#COVID19: Teamwork Makes the Dream Work

Lindsey: This is *The Antigen*, and I'm your host, Lindsey Dietschi.

On this last episode of this special miniseries, we're connecting with experts to give you accurate information on COVID-19. As you know, we're still hard at work with our partner, BioNtech, to find a potential vaccine for coronavirus. So today, we're asking: what does partnership look like as we head toward the availability of the first COVID-19 vaccines and how does it actually work.

Today I'm speaking with two guests — first we'll hear from Elsie Soto, Vice President of Emerging Markets for Pfizer's Global Supply also known as PGS. Elsie brings 20 years of manufacturing experience in the areas of new products, site production planning, supply chain management and logistics.

Lindsey: So Elsie, I'm really thrilled to have you join today. There's so much discussion about the development of vaccines to address the COVID-19 pandemic, but maybe less so on what the role of manufacturing is in that process. And I think you joining today will help give us a nice lens into that. So, what are some of the things that you're thinking about on how to scale the vaccine, given the simultaneous global need for them?

Elsie: Hi Lindsay, I'm so excited to join you on this podcast to discuss this topic, which is so important for us in manufacturing for Pfizer and for the whole world. Our Pfizer manufacturing organization is very energized by the opportunity we have to deliver a vaccine that will help address such an urgent need. We're very proud that we actually get to manufacturer this vaccine, and we recognize the great responsibility that entails. Just a week ago our PGS lead for this program was sharing some insights, and he mentioned that we're experiencing a lot of firsts in manufacturing through this process.

It is the first commercial scale of implementation that we've done in PGS on a new manufacturing technology ever used by Pfizer. And for us, it's the best example that we have of repurposing facilities that we have, and using them in manufacturing of these vaccines. For example, we were repurposing a suite that we used for a pharm site and were using it to do drug substance manufacturing. We're converting a suite that we have in Kalamazoo and using it for formulation. And interestingly enough, we're transforming our warehousing space to new spaces that can store product under freezing conditions. So a lot of firsts for us and we feel very proud of the incredible agility and ingenuity that we have to find new solutions.

Lindsey: Yeah, that's really exciting, Elsie. It sounds like this unprecedented scale, this new technology that has a lot of people excited. Not just the one that Pfizer's working on, but all the companies working hard on this and then looking into the existing manufacturing footprint that we have to transform existing locations to meet the needs of this clinical development program. So, all really exciting steps that the company has taken and I share your pride in the work that the manufacturing team is working so hard on. So, when you're a manufacturing expert, like you are, what sort of partnerships really come up for you in how you solve, for example, the materials we might need to manufacture a vaccine? New technology, new approach at such a fast scale. Maybe you could share a bit about that?

Elsie: Absolutely, Lindsey. It has been very evident to us during these unprecedented times we are living, how critical it is to leverage the right capabilities and partnerships that we have. In our quest to be able to launch this vaccine in record time, we are definitely relying on our partnerships with new and existing suppliers. For example, some suppliers of glass and stoppers are experiencing very high surges in demand, as other companies like us are planning other critical launches. So we

are working closely with them to make sure that the needs that we have to support these aggressive timelines are met.

We're also leveraging our partnerships with raw material suppliers that need to deliver raw materials in record time. Materials that maybe takes a year or two to deliver, we're working with them to get it very fast so we can really be able to manufacture and deliver this vaccine this year. We are also leveraging our partnerships with our equipment suppliers. For example, production equipment and freezers that we need to put in place as we get ready for our launch, hopefully later this year. So it takes a lot of orchestration and support to deliver such an ambitious project.

Lindsey: Yeah, I can imagine. It's interesting, in earlier conversations we had talked about the personal protective equipment and the surge in demand for those. And now here what we're talking about is actually not just what goes in the vile, but the actual glass vile itself, or the stopper itself, and how important the role of partnerships are and actually making those happen as quickly as possible so that we can bring vaccines to market to meet the need that we have to address the COVID. So, when it comes to a single dose to a multi-dose vile, what are some of the other considerations when it comes from a manufacturing standpoint?

Elsie: We have a lot of great experience in the past around the multi-dose vial presentation. Our history with the PCV 13 MDV presentation has demonstrated how impactful it is to provide a presentation that optimizes our ability to reach remote places and also optimizes transportation and storage in locations that would otherwise struggle. The decision to launch the new vaccine in MDV format, it is a great path forward. It enables us to produce more doses for pandemic supply in the short term, optimizing the existing equipment, and it also streamlines our storage and distribution processes. One of the particular requirements of this vaccine is that it has to be handled in freezing conditions. Having an MDV means we can store more doses in less space. It will also help us serve better our patients in remote locations that do not have unlimited storage space in special cold conditions. So very impactful in the short term, but also as we look to support every patient in every location in the world.

Lindsey: Yeah, absolutely. So not just the materials that we put the doses in, but actually how many doses we're able to put into the same sized vial and the difference that can make given infrastructure constraints that exist and even some of the pictures you see over the years of those who deliver vaccines scaling across rivers and things like that with small vaccine packs. Our ability to pack more doses into the same size vials really makes a big difference in patient access.

So, we're hearing over and over the unprecedented scale and speed that all of this important work is happening both to develop the vaccines and manufacture them. From a manufacturing perspective, what continues to be top of mind when it comes to keeping quality and safety at the heart of everything being done to deliver a safe and effective vaccine?

Elsie: We are facing a very interesting challenge in being able to deliver a vaccine in a very short time. That doesn't mean that in any way we are compromising the quality standards that we have. Us and PGS are very, very, very proud of our history of quality in our processes and operations and all we do. Quality has always been at the heart of what we do in manufacturing, and the same principle applies to the manufacturing process of this vaccine. In the first stage we will be manufacturing the vaccine in Pfizer sites, which operate with the highest standards of GMP control, good manufacturing practices control. We're using skilled and experienced subject matter experts, which bring the highest expertise in vaccines technology and processes the table. And we're also implementing all the required, validated cold chain transportation controls and data monitoring to meet the specific needs of the COVID-19 vaccines.

Lindsey: Really helpful background to hear and also that no matter where the doses go around the world, the same quality and safety considerations are kept at the heart of the manufacturing

operations. So Elsie, when it comes to scaling a vaccine like this, that's got simultaneous need forward globally, what are some of the things you're considering from a manufacturing standpoint to really scale at that level?

Elsie: As we think about the topic of scale up of this vaccine, in the long term we're definitely looking to build additional capacity, either internally or through contract manufacturers. In this effort, we're already engaging others to identify the best solutions and locations that could help us support the significant needs of patients in the future. In the very short term, we're also taking very immediate actions to support the needs for 2020 and 2021 through internal manufacturing. It is not an easy feat to scale up production in such a short time, but our team has been working very hard to ensure the availability of raw materials to support the ramp up of drug substance.

We're scaling up and simplifying the process. We're also developing a new process. So doing that, developing a process and scaling up, always presents a lot of challenges, but we have an amazing team in manufacturing behind this effort.

Lindsey: That's great, Elsie. So it sounds like the partnerships extend beyond just within Pfizer and within our own program. But we're looking at partnerships with suppliers of the products that help enable us to make the vaccine, like vials and stoppers, and the partnerships extend potentially down the road to other contract manufacturing organizations that could support scaling up at a level that the world could possibly need to meet the demand for vaccines of our companies and of others. So that's great context to have. Elsie, it was really great to have you join the discussion today and very much appreciate your time.

Elsie: Thanks Lindsey, it’s been a pleasure to join you in this conversation.

Lindsey: For more insight, I also spoke with Dr. Frank Mahoney, Senior Immunization Officer at the International Federation of Red Cross and Red Crescent Societies or IFRC. Prior to this, Frank worked at the CDC for over 30 years and assisted in the development of strategies to prevent hepatitis B and hepatitis C virus transmission in the Eastern Mediterranean region. Let’s jump in!

Lindsey: Well, Dr. Mahoney, really excited to have you here on this episode, and maybe you could share with us to start what your role is at the International Federation of Red Cross and Red Crescent and how you're involved in the fight against COVID-19.

Frank: Thank you, Lindsey. Thank you for inviting me to participate in this podcast. I'm the senior immunization officer at IFRC. I'm seconded there by the US Centers for Disease Control. I'm a medical epidemiologist and I've focused on immunization most of my career. In terms of my role with the Red Cross, the program on immunization is really focused on reaching children in fragile contexts and conflict areas. And since I've been working there, we have programs to vaccinate children in fragile settings like northern Nigeria, Pakistan, Afghanistan, Central African Republic. We also support some of the global work on disease control programs like polio campaigns, measles campaigns. And so the focus within the Red Cross movement has been reaching those underserved last-mile populations.

Part of my job with Red Cross involves working with the Gavi through the CSO constituency. IFRC hosts a constituency of community based organizations. I happened to be chair this year, and we work with Gavi on having CSO representation in all of the policy work that Gavi does. When COVID came, of course I was greatly concerned about how this would impact the groups, the teams we're working with through the Red Cross movement, and then the different countries where we're working.

Within the bigger picture, we recognized within the Red Cross movement that COVID was going to be a real challenge in many of these countries. And so I've spent a lot of time working with partners

on guidance on how to mitigate COVID transmission in settings where the clinical care may not be as advanced as other countries, where they may not have access to PPE.

We more recently have been involved with Gavi on their partnership to purchase the global COVAX vaccine facility. Gavi has been sharing with us some of the initial ideas about the COVAX facility, and we've provided feedback from the global constituency on how the COVAX facility is being structured and how it's going to work.

Lindsey: Thanks for sharing that perspective. It's fascinating how fast everything is moving around COVID and seeing things like the COVAX facility really meant to both help procure and finance COVID vaccines in the future, once they're available, coming together as quick as it has. And from your work in the civil society group, supporting Gavi and Gavi's work, how are you seeing vaccine development? What do you think is going well? And how are you tracking it?

Frank: I think our society is very clearly focused on equitable access to vaccine, having it at an affordable price, making sure that it can be produced to scale. Let's say a manufacturer doesn't have capacity to provide global supplies. Can there be a way that the developing world manufacturers can contribute and transfer to rapidly scale up production? I think a lot of those discussions are going on behind closed doors. Certainly civil society has a great deal of interest in that.

I think the other big thing right now about the COVID is of course the vaccine hesitancy that's emerged. I mean, it was a problem before COVID, but now with the COVID vaccine, we're getting feedback from many of our national societies is that caregivers are concerned about getting COVID within the healthcare setting and not coming for immunization sessions. And a lot of our outreach teams that go to remote communities and hard-to-reach communities have been unable to travel due to measures put in place by the government to prevent travel.

And so I think those are issues we're developing guidance on or structuring some support on how to maintain essential services in the context of all of these constraints. I will say that the Red Cross itself is committed to supporting immunization services. I was just on a call with our secretary general and he has raised immunization and support for equitable distribution of a COVID vaccine as a key priority for the whole of the Red Cross movement. And so he has called a number of national societies up today to discuss this issue. And I think there'll be advocating more support for global vaccines and also for maintaining essential services.

Lindsey: Yeah, absolutely. We're seeing a lot of the importance of continuing essential services like routine immunization, despite some of the social distancing requirements and stay-at-home orders, because we know there's diseases that we can prevent through immunizations that we already have. And it sounds like the IFRC is deeply involved in how to engage communities and keep those programs going while keeping people healthy.

As we think ahead to the not-so-distant future, when we're looking at vaccines that will be coming and what those vaccination programs could look like, maybe you could share your perspective on what the program could look like, what organizations like yours, what role you might play on the ground in communities as vaccination programs start to be implemented with some of the new vaccines that will be coming?

Frank: Particularly the COVID vaccines, I think it will really require a whole-of-government approach for many countries to effectively distribute a COVID vaccine. Yeah, my guess is that very likely initially it would be targeted to high-risk because of the limited supply. And so there would be efforts to push vaccines out among healthcare workers and high-risk elderly populations. My experience has been that countries can do this. We've done this in many countries to support wide-

age-range campaigns or targeted campaigns, if the government has a whole-government approach and real commitment to do this.

Obviously ultimately you would anticipate that a COVID vaccine would probably be, eventually be, recommended for almost all adults. And so you would expect to have a wide-age-range campaign and I would anticipate the government would enlist a number of partners, maybe faith-based organizations, or schools, factories, and provide services in diverse settings. And I think that a partner like Red Cross or other CSOs, faith-based organizations, would have a very important role to play in helping organize those efforts and operationalizing some of the services. I'm giving away my age here a little. To the early days of the polio campaigns when we were getting sugar cubes at church and things like that and had polio vaccines in them. So I would anticipate there'd be a very similar effort.

I personally have had experience in a number of countries where they've done that, where they've done a wide-age-range campaign. The one that I was very impressed with was working in Iran one time and they had mobilized the whole of society to vaccinate a wide age range for a measles vaccine. And it was really impressive how effective they were, but they were vaccinating in all kinds of settings, like I just mentioned, and really reached a high proportion of the population.

Lindsey: It's really interesting to hear those examples, both with polio and with measles, in that maybe we think about immunization across many countries as really being for babies. But it sounds like there's a lot of good examples that you've been a part of where there's experience in immunizing people of different age groups, which inevitably the COVID-19 vaccine candidates that will be available down the road would reach populations besides babies. And so it's good to know that there's organizations like yours that have that experience in reaching adult age-groups, healthcare workers, as a target immunization population. And thinking about it a bit more deeply, are there any suggestions, ideas that you have for companies as they're continuing their vaccine development to have in mind, recognizing ultimately down the road the goal is going to be to get the vaccine into the patients' hands in the communities that organizations like yours are reaching? What are the things we should be thinking about to get this right, suggestions of partnerships that you've seen go well?

Frank: Yeah, I can share one of my experiences earlier in my career. I worked a lot on Hepatitis B and at one point I was working in Egypt. And Egypt had a really serious problem during that time about bloodborne pathogen transmission in the healthcare setting. And I had been in Egypt four or five years trying to get them to vaccinate their healthcare workers through the national immunization program and the standard approaches. But in the context of preventing bloodborne pathogen transmission, we started working with the hospitals and healthcare facilities. And one of the barriers we had on using Hep-B vaccine at that time was it was very expensive.

So anyway, as we were doing this infection control training in a number of hospitals around the country, and we had a module on employee health and the importance of being concerned about your employee's health, making sure you have protocols to prevent needle stick injuries, and if there is a needle stick to test people and provide an immunization if they haven't been vaccinated. Anyway, we did this training on employee health and the Hepatitis B vaccination. And every time we did the training, the hospital was able to organize itself and vaccinate all their health workers without any additional money from us. They went out and just did it.

And so I think empowering communities to do that work on their own is really... I was amazed. And all it took was working with them about the importance of employee health and employee health programs, and independently they were all able to find a way to vaccinate and cover all of their healthcare workers. And I would expect with COVID that the hospitals will be ready. I mean, they'll stand up and provide services and take care of their workforce.

Lindsey: Yeah. It's interesting between the examples you shared around taking these moments in time when healthcare workers are getting education on the implementation of vaccines programs, and empowering the communities and the hospitals and the governments to actually educate people and immunize people as they can. There's a real implementation side of this that's key to get right. And it sounds like we've got a lot of good examples that we can learn from, from you and organizations like yours, on measles and polio and now your example of Hep B in Egypt.

Dr. Mahoney, thank you very much for joining me today for this discussion and really appreciate all that we could learn from you, and also the partnerships that we'll have down the road with you and your organization. So thanks so much for spending some time with us today.

Frank: Thank you for having me.

Lindsey: Thanks for tuning in to my conversation with Elsie Soto from Pfizer Manufacturing & Dr. Frank Mahoney from the IFRC. This episode concludes our special COVID-19 mini series of The Antigen, but the work doesn't stop here. At Pfizer, we are committed to helping bring an end to the COVID-19 pandemic. We will continue to work towards this goal and communicate our progress along the way. For the latest updates visit pfizer.com slash coronavirus.

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