**PUTM Ponders**

[00:00:00] **Ellie:** [00:00:00] Hi everyone and welcome back to Politics Under the Microscope. It's Ellie here and before interviews, we will begin our episodes with a PUTM Ponders segment where we will have an informal, wine night-style discussion as a preview to our interview. Our topic for this series is the COVID-19 vaccine and its distribution.

[00:00:17] And so Nina, what have you been kind of thinking, while the vaccine was being produced and while it's being currently distributed?

[00:00:25] **Nina:** [00:00:25] Yeah, so I think a lot of my initial thoughts were kind of the same way they were in hearing about the crisis and sort of worrying about how communities that are normally marginalized when it comes to medical care or scientific access would have access to this vaccine.

[00:00:38] And if they'd be hesitant in taking it, you know, we understand that this country does kind of have a long and storied history of medical and scientific racism and abuse. So it's also a question of whether certain communities would want to necessarily voluntarily take this vaccine. Another question would be sort of some of the issues that come up between, say the federal government and the Indian health system, right, [00:01:00] which serves reservations. How accessible is this vaccine for populations of people like native Americans who may live somewhere like in the middle of Oklahoma? It may not always, always have access to standard healthcare and good healthcare because there may be less physicians out there anyways, and less access.

[00:01:16] So I think even thinking about the vaccine and distribution, there's always this question of access. And even once somebody has access, is there trust there in order to actually take advantage of that access. Naira, what were you thinking?

[00:01:35] **Naira:** [00:01:35] So I've noticed a very interesting interplay between the public and scientific experts lately. And honestly you need not to, to your point, right? Of course, there's this worry about vaccine hesitancy, especially given, you know, our history as a [00:02:00] country, not just. You know, sort of neglecting the, the already underserved in times of crisis, but also that people are already afraid of vaccines.

[00:02:11] So now experts are kind of exacerbating this problem. And one of the ways that they're doing this rather is they are talking about the vaccine like it's, you know, you have to do it because it's the only way things can go back to normal. But if you do get it, it doesn't mean it's like a get out of jail free card.

[00:02:39] It doesn't mean, you know, you have to stop wearing a mask and like doing all of these things and the everyone, like the general public is responding, "like, okay, well, what's the point? Like if you're telling me, you know, and this isn't true, by the way, if you're telling me that, like I still have to follow all the rules, I could infect somebody."

[00:02:59] "If I get the [00:03:00] vaccine, what's the point of me even going out there and taking it?" Right? The truth is clinical trials haven't actually tested whether someone that's vaccinated and got COVID, which is, you know, pretty unlikely sort of given what it looks like now, and that's why it's really hard to test that.

[00:03:21] And, you know, if they could pass that on to someone else that maybe isn't vaccinated and then make them really sick. So, so many crazy things have to happen for them to test it out. And it's so hard to do that in clinical trials in a very controlled way. So, you know, that's kind of an argument, but what scientists have actually found is that it's so rare, like it's highly unlikely that if you do get vaccinated, you could, you know, get sick and then pass it onto someone else and then make them really ill. It's so, so, so unlikely. And experts are underplaying the value of [00:04:00] being vaccinated. It's like, "Dude, you could go see your grandma." What do you mean? You know, so,

[00:04:07] **Ellie:** [00:04:07] Or your grandma can see you!

[00:04:09]**Naira:** [00:04:09] Exactly, right? Because "Hey, you know, your grandmother was probably vaccinated first," hopefully. And given the current circumstances. So I think we really need, you know, along with vaccine hesitancy where it's like, "I don't even want to put that in my body."

[00:04:28] You know, there's another level on the spectrum where it's like, I don't see logically how this would help me. And that's wrong guys. Like you've been ever since you were a child, legally you had to be vaccinated for all of these things. I don't think it's that different, you know?

[00:04:48] And think about it. Like, of course when you were an infant, you couldn't say no, you couldn't make the decision, but they've made it mandatory for a reason. Okay. It's so that you could make it to the age of 35.

[00:04:59][00:05:00] When I took it for like my first dose, it was scary. I'm not gonna lie, because I didn't know what was going to happen.

[00:05:08] Obviously I talked to many people around me that took it. But, you know, we need to really face it. We need to face it. If you're afraid of it, think of it as a civic duty because it is.

[00:05:24] **Nina:** [00:05:24] That was beautiful. Go ahead and do that. It's a civic duty not to cut you off, because they talk about people who may not want to take the vaccine in such a captious manner. But part of it is that so many people don't understand that there was a time, not that long ago when our grandparents were kids, when your parents were kids based on how old they were, that not being vaccinated could kill them or could harm them in some way. We're so accustomed to a world where we've been vaccinated against everything.

[00:05:50] I've never had measles. So I'd maybe don't understand quite how scary it would be to have measles. And I don't think that people understand that in a world where you've always been [00:06:00] vaccinated, you kind of are insulated. And you don't know how scary some of these things can be because we're so accustomed to everyone around us being secure and being protected that we don't realize that there are dangers out there.

[00:06:12] So I think that that's such a holistic approach to take just being really fair and really measured about it.

[00:06:20] **Ellie:** [00:06:20] And also just to provide our listeners with some more concrete facts about vaccine hesitancy and this attitude that it seems to really permeate our society, just to quote some of the statistics from my New York Times morning briefing, but about one third of our members of the U S military have declined vaccines. And when shots first became available to Ohio nursing home workers, about 60% said no. And so nationwide, nearly half of Americans will refuse a shot if offered one immediately without hesitation. And so I am very much interested in unearthing some of the reasons why this may be and really [00:07:00] understanding what really happens during the vaccine production and why we were able to get a vaccine out so quickly. I think a lot of this hesitation stems from how fast we were able to do it, you know, I was telling you guys earlier at first I was a little hesitant because we know that vaccines takes such a long time to produce.

[00:07:19] And so with this short turnover, I thought, "Well, something had to be compromised, right?" A rule had to be thrown out or something, something like that. But as Reverend Holt will talk about in her interview, you know, operation warp speed was not, was not a year, was not however long the vaccine took.

[00:07:39] It was actually in progress for over a decade before this vaccine was released. And so I think really unearthing the vaccine hesitancy and why the hesitancy exists will be so important for our coming interviews as well.

[00:07:56]So Nina, will you be getting vaccinated , [00:08:00] as part of your master's program?

[00:08:02] **Nina:** [00:08:02] They have not alerted us as to if we will be vaccinated yet or not. I think that there are still a lot of conversations that have happening internally at Weill because they know that Presbyterian, which is obviously connected to Weill is sort of changing who can be vaccinated.

[00:08:17] So right now I think it's something like employees can no longer be vaccinated after a certain point, so it's expected to are beforehand if you're an employee or a volunteer, because then they're moving those vaccinations into different phases. So we haven't heard anything yet, but I'm going to cross my fingers and hope we get vaccinated as soon as possible, because I would love to be vaccinated and, mask and all, go back into the world and sort of not have a fear of contracting COVID. Niara? What were your experiences like since you've had the vaccine for a couple of months?

[00:08:48] **Naira:** [00:08:48] Yeah. So I'm going to start talk about like my experience, how I felt about it. And personally, when I got there and I'm like sitting in front of the nurse and she was going to jab me with this [00:09:00] needle, right? Obviously there's a little bit of hesitancy and sort of fear.

[00:09:06] Cause I'm just like, this is a new construct, right? This is our first mRNA vaccine. I mean, I sort of felt honored like in the moment, I'm just like, wow, like it's 2021. We have this brilliant technology and science is moving so fast and now it gets to impact me personally.

[00:09:32] It gets to protect me. Like science actually gets to do its work. There have been people that have been studying these kinds of viruses for decades and decades. And like Ellie mentioned operation warp speed wasn't like we're neglecting all of the rules and regulations and we're just going to make it and get it over with. No, this is backed by decades of, of [00:10:00] Coronavirus research. Uh, and that's why, you know, every single scientist that studied Coronaviruses and maybe didn't think their research even made a difference at the time. And then they're now maybe 10 years later, 20 years later, maybe a year later, they're watching the world and they're like, "Oh my God, a discovery that I made that no one really cared about 10, 20 years ago is now saving lives." Like how incredible. So I think really in that moment, when I was getting the vaccine, my fear turned into those goosebumps you get when you're witnessing a miracle, because let's face it. It's a miracle.

[00:10:48] **Ellie:** [00:10:48] Yeah. And just, just to highlight something, you said, Niara, this isn't the first coronavirus. Coronaviruses are a family of viruses that have existed you know and so I think that that [00:11:00] also is super important to note. And so I'm so excited that we will have , interviews with Reverend Holt and Dr. Garcia-Sastre and will be able to answer the questions that a lot of Americans have on their mind and I know that we have as well. And so after all, we got to ask the questions.

[00:11:18] And so we were so thrilled for you all, our audience to listen to the following interviews by both Dr. Adolfo Garcia-Sastre of Icahn School of Medicine at Mount Sinai in New York City and Reverend Diann Holt, the Founder of Durham's Maternal Stress Free Zone. And we look forward to hearing what you think.

**Interview with Garcia Sastre**

**Joanna:** [00:00:00] [00:00:00] hello, and welcome to Politics under the Microscope. My name is Joanna and I am joined today by my cohost, Naira, and Dr. Adolfo Garcia-Sastre, appointed by New York Governor Cuomo as a member of the COVID-19 ,Clinical Advisory Task Force. This independent task force was created to review every COVID-19 vaccine authorized by the federal government and will serve to advise the state on the vaccine safety and efficacy in fighting the virus. On December 10th of 2020, the taskforce unanimously approved that the COVID-19 vaccine developed by Pfizer and BionTech while on December 18th, the taskforce approved of the COVID-19 vaccine developed by Moderna. The taskforce is composed of experts, scientists, doctors, and health experts, one of them, which is Dr. Garcia-Sastre. Dr. Garcia-Sastre Received his PhD from the University of Salamanca in Spain and did his postdoc in the Icahn School of Medicine at Mount Sinai here in New York City. [00:01:00] Currently, Dr. Garcia-Sastre is a professor in the Department of Microbiology and Director of the Global Health and Emerging Pathogens Institute of Icahn School of Medicine at Mount Sinai in New York.

[00:01:11] We here at Politics under the Microscope would like to ask Dr. Garcia-Sastre about the review process undertaken by each member of the task force and how he used his scientific training throughout this process.

[00:01:23]Dr. Garcia-Sastre, you've made significant contributions to the fields of virology, vaccines, and immunology. And, some of your research includes generation of safer influenza vaccines and how viruses interact with the immune system. And more recently you've been studying, COVID-19 viral protein factors and how they interact with human proteins. So I wanted to just ask you, what areas of your research have helped you participate as a member of the COVID-19 Clinical Advisory Task Force?

[00:01:55] Yeah, **Dr. Garcia-Sastre:** [00:01:56] thank you very much.

[00:01:56] I'm happy to explain some of my roles. [00:02:00] First of all, just to say that we didn't approve any vaccine. Vaccines are approved by the FDA, federal regulatory agencies.

[00:02:07] So we are not a body that is doing a second recommendation. We are just advising to the governor, whether we believe that, that what has the process of has been done has been a good process. And I think that was triggered mainly because in the beginning there was some doubts whether there will be a lot of pressure in the regulatory agencies, to bypass some of the safety nets which, it tends to be that at least from the ones that we have seen right now, that has not been the case. So the task force is composed of multidisciplinary group all based in New York without any conflict of interest with industries. And my expertise has been in the area of vaccines and molecular biology of respiratory RNA viruses. In the last year, have doing a lot of work also with this new SARS-Cov2, I have done coronavirus research before also, although most of my research [00:03:00] has been focused on influenza.

[00:03:01]**Joanna:** [00:03:01] That's really great to hear. I know you advise the governor but is there anything else that you do?

[00:03:08] So we have reviewed **Dr. Garcia-Sastre:** [00:03:09] public information, on these vaccines. The FDA asks, for one day to conduct a review, together with the companies that make presentation on the data about the phase three clinical trials.

[00:03:23]**Nina:** [00:03:23] It seems that there are two kinds of data that were reviewed by the taskforce. The first is from the phase three clinical trials, and Dr Garcia-Sastre also reviewed reports that came from the companies when they submitted for FDA approval . Here's a look at the factors they considered:

[00:03:38]**Dr. Garcia-Sastre:** [00:03:38] What is the indication that the company that has submitted this for review to the FDA. What is the intended use for the vaccine? And then we have reviewed the available literature also from the published data about the clinical trials, with these vaccines.

[00:03:56] And then we have been looking to the final [00:04:00] recommendation of the FDA for the vaccine that has been approved. And we have looked whether we are actually in agreement with the recommendations and whether we can add something else to explain some of the process why this thing has been approved.

[00:04:14] So it's mainly has to do with the intended use of the vaccine. . Specifically the science behind the vaccines, what we know about it, what is the efficacy and whether the intended use that has been approved for, whether it's emergency use right now and later on, hopefully there are now a general use of the vaccine, whether we agree with what the process has been done, according to the data and on the process of evaluation by the vaccine advisory board.

[00:04:39]**Joanna:** [00:04:39] I'm wondering since there's other people on the task force, how do you guys work together to go through this review process? Because it seems like there's just so much information that you would have to go through.

[00:04:51]**Dr. Garcia-Sastre:** [00:04:51] So first we, we know in advance when these committees are going to take place, which are public committees, hearing committees, for the [00:05:00] evaluation by the vaccine advisory board that has been put in by the FDA. We reviewed already the published literature and then we follow up the whole day process about back and forth. And then according to that, then we write quickly a recommendation, even before the FDA puts the recommendation in order to avoid any potential delay. And then at the end we see whether the recommendation that we do that we have made is in alignment with the recommendation of the FDA. If the FDA starting some more things, then we may actually tweak the things we agree with, what the FDA has been saying and then we release it. So we try to be as fast as possible in order not to delay vaccination because we believe that we need, if a vaccine is working, it needs to be used very quickly. We don't want to put any stop for the use of the vaccine if we actually agree that the vaccine needs to be used according to recommendations of the FDA. And we know we are scientists , the same thing as the FDA, are scientist. So it's not so [00:06:00] difficult to be more or less an agreement because it's basically looking into the data and knowing what this pandemic is causing.

[00:06:07] Then make a recommendation that takes into consideration the potential adverse events of the vaccine, which can happen, but they are very little, whether benefits that you get the vaccination overshadow the potential side adverse events of the vaccine, which always happen especially because right now the clinical trials have been thousands of people, 30,000, 40,000, but still when you start to vaccinate 1 million people, you may still have some adverse events and this question of monitoring. But there is always some risk, some benefit and are the benefits much, much more than the risk for these ? Are we saving lives with these vaccines?

[00:06:43] **Joanna:** [00:06:44] Okay. And referring to the risks and potential adverse side effects that we might see even after phase three clinical trials given that both the Pfizer and the Moderna vaccines were approved around the same time [00:07:00] , why should people trust in the safety and effectiveness of these vaccines or are they even safe and effective for people to use?

[00:07:07]**Dr. Garcia-Sastre:** [00:07:07] So right now the vaccines are approved for emergency use. So they are not completely approved. Emergency use means that at this moment, we are in emergency with a lot of risk of people in this country, in the world to contract a disease that is lethal, very severe in a high percentage of people that contracts this disease.

[00:07:30]It's clear according to the data that we have seen, that the vaccines at this moment represent a higher benefit to everybody that receives the vaccine than the risk of this person has of contracting the disease. Now, this may change later on, for example, if there is a lot of reduction in the number of infections and we see that there is some problems with some vaccines, which we don't know yet. Based on the available data it's much better for a person [00:08:00] to become vaccinated, so right now it's is clear that these vaccines represent a decrease in risk for the people that become vaccinated for their lives than if they are not vaccinated and therefore that's the reason why we are recommending the same thing as the FDA.

[00:08:15] The reason why it's emergency use is because these vaccines have not been looked for the long time. What could the side effects for a long time of these vaccines? It's extremely unlikely that there will be adverse events that they have not been seen in the clinical trial for the first month. But that's one of the reasons why it still has been approved only for emergency use, because we need to be 100% sure that there is no potential adverse event that comes later on. But again because of this unlikeness that's why they are now being approved for emergency use.

[00:08:50]**Joanna:** [00:08:50] Thank you so much for clarifying. I guess I'm a little bit confused as to what kind of data will we see if it wasn't for emergency [00:09:00] use? For vaccines that don't require such speed in order for them to go to the public, what would the data actually look like?

[00:09:07] The only thing that has been different from all the vaccines is that this is the first time that vaccines are being approved for emergency use. **Dr. Garcia-Sastre:** [00:09:15] Because the urgency of the situation, if they wouldn't have been an emergency, like right now , they will have been monitoring people for longer periods of time before they review.

[00:09:25] And the other thing that will have been done different , the regulatory agency will not have been receiving on-time information, but it will have been a study that they will have seen as, okay. You need to do a six-month study. When you finish the study, give us all the information and then we will review the study.

[00:09:46] Right now, what it is, give us the information that is happening real time as the study's been progressing. And then at the time that is a few months after vaccination if [00:10:00] the committee believe that there is enough information to actually make the case that this vaccine will help at this moment for the people. And they will have a benefit of being vaccinated versus not being vaccinated. Then you tell us, and then we trigger their review process. So that's the only difference that there is. And I think it's motivated because of this emergency that we have right now. We are not in a normal situation , but it's not actually that you'd require less data. it Is basically that normally they wait more time and they've required all the data at once at the end. So when you provide with all the data at once at the end the regulatory agencies, obviously , they need more time to go over all the data because they have not seen it before. This time they have been seen in real time the data. And that's what makes us a far more speedy process for the regulatory component.

[00:10:57] **Joanna:** [00:10:58] That was such a great explanation. [00:11:00] Thank you. And I guess just switching gears , we want to know what is the difference between the Pfizer vaccine and the Moderna vaccine.

[00:11:08]**Dr. Garcia-Sastre:** [00:11:08] Yeah, the composition is very similar. So they are both RNA vaccines , that means that they are made out of a messenger RNA.

[00:11:17] Messenger RNA is a molecule that is a biological molecule, that is part of life. We make hundreds and thousands of millions of messenger RNA molecules in order to be translated into proteins so that they can make up what we are . Viruses also express messenger RNA as part of the biological cycle that have been translated to viral proteins that are making the viruses themselves.

[00:11:44] So this is a biological molecule that is very common in all life forms and traditionally vaccines have been made out of proteins, not out of the molecules that will give rise to [00:12:00] the proteins, which is what a messenger RNA is. So traditionally vaccines have been proteins, which could be inactivated virus, which is the proteins of the virus, but they don't cause disease.

[00:12:12] The antigen that is required for production of antibodies is the protein itself. But in order to make a protein, you can deliver messenger RNA. Then the messenger RNA gets inside cells and it's used as any other messenger RNA to make proteins. It does not produce the virus, it produce only one single protein of the virus that is not infectious. So by producing only this protein, then what has been achieved is that one induce an immune response against this protein without making the virus completely.

[00:12:40] Also, people that get infected make an immune response against the same protein, but they go through infection, which is more risky than getting vaccination and expressing one single protein.

[00:12:51] The difference though between the Pfizer and Moderna is a little bit on how the RNA is being mixed in order [00:13:00] to be delivered inside cells because the messenger RNA needs to go inside cells. They're both based in a formulation that contains some type of lipids that allows the messenger RNA to be delivered inside the cells. But the lipid composition is slightly different and there is also some difference with respect to the amount of RNA that they hav and because of the formulation, they have some differences about the stability of the RNA at different temperatures. That's why the Pfizer vaccine requires ultra freezing and use right away after thawing while the Moderna can be stored at minus 20,. And then there is a difference between amount and time between prime boosting. But this is more related to how the company decide to make the clinical trials.

[00:13:44] So I don't consider this a many difference, but because the Moderna has been testing four weeks later, the boosting, and the Pfizer three weeks later the boosting, that's the reason why the time between the prime boosting changes for both of them.

[00:13:59]**Joanna:** [00:13:59] [00:14:00] And I guess I just wanted to go back to how the mRNA of these viral vaccines doesn't include the full mRNA or it doesn't make the full viral proteins. Yeah, the full viral RNA. So why is that? Because you did mention that traditional vaccines are protein vaccines. Why is this one not a protein vaccine but an mRNA vaccine? Does it have to do with how much viral loads that I guess the virus has on the body?

[00:14:30]**Dr. Garcia-Sastre:** [00:14:30] No, it doesn't have to do with that. In fact, there are some other vaccines that are being tested that are based on protein. The only thing is that protein-based vaccines in general, require more work for production, for getting a good deal on production of the protein. They require more optimization of manufacturing, while RNA vaccines are a technology that is faster with [00:15:00] respect to optimizing . The RNAs are being made no matter what. Some proteins are more stable than others. Therefore , a protein based vaccine for a particular virus may be different in terms of optimization of yields of vaccine than another. But the RNA molecules, they are very similar with respect to how they look like. Proteins, they look different from one another, so therefore , the speed of manufacturing is, in general, faster for RNA vaccines, that this bit of manufacturing for protein vaccines. Now, the other hand, while the speed of manufacturing for RNA vaccine is faster, the capability of manufacturing a lot of doses is lower than there is for protein vaccines. We don't have yet the data, but there is no big reason to think that it's going to perform not as good as the messenger RNA vaccines, but clinical trials are still in completion and therefore we need [00:16:00] some more time to figure out how these, all the technologies that perhaps are more traditional, are performing with respect to COVID-19 vaccines.

[00:16:09]**Nina:** [00:16:09] So now that we've heard a little bit about how a vaccine is made, let's hear a bit more about how it's rolled out and what barriers there are to rolling out a vaccine.

[00:16:19] Thank you. That was so informative. **Joanna:** [00:16:21] That's all the questions I had for you. I'm just going to transition now to Naira, who will just ask more questions now regarding vaccines and your role in the advisory clinical task force.

[00:16:33] **Naira:** [00:16:34] Hello, thank you so much, Joanna. I think your answers highlighted a lot for our audience that might not have a background in science. We really appreciate that. The development of vaccines, as you were saying is usually a very lengthy and complicated process. So from your perspective, how were we able to develop a vaccine for COVID-19 within a year? We hear other experts saying like, "Oh, well, we've [00:17:00] studied SARS viruses before, so that helped," but what do you think really helped mobilize scientists to achieve such an important milestone?

[00:17:11] Yeah. **Dr. Garcia-Sastre:** [00:17:11] I think to me the question is not why this vaccine took this such rapid speed . To me, the question is why it was so slow before. Because to tell the truth it's actually the same procedure has been done for this vaccine that is done in the past for all the vaccines. To get the vaccine approved is a process that takes a very long time, but it should not take such a long time. There are some reasons why they contributed to the speed that we have. The RNA technology, as I mentioned before, allows for rapid manufacturing. This is still very fast as opposed to traditional vaccine that takes 10 [00:18:00] 12, 15 years to develop.

[00:18:03] So why does it take 15 years to develop? The main theme is economic risk. The final clinical trials for a vaccine, even when you move from Phase I to Phase II, we are talking about millions of dollars investments in trying to develop a vaccine. So in general, companies are very reluctant to move faster till they know for sure that everything is in a really good place to make sure that they are going to be less risky as possible and there is going to be a margin of profits once the vaccine has been developed. There are some vaccines that are not being developed just because there is no profit for a particular vaccine, not because they are going to be very difficult to make. I can put you an example.

[00:18:51] **Nina:** [00:18:52] In discussing the difficulty of creating new vaccines, Dr. Garcia-Sastre is going to talk a little bit about West Nile [00:19:00] virus. West Nile virus is a mosquito borne disease and has appeared in Africa, Asia, Europe, and the Middle East. Per the Mayo Clinic at first appeared in the United States in the summer of 1999 and has been reported in every state except Hawaii and Alaska. Many who have it are asymptomatic and usually mild signs and symptoms that develop often go away on their own. Less than 1% of the people who are infected become severely ill, developing an issue such as inflammation of the spinal cord or brain. Let's hear him talk a little bit more about the barriers to creating a vaccine for a virus such as this.

[00:19:34] **Dr. Garcia-Sastre:** [00:19:34] It should be possible to get West Nile vaccines. There is no reason to believe that they are not going to work. They work quite well in animal models. It's should be possible, but what is the problem? One is that there is very small market: who is going to get vaccinated with a West Nile vaccine? Probably very little people. So there is not so much benefit. The second is how you do an efficacy [00:20:00] trial? You need to vaccinate a huge amount of people and follow them up in an area where there is a little bit of West Nile, because there is not so much West Nile around and then figure out that the vaccine is working a little by efficacy. So the trial that requires to at the end, Phase Three , for approving the West Nile vaccine is it requires huge amounts of money for something that at the end may not provide too much benefits. So that's the reason why there is no development at this moment of West Nile vaccines. Now this is an extreme.

[00:20:36] But if you go back to another theme for which we need a vaccine for something that should be possible to get a vaccine , you have also these type of hurdles: how much it would cost what are the risks? What happens if at the end it doesn't work? What is going to be the benefits? So now there is another case, which is the case of vaccines that people will like to [00:21:00] have, and they will be actually commercial success if they come, but they are extremely difficult to make for whatever reason. That's the case of HIV, that's the case of tuberculosis. HIV virus or hepatitis C virus is much, much more difficult to tackle with a vaccine than SARS-Cov2. Because of the huge vulnerability that there is and because most of the vaccines that have been tried in the first clinical trials, even in animal models, they don't work very well. And there are multiple strains at least with this COVID-19 , but they don't seem to be very different. The antibodies are very powerful, potent neutralizing. That's not the case with HIV. It's very difficult to get a good neutralizing antibody response. And even if you get the good neutralizing antibody responses, it only works against some of the circulating HIV viruses. And that that's much difficult to get a vaccine. So there is two reasons for why it took only one year. One is because there was [00:22:00] the willingness to do it, which is for some of the vaccines , it takes more time to get the willingness and the other, because we were lucky. This is a virus that seems to be easy to be neutralized by vaccine.

[00:22:13] Yeah. **Naira:** [00:22:13] And a distinction to make, especially about HIV: HIV evolves very rapidly. Whereas, COVID-19, it's been passed through many members of our population, and there's just an emerging variant that is hopefully getting under control. Thank you so much for such a great and clear explanation.

[00:22:33]**Nina:** [00:22:33] Of course, this was a brilliant explanation by Dr. Garcia-Sastre and I really appreciate Naira adding that point of clarification out there for people who may be less familiar with HIV. Her next two questions are going to focus on the synergy between government and science-- of course, facilitating interactions between scientists and policymakers-- because this is a science policy podcast and hey, who would we be if we didn't mention that?

[00:22:58]**Naira:** [00:22:58] As a part of the [00:23:00] task force and the advisor to several biotech companies, do you ever interact with policy makers and tell them a little bit about these challenges of the economic risks that it takes to develop vaccines? Because what I've been hearing from other experts is if we want to develop better vaccines and better antibiotics , we need to start engaging the government and funding these initiatives. And in fact, there was a funding initiative from the government that supported vaccine research to lower that economic risk. So what interactions have you had with policy makers and what do you think the government can do to really help speed up vaccine production in the future?

[00:23:47]**Dr. Garcia-Sastre:** [00:23:47] To tell you the truth, I don't have too much interaction with policy makers. So I'm like most of the scientists we live in a world that is the world of science with very little interaction with the outside world , unfortunately. [00:24:00] It's a very demanding more this side. There are some scientists that are great interacters with policy makers, I mean, an example is Tony Fauci, right. He's a great advocate, not only a great researcher, but he can articulate things very well to different people that are in charge of funding and things like that.

[00:24:18] I think there are two questions here: one is the industry, the role of industry and the role of government. I think at the end vaccines problem of everybody. To me, the idea will be a pact between industry and government at international level. Because at the end it's very hard to develop a vaccine completely with government funding . It's very cumbersome. In terms of money , you need to give the motivation to the people. Expertise for manufacturing, all of that is actually in industry, which it has been spending time required for [00:25:00] optimization of manufacturing processes to get things that are safe. But with less expenditures as possible in order to make a viable commercial product right?

[00:25:09] The main problem is that vaccines economically for a company are giving very little amount of money as compared to all the biologicals or drugs. Right now, most of the money that goes to industry is for treatment of chronic diseases. It could be for treatment of obesity, treatment of diabetes, treatment of neurological disorders. Drugs that you need to take, let's say once a day, once a week, for your whole life, in order to treat a particular disorder, these are the moneymakers. Vaccines, they give very little economical incentive for companies to develop vaccines because they don't give too much money. They are not the big money makers . However, they are the big money savers. A treatment is [00:26:00] very cost-inefficient as compared to a vaccine, a vaccine is cheap. You give it, that's it.

[00:26:07] And then you save all this money that otherwise insurance companies need to pay for people that get treatments. But the companies don't see the benefits that there is all the amount of money that is being saved because vaccines, is somehow lost among the society, which could be good, but I think there need to be some more incentive in order to get vaccines. It could be incentive to companies or that will benefit people that are developing the vaccines because all the amount of money that they are saving, if a vaccine is successful. This pandemic has already cost trillions and trillions of dollars that have been lost because of economical problems, but it could even be 10 times more the cost if there is no vaccine. Now the vaccine will prevent all this economic health costs. I think we need to find another way, how to make incentives for making vaccines so that [00:27:00] we can work together. Basic scientists, industry, and government together in order to speed up vaccines for the benefit of humankind.

[00:27:10] **Naira:** [00:27:10] Yeah. That was a brilliant explanation. Thank you for that. And you're right, you've really highlighted that vaccines are immense money savers. I think COVID-19 really put pressure on a lot of things, not just the economy, but the vaccine-making process.

[00:27:25] And in some ways, a lot of positive things emerged because we've seen the potential of science. And what happens when we unleash that, fund it properly, and incentivize it. The best, biggest takeaway from what you said was that we need to start working on a new paradigm, a new perspective in funding vaccines. And I think really the government and industry have to step up here and create a partnership, very similar to what happened in COVID-19, but long-term, so that something like this can be [00:28:00] prevented so that we don't have to quarantine for months and months on end. And we don't have to take all of these losses and the scientific community and the government can be primed if something else like this happens in the future. So any final thoughts from your experience regarding the task force? Specifically what were your reasons for recommending the vaccine and maybe a little bit of your thought process when you were looking at the data?

[00:28:30] Yeah.**Dr. Garcia-Sastre:** [00:28:30] Basically we looked to all the debate, also, that there was for the vaccine advisory board of the FDA. And then what type of potential drawbacks have been putting together. We also discussed among ourselves, "What does it mean?" I mean, there are a couple of things that we still don't know about the vaccines. So we don't know how they work on kids. We believe that at this moment, it's much better to continue doing clinical trials to figure out how they perform in kids to start vaccinating kids. It will take [00:29:00] time to vaccinate people. Hopefully by the time that we have most of the people vaccinated that are not kids, there is already data and then we can start to vaccinate in kids. They are not in the high group risks, but still, there are kids that are dying of this disease. So there is an immediate benefit to have a vaccine available as for kids, because it will save this small number of kids that they may die of COVID-19, plus they contribute also to the spreading of the virus. So that will be good also for the whole community, but it's not only the whole community.

[00:29:34]These are the type of things that we look at. And whether we agree with the recommendations that have been done, according to the data, according to the debates on what we have seen. This is a very clear decision. We are not talking about something that perhaps there is a little bit of a benefit but we don't know how much. No, no. There is a tremendous benefit from vaccination. This is very clear with this efficacy that the vaccines have with [00:30:00] respect to prevention of disease for the studies have been done these days. There's a huge difference between the benefits that the vaccine will have versus the risks . So it's an easy decision for us. Same message would be more difficult if the vaccines will have been for example, 40% efficacy. That will have been a different story. Again, we have been very lucky with the results with the vaccine. So it makes our task more easy, because it's very obvious what it needs to be done.

[00:30:28]**Nina:** [00:30:28] Because Dr .Garcia-Sastre has mentioned efficacy here, Naira's final question is going to be about efficacy of the vaccine in children.

[00:30:38] **Naira:** [00:30:38] . And one final question, because we are curious here , what would it take to demonstrate efficacy in children? Is the vaccine in children going to work differently because some children might still be developing or is it that there haven't been enough children in clinical trials for us to make a definitive [00:31:00] conclusion?

[00:31:00] Yeah. **Dr. Garcia-Sastre:** [00:31:01] Children are considered more vulnerable populations. Before you do a clinical trial in kids, you want to confirm it does not cause adverse events in adults. So first you need to go through a clinical trial to demonstrate that there is no adverse events in adults and that there is a reason to believe that there's going to be a benefit from the vaccinations in some efficacy data before you go down into kids. People are going quickly into kids, but actually first you go into adults and then you go into adolescents, which is what is happening right now. There are clinical trials that have been conducted in the 12 to 16 or 12 to 18 group. And then if it's working well in this group and does not induce adverse events, then this is when you can move into kids. Still, it's unclear how this is going to be in [00:32:00] kids, but it's likely that they will start first with again, Phase One to see what did you get in kids, whether you can live with a lower dose for getting the same amount of antibodies that have been produced in adults. And perhaps then you have less pain. Some people develop a fever during one day or two days, a lot of people develop pain, and if we can spare kids for having pain and fever by giving them a lower dose of the vaccine, but they use the same amount of neutralizing antibodies, then is probably that you choose a lower dose for the efficacy trial, because there was some evidence that induce the same neutralizing antibodies.

[00:32:45]**Naira:** [00:32:45] Okay. I see. So it seems that right now there are ongoing clinical trials with adolescents and then in the future, they will incorporate children and they will adjust the dose such that [00:33:00] adverse effects are avoided. I think it's an important distinction to make for our listeners, that clinical trials don't just happen for a new drug or vaccine. They're also required when you are testing the efficacy of a drug or vaccine on a group of people or an age group that haven't received it before, so that you can understand in a controlled away the impact of this treatment on this specific group. So exciting .

[00:33:28]Dr. Garcia-Sastre, thank you so much for your time today. We appreciate it more than, you know, Our listeners are going to be so excited to finally hear some truth from a fellow scientist about this vaccine so that we can settle it once and for all, because there is so much concern regarding the vaccine these days. To our listeners, we hope this was insightful. To learn more about the vaccine or Dr. Garcia-Sastre and his work please visit our website at www.Politicsunderthemicroscope.com or follow us on [00:34:00] Instagram @PUTMpodcast that's p u t m stay tuned for part two of our COVID series and stay safe.

[00:34:08]**Ellie:** [00:34:08] Hi, everyone. Thank you so much for listening to this episode of Politics Under the Microscope. Just because a lot was said during this interview and a lot of it was very scientific, we just wanted to provide a quick sum-up just in case you wanted all of your information from this interview to be consolidated.

[00:34:24]And so, first of all, the COVID 19 vaccines from Moderna and Pfizer are approved for emergency use only and this is the very first time of vaccine has been approved for emergency use only. And so what this really means is that the risk of contracting COVID for example, is much higher and deadlier than the risk of taking the vaccine. It also means that it's not approved for kids.

[00:34:50] And so a lot of the data has not been accumulated for children specifically with the vaccines. And so that being said before they move into vaccinating children, they want [00:35:00] to accrue more data and ensure that adverse events are not occurring in the adults involved in the clinical trials.

[00:35:06]Important reasons why the vaccine production and approval process was so fast for the COVID-19 vaccines really goes into the fact that the administrators, agencies, reviewers and task force are receiving the data as the studies and clinical trials are happening in real time. And so what has been done in the past and why it has taken so long previously for other vaccines is that all of the data has to be consolidated at the very end of the study and then delivered to the regulatory agencies to be approved in the end. And so this is why it's so fast because they don't have to wait for this study to be completely over. It's also really fast because these vaccines are mRNA vaccines and they're much faster to produce than protein vaccines, which have been used in the past.

[00:35:50] Another reason is economic. And so when the demand or urgency is not very high, like for West Nile vaccine that Dr. Garcia-Sastre described [00:36:00] in his interview, companies are very reluctant to move quickly because they've already invested a sizable amount of money and they don't know what the yield on their investment will be in the future. However, the will, demand, and urgency for the COVID-19 vaccines are very high because we are in a unique situation. And so that being said, companies are more likely to move quickly.

[00:36:19]We hope that this interview has shed some important insights on why the COVID 19 vaccine was developed so quickly and why we should be able to feel confident in taking the vaccine should it be offered to any of us.

[00:36:30]We hope that you listen to the next part of this COVID series with our interview with Reverend Diann Holt, a member of the vaccine distribution task force appointed by Governor Cuomo. She will be providing us with key insights into the vaccine distribution process and what we can expect in the coming months.