

Sharmin Mossavar-Rahmani: We are thrilled to be joined by Dr. Seth Berkley, who is the CEO of GAVI. Dr. Berkley, thank you so much for joining us.

Dr. Seth Berkley: Thank you for having me.

Sharmin Mossavar-Rahmani: If we could dive right in, can you tell us a little bit about GAVI, its mission, and how it got started?

Dr. Seth Berkley: You know, GAVI may not be something people have heard of but it vaccinates more than half of the world's children. It started about 20 years ago. It was launched at the World Economic Forum because there were new and powerful vaccines that weren't getting to the people who needed them the most. And so its mission is to save lives and reduce poverty. And it's been very successful.

We've immunized more than 820 million additional children, preventing 14 million future deaths. What's kind of cool about it is the model. There's no free lunch here. Everybody pays something. No matter how poor you are, you pay a little bit. As you get richer, you pay more until you eventually transition out of GAVI's support.

And with this program, we've launched 496 new vaccines over the last 20 years against 17 different diseases. So a really extraordinary accomplishment. The largest killers of children - - diarrhea, pneumonia, and things like Ebola most recently.

Sharmin Mossavar-Rahmani: We've had very good news on vaccines over the last few weeks. We've had the good news from Pfizer. We have good news from Moderna. And most recently from AstraZeneca-Oxford vaccine. How does that impact your view of vaccines broadly? And then among these different vaccines, how will you decide which ones to actually acquire?

Dr. Seth Berkley: So when the COVAX facility was originally set up of course we had no idea whether any vaccine would work or which specific vaccine. So the first thing we talked about was how do you create a portfolio of vaccines? And the goal was to try to have 10 to 15 different vaccines. And we were aiming to have 2 billion doses available in 2021. A billion doses for low-income countries, a billion doses for upper-middle and high-income countries. So those were the plans.

Now, as these results began to come in, the first thing that it

told us was immunologic protection against this organism was possible. And that I can't emphasize how important that was because we know there are many diseases where we still don't have a vaccine. So now we know you can get immunologic protection.

The second thing is we didn't know which part of the organism you needed an immune response to. And the reason that was critical is all of the frontline vaccines have the spike protein. Those are the little things that stick out of the top of the virus everybody's seen. And if it turned out that was the wrong antigen, which is what we call that protein, then maybe all the vaccines would fail. So it really was, you know, an exciting thing for science to say, first of all, you could get immunologic protection. Secondly, we had the right antigens in it.

And third, of course, people had said that 50% was the level at which you could get an approval. So the fact that the first vaccines came in above 90% was a really exciting story for the world. Of course the challenge now is not all the vaccines are the same. There are many questions. Do they protect against infection? Do they protect against disease? Are they going to be safe in pregnant women? Do they work in the elderly?

Obviously for us we'd rather have single-dose vaccines, ideally ones that do not require an ultra cold chain because that makes it logistically more difficult. So a lot of questions are going to have to go forward. And what we will do is choose vaccines based on the science but also based on these characteristics that will allow us to, you know, get the right vaccines for the right situations.

Sharmin Mossavar-Rahmani: Do you think that your goal to actually get 2 billion doses out there is feasible? And what is the time table for that, given we already have three vaccines? It looks like AstraZeneca has said that they expect to produce at least 100 to 200 million doses by sometime in the spring per month. So what is your view of that? And do you think that 2-billion-dose target is realistic?

Dr. Seth Berkley: Well, let me start with this whole thing because it's been a crazy ride. I mean, if you think about it, it normally takes 7-10 years to have a vaccine be developed. And obviously some vaccines much longer. It was 303 days from the time that the sequence was made publicly available until we had the results of an efficacy trial and a large efficacy, not a

small one. So I think when the chapter is written about this, the science has been really extraordinary.

Of course, now we're talking about the largest rollout of vaccine in history at this speed. The world provides about 3.5 billion doses of vaccine a year. And now we're talking about doubling that, maybe even increasing more than that. So it's a big deal. What we don't know yet is what is the yield of production when you scale up to large production for all of the vaccines, not just the three we've talked about. And by the way, none of those are licensed. They're still, you know, interim results, and we have to get the full results to make sure they're safe and efficacious. But once we understand that then we'll know how quickly we can move.

But I believe we can get to not just 2 billion but perhaps more than that for the COVAX facility in addition to the many billions that are already in production for the countries that have done bilateral deals. And so I think we're going to see this extraordinary movement. We'll start seeing vaccines scale up at the beginning of the year. Already some are being made and we will have access to some. But of course the licensure may take a little bit of time.

But then the really big scale-up will occur probably in the second half of 2021 when we have maybe another five or six vaccines are going to be entering the pipeline. We don't know whether they'll work, but of course the more vaccines we have in different manufacturers, the more quantities we can get to.

Sharmin Mossavar-Rahmani: One of the big hurdles for GAVI, I assume, will be the logistics, not just of getting vaccines out even if it's single dose and regular refrigeration. But how will you deal with the issue of regulatory hurdles, with liability issues in each country, with registration? Those are a lot of hurdles to overcome.

Dr. Seth Berkley: Absolutely. So again we have a jumpstart in providing, you know, a now very large numbers of vaccines working with our partners. But this is going to have to be an unbelievable challenge in terms of moving forward. So we just need to bring all level of logistics company in the world together. You know, we've looked at obviously we won't be vaccinating everybody everywhere at the same time. So the fact that there will be waves of vaccine coming will help with that process. But even the simplicity of do we have enough syringes? We just bought, you know, a few billion syringes to have. Are

there enough glass vials? SEPI [sp?] just bought glass vials for 2 billion doses.

And some of the logistics you talked about we're right now struggling with some of the indemnification and liability issues. How do you do that for the whole world? After all, these are new vaccines. Making sure that we can deal with that. Regulatory, we want one system which is not what we have now. Right now everybody does it themselves. But if you want vaccines in record time, you need to have an approval. And maybe the WHO prequalification will help with that. So we're trying to solve all these problems at the same time.

Again, it's doable, but it is a mammoth undertaking.

Sharmin Mossavar-Rahmani: One of the expressions people have used is "when will we manage to control the acute phase of this pandemic," where life can resume some sense of normality. And some dates that have been put forth is the first half of the year for the United States and all of 2021 for the rest of the world. Is that a realistic timetable based on what we know today?

Dr. Seth Berkley: I think it potentially is. The challenge if you look at the way countries have been affected, the devastation of the health system has been the major problem initially. And that was not only health workers getting sick but also the elderly and people at risk getting sick. And so one of the things we talked about in rolling out vaccine is to try to cover those groups.

So the first thing we believe ought to happen is to vaccinate all the health workers across the world so they're ready to take care of sick people and they're not transmitting infection. The next part of course then is to go to the high-risk groups and begin to vaccinate them. We came up with a number of 20% on average. If you could do that, you would dampen down dramatically the effects of the disease.

And of course it would have an epidemiologic effect as well. We don't know how much. You then from there could go to the next groups, the next groups, and follow it over time. And we think that's the way we're going to get the control.

What I can tell you doesn't work is taking -- if we took those 2 billion doses and we put them just into the high-income countries, we would reduce deaths by about 30%. By taking it

and distributing it globally, you double that death reduction to about 63% according to modeling. So this is one of the reasons that the original model of let's just vaccinate a few countries fully is not the best way.

After all, we're only safe if we're all safe. And the challenge with this virus, we know how quickly it moves around, is how do we really get control of it globally and not just in a few countries?

Sharmin Mossavar-Rahmani: What is your view of among the high-income countries that have actually procured their own vaccines outside of the COVAX facility? Let's say the UK gives authorization to whether it's Moderna or Pfizer before the US gets it? How will vaccines actually get allocated? I realize it's outside the GAVI and COVAX purview, but do you have any thoughts on that? Because a lot of our clients and investors are asking will regulators actually rush getting the emergency use authorization because then they can get their hands on the vaccine sooner before those who might be slower to get that kind of authorization?

Dr. Seth Berkley: Well, of course it's hard to predict exactly what's going to happen, but there is certainly a rush. And I have to say in working with regulatory agencies, you know, traditionally they're very conservative. They're after all there to protect the people's health. They have been extraordinary in this, you know, circumstance, trying to work together, trying to share information, trying to move as quickly as possible.

I was on a panel earlier with a manufacturer who said, you know, "It's amazing. I go to the regulatory agency. I get an answer within, you know, 12 to 24 hours on any question I ask for." So I think we will see very quick regulatory approvals, assuming the correct data is there, the safety is there, the transparency is there. And that is absolutely critical.

We have a big problem right now with vaccine hesitancy. With right now the issue of rumors going around and conspiracy theories and bringing together unusual groups coming together. It's worse than it's ever been. And I think one of the things that will reverse that is if people know that these vaccines are safe, are efficacious, went through the proper process and therefore feel comfortable with it.

And so that's going to be a really important thing. We cut

enormous corners in doing trials not sequentially but in parallel and trying to cut out any bureaucracy that was there. But we have to make sure the regulatory work and the safety work is absolutely, you know, up to par.

Sharmin Mossavar-Rahmani: As you get through the vaccination process, are you concerned that the virus might mutate in a way that could evade the, whether it's human antibodies or actually the vaccines, based on the initial news that came out of Denmark with the minks and the University of Glasgow published that paper claiming that?

Dr. Seth Berkley: Well, certainly vaccine will mutate, and we're going to see mutations that, you know, will change constantly. That's the nature of viruses. So far, the part that we're attacking is stable, has been stable, looks like it's stable. And I think we have to keep in mind that, you know, viruses like measles we've had a vaccine for more than 50 years for that virus. And that vaccine has remained completely effective.

It's interesting because unlike using, you know, antimicrobials or antivirals where you have a selective pressure for the virus to try to escape from these and they're produced in, you know, very large quantities, with vaccines you're preventing it. So a person is only getting infected with a small number of doses, and that's why generally we don't see, you know, a problem with resistance to vaccines.

But of course it is possible, and that's one of the reasons for the good of the world. You don't want it circulating all around the world. You want to dampen it down as much as you can. It's a global problem. We need a global solution.

Sharmin Mossavar-Rahmani: Dr. Berkley, thank you very much.

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