have thought of how do we create a different vehicle that sort of combines CDC's high science with a more operational component like FEMA? And something else had to be created. So that was a lack of vision of the people who were in charge. It was partially a reflection of the fact that HHS wanted to control this, and so there weren't other agencies brought in. And it was partly I think a lack of self-awareness by CDC of where the limitations would be with respect to what they were being asked to do.

Sharmin Mossavar-Rahmani: Do you think we'll ever find the origin of the virus? And why is that actually that important in terms of China reporting it?

Dr. Scott Gottlieb: It's important because, if this came out of a lab, this was a lab accident, it changes how we govern labs going forward. We need to get better surveillance around BSL4 labs. We need to make sure certain high-risk things are only done in sophisticated labs.

In China, they were doing research with novel coronaviruses in BSL2 lower security labs. That should never have been done. You shouldn't be researching a novel respiratory pathogen in anything but a BSL3 or BSL4 lab. You know, BSL3, BSL4 would be impractical.

But we would have better international governance around

labs. We should do it anyway. But I think if we assess that this came out of a lab, it would give a great impetus to doing that. So this is an important question to answer.

I don't think we ever will. I think this is going to be a battle of competing narratives in perpetuity. And people have sort of broken into their camps based on different rationales and sometimes political feelings. But barring a whistleblower from China or finding the bat that this came from or the pangolin that this came from and exotic source, this is not going to be solved in a definitive way. And it's going to be a battle of competing narratives.

I certainly think over time that the side of the ledger that suggests that this could have come out of a lab has grown over time. And the side of the ledger that suggests this came out of nature has been at best stagnant. There's no new evidence.

I mean, the early evidence was the sequence looked like it could have derived from nature. Largely, they were looking at sequence data. There's at least circumstantial evidence on the other side of the ledger that this could have come out of a lab, and certainly the conditions were there.

And I think another factor is the behavior of the Chinese government and how they've been not forthcoming with very critical information that they should be willing to share. You certainly can draw inferences from that.

Sharmin Mossavar-Rahmani: As we think of the length of this pandemic, how long it's going to last, Dr. Hazeltine has said it's going to last a few years. We're looking at it. What happens in terms of your advice and your recommendations in the book on what policymakers should do? And what's next for you in terms of this

pandemic and where it goes?

Dr. Scott Gottlieb: Well, I really thought that this Delta wave would be the last major wave of infection and we wouldn't be in the situation we're in right now having to contemplate another surge of infection. I think this is going to become an endemic virus, and we need to understand what that looks like.

If this is something that diminishes in its sort of severity over time either because it migrates into a less virulent strain or we just develop a lot of baseline immunity to it in the population and eventually everyone's had this and has been vaccinated for it successively, this becomes I think at best like a second circulating flu, at least for a period of time.

And the problem is we already have a flu. And if we have two flus circulating every winter, we have two pathogens circulating every winter that causes the same level of death and disease that flu does, I think that's too much morbidity for us to really tolerate. And we're going to have to be more prudent about how we approach respiratory pathogens in the winter, how we create healthy conditions to prevent the spread of respiratory diseases. So some of the things we're doing I think are going to persist.

I think the idea of wearing masks in public, even if it's not mandated, is going to become more socially acceptable. More people will be doing it, particularly people who are vulnerable. I think there's going to be more of an impetus to try to get people vaccinated for probably both COVID and flu each winter.

You have to think about creating very dense settings right at the height of flu and cold season. Holiday parties timed

right at the wrong time. Trying to create better air filtration. Trying to put in place HEPA filters and things like that in indoor settings to improve air quality. I think we're going to have to think about all these things. And a lot of it's going to be superimposed on sort of normal life.

I think we get back to some semblance of normal activity with some added caution that's going to be adhered to during the height of respiratory virus season, which is basically the winter. Coronaviruses are typically winter pathogens. As this becomes an endemic virus, this will become more seasonal, and it will typically be a winter pathogen.

Sharmin Mossavar-Rahmani: And in terms of your recommendations on what the government should do in the US?

Dr. Scott Gottlieb: Well, look, I think we need to start that conversation about how we have better pandemic preparedness going forward. And I think we're going to have to look at public health through a national security lens and start thinking about how we make investments in capabilities and capacities that we hope we never have to use, the same way we do for other national security priorities where we invest in certain things to prepare for contingencies that we hope never happen.

We're going to have to do the same thing here. And that means building capacities that we don't have and keeping them hot. Keeping them functional. Not just the idea of you can stockpile a whole bunch of stuff in a warehouse and build a facility and mothball it and it's going to be ready when you need it. That was the old thinking around pandemic preparedness. Or that you can guess what the pathogen's going to be and what its characteristics are

going to be. That was the old thinking. We're not going to be able to engage in that.

And if anything, we've seen this was an asymmetric risk to the United States. Certainly the West but the United States in particular. We proved uniquely challenged implementing respiratory precautions. Every other country has probably seen that, including our adversaries. It probably changes the calculus around would anyone be willing to use a respiratory disease deliberately.

Clearly this wasn't a deliberate pathogen, but you have to think differently about how people perceive respiratory diseases looking at what an asymmetric risk this was to the United States. It crowded out all our other national priorities. It changed the course of history. It hurt us geopolitically. I mean, would China have moved on Hong Kong? Would they be threatening Taiwan if the world wasn't distracted by COVID? Things would probably be different.

And so looking at how this set us back, I think that justifies the kinds of investments we're going to have to make to make sure this doesn't happen again.

Sharmin Mossavar-Rahmani: Thank you very much, Dr. Gottlieb.

Dr. Scott Gottlieb: Thanks a lot.

Sharmin Mossavar-Rahmani: We really appreciate you being here. And to everyone here.

Dr. Scott Gottlieb: Thanks.