

## Module 3 Video Class 2: Interview with Julie Gerberding

Hi. Welcome back to the video segments for our course, Journalism in a pandemic: covering COVID-19 now and in the future.

We're now in module three looking at the hopes for potential impact of treatments for and vaccines against this pandemic. And in this segment, I'm speaking to Dr. Julie L. Gerberding. She is an executive vice president and the chief patient officer at a company that you will probably recognize known in the United States as Merck and outside the United States as MSD. She's responsible for policy, communications and population health. And she's a former director of the United States Centers for Disease Control and Prevention. She was in that position from 2002 to 2009.

So thank you, Dr. Gerberding, for speaking to our class. Thank you. Thanks for having me on. Can we start? Since the experience of the students in this class is so varied and covering health and medicine. Could you describe a little bit exactly what it is and you do at Merck?

I have a wonderful job at Merck. I have responsibility for our global policy, which these days is really important and far reaching job. So we help shape policies that are relevant to our industry, to our business and in my bailiwick. Especially important is our ability to reach patients with affordable medicines that they need.

But I also have the communications function and have responsibility for our corporate social responsibility portfolio, which includes our Merck for Mothers program, which is a very large \$500 million program that operates globally to try to address preventable causes of maternal mortality and a number of other things, including all of the things we're doing to try to be supportive of the people who are really afflicted by this Corona virus pandemic.

So thanks for that description. Let's talk about the coronavirus pandemic. As with almost every pharma company on the planet, I think Merck has announced that it's pivoting to begin looking for a Corona virus vaccine. So before we get into what the company specifically is doing, could you talk for a minute about why achieving an emergency vaccine for this is going to be challenging?

You know, one of the things about vaccines in any setting is that not only do they need to work and hopefully have a long duration of protection, but they need to be extremely safe. And here we are in the middle of a pandemic that affects basically everyone on earth. And so we're going to need to protect even some of the youngest, the oldest and the most vulnerable people in our society. And because these people are taking a vaccine to try to keep from getting sick, we have to be absolutely confident that we're putting out the safest possible vaccine. And the challenge with that is it takes time to prove the safety. You know, some of side effects of vaccines are delayed. Some are very rare. And you have to observe large numbers of people being vaccinated before you can detect those complications. So balancing the ability of the vaccine to offer fast protection, but at the same time making sure that we're not inadvertently creating a harm to people in the process. That's a really tough balance and it's especially tough when it has to be done this fast.

So I have noticed over the past couple of weeks that some companies have moved really quickly to put vaccine candidates into trials. But turning to Merck's effort, it seems that you are undertaking a more broad based research effort and it would help for us to hear about that.

And so Merck has a long tradition of developing innovative vaccines. In fact, a large number of the most recently approved vaccines have come from Merck Laboratories. Most recently, our vaccine for Ebola, which was also developed under emergency conditions and that's kind of why we feel like we have recently learned a lot of lessons about what it takes to move a vaccine very quickly through the process of defining the safety and the benefit of the vaccine. So our Ebola vaccine is known as ERVEBO and it's currently being used in the DRC for the tragic situation there. But in the process of working through how do you do this fast and how do you create the proper scale to make sure that the doses that people need are available? We have learned a lot about international clinical trials.

We've learned a lot about all of the different regulatory agencies that have to weigh in. And we've learned how challenging it is to manufacture a brand new vaccine as fast as needed under these very, very stringent quality conditions necessary for making a safe vaccine. So our expertise has been long standing and the more conventional vaccine domain. But now we are one of the companies, in fact, probably the only company recently that's crossed the finish line in terms of creating a vaccine under emergency conditions.

And I think that expertise is what we are using in-house to make sure that the products that we pursue are going to be really contributory to the effort. But also we have a lot of expertise and capacity that we're lending or sharing with our partners, both in the private sector as well as in the government sectors to try to help other people also speed their candidates. We're in a situation now where what we really want are a lot of candidates so that at least one of these will hopefully cross the finish line for COVID-19 and provide the protection that we need, fast.

So fast. I think probably lots of people have heard the very rough estimate that's been tossed around that there might be a vaccine in 12 to 18 months. On the other hand, some vaccine experts, developers of former vaccines have said that, some, a vaccine might not be achieved for three or four years. What is your opinion of what timeline might be possible and what would be the major hurdles in moving along that timeline?

Well, you know, you have to have the science and the science of this virus is still unfolding. Now, we're only a few months into the pandemic and already our learning curve about how the virus infects people, how it's transmitted, the kind of disease that it causes, continuing to expand as we see some of the rare manifestations of infection. So we are just at the beginning of understanding the basic biology and immunology of the SARS-COV-2 virus. That means that we haven't yet developed the confidence that we know what it's going to take to create protective immunity and to make sure that immunity lasts for a long period of time.

So the barriers are number one, what is the best way to have the hosts develop a protective antibody response? Number two, how can we assure that that response is going to last long enough so that we don't have to vaccinate people frequently? Three, how can we get enough of a robust antibody response so that if the virus does continue to evolve bit by bit, that we still have a chance that it will remain effective? In other words, that the vaccine we make to the strains that are circulating today will still protect us if the virus is still around next year. And of course, we don't know that yet. So that's an important consideration that we have to think about when we're looking for broadly neutralizing activity in a vaccine. So there are the basic science requirements of a efficacious vaccine.

Then as I mentioned earlier, there are the safety considerations. And that, of course, has to be paramount. And the only way we can really understand that is by observing what happens in clinical trials as we adjust doses and and follow people who are being evaluated for both safety and efficacy. And then, of course, there's the practical considerations about how can we formulate a vaccine that's convenient to use even in resource limited areas, because this vaccine needs to be something that everyone can benefit from. And then finally and not trivial in this consideration is how on earth do we scale the manufacturing to such an extent that we will quickly have the doses that we need?

Now, if we were all just concentrating on only one vaccine and everybody put their heads to the task of trying to figure out how to scale the manufacturing of a single product, we could do it. But right now, we don't know which product that's going to be and it's impossible to scale everything. So this is the reason why we have so much collaboration going on. Scientists and governments and all kinds of experts are coming together to say, what are the best candidates? What are the qualities that we're looking for in medicines and vaccines for this disease? And how can we work together to help pick the best candidates and really shoulder to shoulder, concentrate on moving those ahead as quickly as we can, building protocols for the research that is collaborative so that you don't have somebody over here doing one kind of a study and someone over here doing an unrelated study. We can't compare the apples to oranges. We need to be able to compile all the information and pick even a better vaccine and antiviral candidates as we go forward.

So all of these things are works in progress and we don't have a crystal ball in our stockpile to tell us which is the best choice to make now. But we hope to get to that point as quickly as possible. We're also, as manufacturers, we know that we will be manufacturing at risk. In other words, we're developing the capacity to manufacture new products for this virus, even if they turn out not to be the best products that we end up going forward with. So we are putting money and people in time and energy at risk to make sure that we don't leave a stone unturned or that we don't proceed as fast as we possibly can.

I was really grateful to hear you mention resource limited areas a moment ago because I think one of the questions already arising around the possible vaccine is how it's going to be affordable and how it's going to be delivered equitably across the globe to both rich countries, industrialized countries or countries in the global south. What are you thinking about that issue at this point? And do you have any sense of how that might be managed?

Well, absolutely. We've been dealing with that in the context of ERVEBO, the Ebola vaccine that Merck brought across the finish line with the final approvals in December, and obviously the Ebola vaccine would primarily be used in resource limited countries. That's what it was designed for. So we've thought a lot about that.

In the case of COVID, if we're really trying to develop a robust global supply to some extent, the volume of doses that are necessary help decrease the cost of each individual dose because the costs of development and the costs of the initial investment in the manufacturing facilities can be spread out over all of these doses that we need. So there is an efficiency of scale in designing a globally relevant vaccine. But having said that, there are still lots of costs involved, not just in getting the product manufactured, but we have to also consider what is it going to take to vaccinate people in resource limited areas? We've seen the challenges of pediatric immunization and despite decades of trying to get all the children of the world properly immunized against vaccine preventable diseases, we are not 100 percent successful, even with a relatively small fraction of the world's population.

So in many countries, there is no health system that's ever been robust to deliver vaccines to teenagers or young adults or older adults. We have to build the systems and they are going to be expensive. There is just no way to think about how to do this without an additional investment in the actual delivery of the vaccine. So that's something that needs to be planned now also. If we wait until we have the product, that will just cause further delay for some eligible people who really need protection to have the vaccine doses and get them administered as quickly as possible.

So you might not be aware of this, but a number of people who are taking this class are people who are completely new to health and science coverage. They have been scooped into covering the pandemics from other jobs, other beats, and we're trying to help them not be so much at sea. So that means they're not necessarily familiar with the structure of the pharmaceutical marketplace. But I think even someone who's very new to these stories can see that already, particularly among the companies that are advancing treatments, that there's a lot of jostling for market attention and for short term gains. And so I'm wondering, as someone with a lot of experience in this space, what would your advice be for journalists who are new to covering this? What should they be looking for and how can they know who the trustworthy sources are?

So first, let me thank the journalists, all of them, for working on ways to make this information as relevant as possible to your audiences and as accurate as possible to your audiences, but especially for those who are new to science reporting or infectious disease reporting. It is, it's a steep challenge. And I really appreciate your willingness to learn from experts and to step up and do the hard job that I know is in front of you. I think the best advice is really to do exactly what you're doing. Ask questions of people who are credible and experienced and have had a track record of providing reliable information. And yes, there is a great deal of enthusiasm for the progress that's been made already, especially in the antiviral domain. I am colleagues with many of the leaders who are working for companies that have these hopefully promising products.

And I can tell you that the enthusiasm is driven almost entirely by their strong sense of purpose and altruism. But of course, they also recognize that whoever is the first to have the best solution

is going to gain a great deal of reputational value. And pride in the employees in that business are going to feel great about what they've been able to contribute. So there is a bit of a race going on. I think what you have to do is dive beneath the promises and the enthusiasm on the surface and really ask the hard questions.

When will you do the Phase 3 study, which is the definitive studies that really show that something is working and that it's safe enough in a larger population of people. When will you file for regulatory approval? How are you approaching W.H.O. pre-qualification, which is the stamp of approval that the W.H.O. provides to member nations that may not have their own regulatory authorities, but helps them understand when a product is safe enough for use in their own country? Is that kind of the milestones of product and vaccine development that are often kind of the indicators of what really is going on in the timeline?

Thank you for that explanation. There's just one more question that I want to ask you. And it's only sort of indirectly about what we're talking about now. I want to dig deep into your resumé because I realize as I look at your CV that this is not your first pandemic, that you were in the directorship of the CDC as the 2009 H1N1 influenza was beginning and you were involved in the response to the anthrax letter attacks here in the United States. But even more, when you were a medical resident, chief medical resident at the University of California, San Francisco, you saw some of the earliest cases of HIV in the United States. And so I am curious to know, out of that long acquaintanceship with pandemic illness, do you have any wisdom for us as we faced down this pandemic about what it will be like, what life will be like on the far side?

I was a medical intern, a young trainee in 1981 in San Francisco, which was the heart of the beginning of the HIV epidemic in the United States. And we were taking care of the first Aids patients then and over the course of my training saw our understanding of this dreadful immunodeficiency disease unfold in ways that at the beginning we had never imagined. In fact, at the beginning, we didn't recognize that it was an infectious disease. We were growing up in a period when everyone thought that infectious disease era was over. We had antibiotics and we had vaccines and we really didn't concentrate on learning infections because we thought that problem had pretty much been solved. So AIDS was a rude awakening.

And what was harder about it is that, in fact, compared to where we are today with COVID, AIDS unfolded fairly slowly. It took us a while to see the people who are at highest risk. And it took us even longer to understand that the heart of the origin of the HIV epidemic was really hitting people the hardest in Africa and in other areas that had not previously been recognized to be an environment where the disease was ongoing. So I think the lesson learned and in a sense my career really is bookended by the two biggest pandemics that have affected the world's population in the last several decades. The recognition is that, first of all, good science takes time.

We're at the very beginning of COVID-19, and we are learning as we go. Just exactly what happened with AIDS at the very beginning, we had to keep an open mind and learn as we go. We had to invent our infection control recommendations because in the early days we didn't know how it was transmitted. And here we are with COVID and we're not really sure exactly how it's transmitted and how risky airborne exposure is, et cetera. So, again, keeping an open mind, asking the hard questions and learning as we go, examining the data as they become available, but also being prepared for things to change and evolve as we go forward. I think broadly, the social impacts of both of these pandemics are hard to articulate in a few words, especially for journalists, because I know you like short answers, but I would say that we need to expect that the World Post SARS Corona virus 2 is going to be very different than the world we knew before this pandemic hit us.

And that's exactly what happened with AIDS. The world before AIDS changed, our sexual behaviors changed, in the United States, how we go to the dentist changed. You know, in the days when I grew up, you would go to the dentist and dentist did not wear gloves or use any particular infection control in the practice other than hand-washing. And now if you go to a dental suite in the US, it feels like you're in an operating room. It's almost sterile. So in every dimension, our society changes in the context of pandemics. Already, we're beginning to see more health care delivered at home. We're beginning to see less work being done in offices, offices. And I'm sure that will be a persistent finding.

The worst thing about both of these pandemics is the very high risk of social stigma. Certainly we experience that with AIDS, the terrible treatment of people who were at highest risk for infection and the incredible stigma that occurred. Things like people's inability to get care or early on to have a job or insurance or to get fair treatment in the employment environment. And here we are with SARS-COV-2, and we see the signs of stigma here as well. We see people treating folks from the Chinese background unfairly because of the origins of this coronavirus coming from the heart of China. We see the stigma that individuals who've been diagnosed and put in isolation or quarantine experience when they come out of those environments.

So whenever there's a new threat, people's tendency is always to protect themselves by trying to stay away from the people that they perceived to be potentially risky. And the end result of that is it divides us as a society rather than helps us come together to really collectively solve the problem. And I think we and all of you as journalists need to be especially conscious of that. Because you are part of telling that story, too, and making sure that when those things happen, that they're made visible and examined and hopefully thoughtfully presented so that citizens can reflect on what does this really mean and kind of put the social construct of the pandemic into a better light.

I so much appreciate those remarks. Dr. Gerberding, thank you so much for joining our course.

Thank you. Thank you. Good luck to everyone and thank you for what you're pursuing. It matters.