PODCAST TRANSCRIPT

In Conversation with Stephanie Nolen: Reality check about “global” COVID-19 vaccine production


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Stephanie Nolen [00:00:09] The sad thing about this story is that I don't think it's going to get less relevant in the near term so...

Mitchell Warren [00:00:19] No. Which is actually one of the things I really want to talk about. What do we do with this? It's such a brilliant piece and really lays out in my mind a pretty clear roadmap in terms of who could do what. And again, that's going to be the purpose of the conversation. I see a lot of the attendees joining in and we'll get started in just a minute. Welcome everybody to this webinar. Mitchell Warren from AVAC here and I'm going to introduce and kick us off in just a minute. There's the chat feature, Q&A and raise hands. And as we get in this conversation, I definitely want to encourage people to raise your hands and we'll get you off mute and let your voices be heard.

Mitchell Warren [00:01:37] There are a lot of webinars and there are a lot of conversations to be had, but I'm super excited about this one because of the person you're going to get to hear from. I first encountered Stephanie when she was a bureau chief, as I recall the title, for Africa, based in South Africa. I won't ask how big the bureau was, but Stephanie has a long and distinguished career. When I first met her at The Globe and Mail, a leading Canadian paper, first in South Africa, then Asia and then Latin America. A number of years in different parts of the world and before landing back in Canada.
**Mitchell Warren [00:02:51]** The New York Times, was able to scoop Stephanie up just a few months ago as their new global health reporter. I know many of you on the line who work with AVAC and in partnership where our focus is HIV, so often we’ve thought together, over the last 18 or 20 months, about the connections between HIV and COVID. And so when Stephanie took on the global health reporting at the Times, I think we all assumed there would be some opportunities to see HIV and COVID connections in her reporting. And with no surprise at all, the first, I think, really in-depth piece that Stephanie did was an article that came out just now two weeks ago about COVID vaccine manufacturing, which is what we’re going to talk about. I’m going to just turn it over to Stephanie in a minute and have her describe the genesis of this story. What she found, what she thinks and hopefully engage with everybody in a conversation of what we do about it. It is a really remarkable piece of reporting. Why this story? What was the Genesis?

**Stephanie Nolen [00:04:37]** Well, thanks Mitchell, and thanks everyone for coming. It's always heartening to know that there are other people besides the four of us who want to talk about these things because that's how it feels sometimes. My very first day as a reporter at the Times, I got handed a quick news story on an HIV trial and I panicked. And then I thought, 'Well, I know a few people to call and one of my first calls, because I've been reporting on other stuff for a while, one of my first calls was to Mitchell. And then I spoke to a number of other people that I knew back from the days when I covered HIV pretty much full time. And the lovely thing, but also the somewhat sobering thing was that it was all the same people. It's a lot of the same really dedicated folks who have been working on this stuff and fighting this fight for a long time. And so it was lovely to reconnect with them. And also a grim reminder, even as the world gets super excited about vaccines and the possibility of vaccine technology, it was a grim reminder that certainly for HIV, the good news is still a long way away. So I kind of stumbled into this is often the way with what turns out to be interesting stories because I was curious. So obviously, the disparity in COVID vaccine access was really stunning. I was fortunate enough to be vaccinated myself in the summer when Canada did a big rollout.
And [I was] very aware that the people who are my close friends, after years living overseas in Brazil, in India, in different parts of Africa, were not getting that opportunity, and that the disparity did not seem to be lessening. And then I thought, 'Well, what do you do about that?'

**Stephanie Nolen [00:06:25]** And the existing model of donations doesn't seem to be working. In North America, we were already talking about the need for boosters, when nobody I knew in Latin America saw any sign of a vaccine on the horizon. And I have to confess that I didn't actually know very much about how you make an mRNA vaccine. I think like a lot of other people, I was kind of convinced that it had to be really new and fancy and complicated, incredibly, really complex to do. And so the question became, how could you tackle this problem of disparity?

**Stephanie Nolen [00:07:04]** There were already some voices saying, the thing you need to do is, you need to make them in different parts of the world. Relying on rich countries to donate them is not the basis for a public health strategy. That was a phrase I'd heard before in the years I lived in South Africa through the peak of the fight for HIV treatment through Zacki Achmat's amazing drug strike and the rise of the Treatment Action Campaign in South Africa and then the treatment action movement across sub-Saharan Africa. And so I started to hear a lot of phrases that were very familiar: 'Oh, donations will fix this problem.' Well, no. 'And well, you know, developing countries can buy them'. Well, there were not very many, for example, sub-Saharan African countries that could buy mRNA vaccines at the prices that Pfizer and Moderna were selling them. Although we would subsequently discover through, my colleague Rebecca Robbins is reporting that Botswana, for example, was paying more than the United States. There were countries negotiating bilateral deals that were being charged higher prices than than the countries in the global north.

**Stephanie Nolen [00:08:17]** And then could we make them? Could you make them in the global south, right? Because that was ultimately the solution to the fight for HIV
treatment. When you had companies like Gilead and Glaxo, Merck, saying there's no possible way we can produce these drugs for under ten thousand dollars per patient per year. It feels like ancient history to a lot of people. But you had countries whose drug companies in Brazil and South Africa and India raise their hands and say 'we could do it for significantly less'. And ultimately, famously, Cipla saying 'we could do it for under a dollar per patient per year.' Right.

**Stephanie Nolen [00:09:06]** So OK, that's great for drugs. Particularly some of those antivirals that turned out to be ultimately not very complicated drugs to make. So now we're talking about a whole different thing, right? Talking about vaccines and we're talking about a brand new vaccine technology that nobody else has used successfully. So could you do it? And I'll say that I went into this thinking, 'this is maybe a long shot, but you have to start somewhere.' And then I started tracking down people who know a lot about mRNA as a platform, who know a lot about messenger RNA and the idea of putting it in a vaccine. Because of course, this didn't start with COVID, right? People have been working on this for cancer drugs, for malaria drugs for a long time, unsuccessfully largely. But so there were a lot of people to ask.

**Stephanie Nolen [00:09:53]** And what I learned is, and this is a gross oversimplification, and I apologize in advance to any biochemist in the audience. Some very patient scientists explained this to me and then explained to me again, and explained it to me again. But basically, it's easier, right? It's, in fact, a lot less complex than making live culture vaccines where you're growing them in live cells, you're using attenuated viruses. The ones they make in chicken eggs, right? When you're using live cells, there's a huge amount of variation in that process. It's very hard to maintain quality. It physically involves just a lot more stuff. Tens of thousands of ingredients. An mRNA vaccine typically might have under 20, a couple dozen ingredients. So there's this one process of encapsulating your mRNA. In Pfizer and Moderna, we know do it in a lipid nanoparticle. It's essentially like wrapping it in bubble wrap so it can sort of travel safely through your system. They figured out how to do that and not have the mRNA break
down before it manages to deliver its little letter. There are a lot of other people who've invented vaccines that say they can do it, that are in clinical trials, the only people with an approved vaccine that's shown efficacy so far are Pfizer and Moderna using this process. So the process itself- and indeed the equipment, this one piece of equipment that you need to do it, which Pfizer and Moderna have bought the future production supply chain of that piece of equipment, like five years into the future- but that's the tricky bit. So, but all in all, not that complicated was the assessment from a number of different people that I asked.

**Stephanie Nolen [00:11:42]** So then I started thinking about, what do you need? You could go through a vaccine producer somewhere in the global south. And there are, I knew from years in reporting in different countries, there are quite a few. You need the ingredients, you need the drug substance. But again, like, not incredibly complicated. You need people who know how to do it. You don't necessarily need a vaccine maker. You could go to a drugmaker because again, the process is actually closer to making an enzymatic drug than it is to making a vaccine. So I started thinking, well, who is there, who could do this and who is there, who might want to do it?

**Stephanie Nolen [00:12:22]** So I was thinking about the parallels with the early days of HIV. Also because at this point you have Pfizer and Moderna, they're increasingly, through the late summer, being pressed on the issue of how are you going to resolve equity? And they're saying 'there's no possible partner. There's no one who could do it. It's too expensive. It takes too long. It's too complicated. No one's trained. We can't spare the people. It would take too long.' They're giving some iteration of all these and they're sitting. There was an extraordinary call with Pfizer in early September, where he was being asked about this push, about access and equity. And well into the call, he just said... It was a press briefing where all of the big pharma CEOs were taking questions from journalists by Zoom, and he's being pressed about access. It's like 90 minutes into this thing, right? It's been going on for a long time. And [Bourla] the president of Pfizer finally just kind of throws his hands up and he's like, "I don't know
what these people want from us. Do they want us to go somewhere and show them how to make it?". It was like,.

**Mitchell Warren [00:13:36]** Yeah!

**Stephanie Nolen [00:13:37]** Actually, I think actually that is in fact what people want. But his point was, 'we already do it and we're doing it and we're doing more and more of it. And we are expanding our production around the world.' The pharmaceutical industry argument since May has been there will imminently be a glut of vaccines. 'We have expanded production so much faster and so much more than we ever thought that we could. Production of vaccines is not going to be your problem. Delivery of those vaccines, the capacity of health care systems to deliver them, that's going to be your problem or vaccine hesitancy. That's going to be your problem. But production is not going to be a problem.' And you know, it is indisputably true. They have made extraordinary progress with production. It's much, much higher than was originally envisioned. I think the concern I heard from, certainly from developing country governments, well, there were three concerns. So this gets to the question of why do you need to do it, right? Do you need to set up somewhere else to do it? The first is that it's great that you say supply is going to solve it. Again, things keep happening. Now it's boosters, right? Kids. I'm sure most of you probably saw that extraordinary chart that the Financial Times put together on Tuesday showing that more people in developed countries have now had booster doses than people in developing countries have had first shots, right? So they may be making a continually larger supply. We also keep seeming to find a way to absorb more and more of that supply in the global north. So that's kind of a problem. One problem, too, is what we saw with COVAX and India in the spring of this year. The majority of supply of the AstraZeneca vaccine for COVAX is for donation. Well, the donations that were being channeled through COVAX were supposed to come from the Serum Institute of India and then India had a second wave, had done a really poor job. Either hadn't correctly modeled what was coming and what vaccination would do or, as one of my colleague Karan Singh found in an investigation,
in fact knew that information and suppressed it for political reasons. Either way, India suddenly decided that it wasn't going to export those vaccines and stopped exports, right? And so then you also had a stranglehold on this, this supposed glut of vaccines. You know, you can be producing them. It doesn't mean they're getting where they're needed. And then we had the situation with Johnson and Johnson in South Africa, where there was a lot of trumpeting about how finally vaccines were being made in the developing world, while in fact, Aspen Pharmacare in South Africa was bottling the JnJ vaccine, but then exporting almost all of that production back to Europe and Canada. So and then I guess I would say the fourth variable here is what we really don't know, right? Personally not as a journalist, but just as a human. I'm uncomfortable taking the reassurance of the executives of Pfizer or Moderna that it's going to be fine, because I think the great lesson of COVID is you really don't know what's coming. It's like anybody who has tried to predict what three months or six months down the road is going to look like. It's a fool's game, right? So I don't think that's a basis for a long-term public health strategy.

**Stephanie Nolen [00:17:09]** So we come back to this idea of it being important that the vaccines are produced in different regional centers across the global south. And so then I started asking people, where would you go? Who would you ask? And I called scientists and researchers and pharmacy executives, pharmaceutical executives and ministries of health and investment analysts, venture capitalists who always have a really good read on who is a promising biotech company. I tried to do a really broad, I don't know, I think I talked to probably 60 different people in the end. And I also asked, I'm really fortunate at the times to have a great network of colleagues. And so I enlisted Karan Singh, who had been reporting on the pharma industry in vaccines in India, and my colleague Muktita Suhartono in Bangkok, who is Thai and Indonesian, and had a good read on what people think of the different companies there. I called the the tireless people in the MSF Access campaign world and a lot of different people in treatment access and said who, who? What do you, first of all, what do you think is important? What would you be looking for? And given those criteria, who would you ask? Oh, I
called some really nerdy supply chain people who know nothing about global health, but who know a lot about where things successfully move. And essentially sort of plotted all the data points and a list of, I would say originally I had probably twenty five companies, that I think were strong contenders and four criteria that had emerged as what people said was important: what do you do now? What kind of facilities do you have? Not necessarily a vaccine facility, but like, what do you do now? Are you making a COVID vaccine? Are you working on an RNA vaccine or are you making vaccines at all? What's your track record like? How much money do you have as a company or could you get, as in how credible are you? What's the regulatory environment like in your country? Which, let me tell you, is a very unsexy but really important topic, right? So you have Brazil, for example, that maintains the European Medicines Council standards, basically FDA standards, right? So it's a lot easier to talk about doing this in a country like Brazil than in a country that has a much lower maturity level for its regulatory environment. But you can get around that if you're talking about a company that already makes WHO pre-qualify products right? They already have a demonstrated track history of being able to produce at a level that WHO says means that they can be exported anywhere, that obviously moves you up in the chain. And then, you know, people were very, very positive, for example, about the Argentine producers of three or four different companies in Argentina, big pharmaceutical companies. But as a person who has covered two giant economic crashes, and I don't know, three political crises in Argentina, you got to worry about that, right? That's again, that's a little bit like the India factor, like the big Indian biotech companies that are doing this are really impressive, but if the Indian government's going to step in tomorrow and shut down your exports, doesn't really help us. So that was sort of the matrix of things that we looked at. And eventually we hold it down to a list of 10. It was hard. I could have put a lot more people on that list.

Stephanie Nolen [00:20:34] I heard from some people once it was published, fewer people than I had thought I would. But who were crabby about who was off, who was not on, who should have been on. And I said, you know, it was a little bit like America's
Next Top Model. But the larger point being, it's a deep field, right? Like, there are a lot of places. And could any of these people do it tomorrow? No. I heard varying lists about what would it cost? How long would it take? What would you need?

**Stephanie Nolen** [00:21:08] Pfizer and Moderna will tell you that it's absolutely not feasible to address the vaccine gap by starting somewhere else. And I think there's two things to take into account when we think about that argument. One is if we had started when we were having that argument a year ago, if Moderna had said we are going to stand up production at this facility in Germany and in New Hampshire or wherever they are, and simultaneously in Sao Paulo and Puning, you know, the world would look really different, right? So we could have done it then, we didn't. We could have done it when we started having this conversation and we didn't. I think the thing to think about is, let's just do it now.

**Stephanie Nolen** [00:21:51] And certainly that's the way the WHO has gone about this. Then the second question is about how quickly you could do it. Moderna went from nothing to shots in arms in between three and six months. Right. And they did it by converting existing drug companies with a kind of pop-up kit that people that I talked to said was like the IKEA kitchen. And it's not a very staff intensive process. You don't need a cast of thousands to do this.Pfizer has tech transfer team run by a woman in India that they fan out around the world and and do this pretty quickly. So I think you can have, on the one hand, the argument of executives at those companies about how long it takes. And then you also have the evidence of actually how long it has taken them. So maybe they can't spare their core team. But at this point, that core team has trained a lot of people. So I think the argument that there's nobody around who could possibly help that happen, I think, is at this point deserves interrogation. And then also, it's not like they're the only people in the world who understand mRNA production right? There are a lot of people, including people who used to work for those companies, but a lot of other people in research institutions and private companies who have been
working with mRNA vaccines for a while. So I think there are a lot of possibilities for creative options of who could help that happen.

**Stephanie Nolen [00:23:34]** So the project in the end was a look at these 10. We sort of mapped them around the world. We said what their pros and cons were, and we tried to lay out for people what you would need to think about if you were going to do it. And we talked a little bit about the WHO hub and the effort that's underway in Africa, which is something that I hope I'm going to get to see in person in South Africa next week, which I'm very excited about. And I'll just say one last thing, Mitchell. Well, very long answer to your question. The thing that I was a bit sad that we had to cut a lot of words out of that piece in order to accommodate the videos and stuff. And I think the videos were important because I think there's a real value in showing it to people that it's kind of actually happening, but to accommodate all that a lot of the words had to go. But the majority of responses that I saw from readers was really at the level of like, 'Wow, there's places that could make this vaccine in the developing world'. Just the whole idea. It was just an interest. It was illustrative to me of the way that the kind of narrative, maybe because we're like, it's partly a narrative from Big Pharma, it's also because we're all feeling really grateful, right? Like I think everybody who's in this conversation and who's had an mRNA vaccine is probably really happy about it, right? So that idea that it's this kind of mystical thing. I cried when I got my shot, right? It's, I think, understandable to have in our minds, kind of exoticize this whole idea. And so the response was, 'wait a minute, there's a place you can go tomorrow in Cape Town or Rio and make this vaccine?' . That alone was a new idea for people. And so probably the thousand additional words that I had written about regulatory body maturity levels was perhaps unnecessary.

**Stephanie Nolen [00:25:34]** Let me say one more thing, which is that the thing that was the most interesting to me, and I'm really interested to see how this plays out. So this piece really focused on mRNA vaccines and how you could make those. There's obviously a number of other different kinds of vaccines and production for those are
also being expanded. We wanted to look at mRNA for a couple of different reasons specifically. One is that I think, especially because of the way that they took on this mystique in the global north, they are the preferred vaccine across most of the global south. Now they are the vaccines that people want. Even in places where people have mostly had access to Sinopharm or Sputnik. And I can tell you that both China and Russia have run quite aggressive misinformation campaigns. This is a story that I'm working on with my friend, with my colleague Sheera Frenkel about the mRNA vaccines, purely for economic reasons they're trying to create vaccine hesitancy around mRNA in order to create a bigger market for the Chinese and Russian vaccines. But ultimately, there's a huge interest in mRNA. But also because it is simpler, quicker, probably ultimately cheaper. That seems like a sensible way to go. And then also because we know there's very strong evidence that the platform is going to transition relatively easily to malaria, to tuberculosis, to a lot of other things.

**Stephanie Nolen [00:27:01]** Again, it seems like this is the kind of expansion of production that we should be talking about doing. And so there are two companies that we featured in the story or two, one company and one research institute, that have their own mRNA COVID vaccines that are in phase III trials. I am relying on their word about the data. They won't let me see it. So that big caveat. But I will tell you that I spoke to a number of people, that before we put them in the story, I asked a lot of people at the WHO who have been to both of those sites and spoken to the people working on it and who were very positive. So what will that phase III trial show you? I don't know. What will that data show you? I don't know. But there's the company in India called Genova. It's headed by an Indian scientist who worked for years for the NIH on malaria vaccines. He has the full support of the Indian government. And he says they've partnered with a Seattle biotech company called HTD and found a simpler way to do the the bubble wrapping. They layered on top of the bubble wrap instead of wrapping it up. That means that their vaccine is heat stable. It doesn't have to be kept ultra cold. So obviously that completely changes the conversation when you're talking about trying to vaccinate in the DRC, right? So that would be incredibly important. I mean, much cheaper to make.
And the Chula Vaccine Research Center in Bangkok also has their own homegrown COVID-19 mRNA vaccine. They were like Genova. They were already working on mRNA pre-pandemic. Theirs is also heat-stable, and they say also could be produced for a fraction of the cost. So those, I think, are really exciting. It would be great if Moderna sat up tomorrow and said the WHO hub is a brilliant idea for addressing access, and we are going to 100 percent fully cooperate. In the absence of that I think these two other independent options offer a huge amount of possibility.

**Mitchell Warren [00:29:02]** Stephanie, amazing. And so many questions, both popping up in various forms on the screen. What I think Ben Ryan is asking about is the response from the companies. I mean, you began with a quote from Stephane Bancel and Moderna. But what did they say? Not only in your reporting, but after, have you heard from them since the article was published disputing it, saying 'that's impossible. It can't be done.' What did you hear?

**Stephanie Nolan [00:29:31]** Nothing. Next question? Yeah. I have had good conversations with people in communications at Pfizer who have a great comms team and who essentially, that is their line: 'we're doing all we can, and we think this is the best way forward to address equity and that's what we're doing.' I heard nothing from Moderna. I could get no one to return a phone call or an email or any one of my dozen messages, including the messages in which I said, publishing the story, I'm giving you every opportunity to respond. This is what others have said. Nothing, nothing, nothing. I didn't hear from them before. I didn't hear from them after. I have nothing for you. I find it, frankly, not that like Moderna owes me a phone call, I find it fascinating that a company that plays as pivotal a role as Moderna does in a massive global health crisis does not feel the need to engage with not you and not me, but like the New York Times. No, nothing. Nothing.

**Mitchell Warren [00:30:42]** Well, I think for a lot of us on the line and I see a hand up, I'm going to call on you just a second, James, some of us aren't surprised by that. But
as I was told by someone many years ago, I'm never surprised, frequently appalled. This certainly falls into that category. And I do want to ask because you started at the outset, something I think a lot of people and we certainly at AVAC have thought this, that you can't donate your way out of a pandemic. But you do mention a bit about COVAX in the article. This question came up from a long time fabulous advocate Bill Snow about COVAX. Is there a role for COVAX or do we need to collectively move our minds to an entirely new architecture or paradigm for access?

Stephanie Nolen [00:31:41] You know, I don't know the answer to that, and it's something that I have been thinking about and thinking about. Also in the context of some other reporting that I've been doing about access to therapeutics and the new Merck drug molnupiravir. We now know within the last couple of days that Pfizer again seems to have an even better drug. And I mean, again, science by press release, right? They haven't made the data public, but they claim that their COVID treatment, and I've heard again from people who know more than I do, that it does seem that it's true. So when people started talking about access to therapeutics, asking are we about to repeat the same problem that we just had with vaccines, how are we going to do it? What are the mechanisms like? Do we use COVAX also for treatment? Do we set up a whole parallel mechanism? I will just say I have not dug into this. My colleague, Ben Mueller, has done much more. I don't really totally understand why COVAX has not been more succes.... I mean, my sense is that it hasn't been all that we were hoping for, right? So part of that is probably no fault of its own, right? If people don't make the donations, if India shuts down your supply, like all these things. Was the problem the fact that it's a whole new mechanism? Is it the fact that it brings together a few different parties? I don't know. I don't know the answer. Rebecca Robbins' reporting really shows that where vaccines have reached the poorest countries, it's been through bilateral deals, right? It's been purchases that have actually, surprise, it's been cold hard cash that have made those vaccines available. So will you see COVAX being supplanted? If, for example, Genova says that they are going to have their phase III data out by the end of the year? They're hoping for the first emergency regulatory approvals in the first part of
next year. They're talking about equity and affordability, they say, is going to be a key part of what they're doing, remains to be seen. They wouldn't be the first people to suddenly, once they have a really successful stable vaccine, to suddenly charge a lot more for it. But if they're serious, you know, then do you see Malawi bypassing COVAX and going right to Genova and saying, we're going to buy your extremely affordably priced vaccine directly from you? I think if those people, if the two or three organizations that say they've got their own heat-stable, very affordable [vaccine say] ‘we're going to sell it at the price of a generic drug'. If those come through, then my guess is that COVAX will be overtaken. I mean, presumably GAVI or whoever will also be trying to buy from those people, and you will have limits on what's available supply wise. But the bilateral deals have continued to be the answer to supply for a lot of places. And I have to confess, I really I don't know what's going on at the core of COVAX. I don't really understand what's wrong, and I have that on a list of things that we're talking to Ben and Rebecca about, whether that's something we need to report further.

Mitchell Warren [00:35:15] I think it's super important. And just to put a pin in it, it'll be interesting to see as the Merck Antiretroviral therapeutic hits the market. I just got approved in the U.K. I believe earlier today, Will it follow an existing mechanism or platform for low and middle-income countries? And it might be an interesting comparison and contrast between how a therapeutic works through potentially an existing infrastructure as opposed to trying to create something entirely new. And I think that's a huge test for advocates about what the future of the global health architecture is like. But as I say, lots of questions. James, I see your hand up, and someone who thought more about mRNA manufacturing, maybe, other than you is James Krellenstein from PrEP for All. So James, over to you.

James Krellenstein [00:36:10] Hey, Stephanie, thanks so much for the article. Longtime fan first-time caller, I guess. I really loved it, loved the article. Among all of us, there's really no question of whether people in the global south, or manufacturers in the global south can make mRNA vaccines. I think the answer is obviously, yes. And there's no
doubt or debate, at the end of this pandemic we need to have a system where there's globally decentralized manufacturing capacity. But the question I want to ask you are, two questions actually, is: in the short term crisis where we're losing, you know, just yesterday we lost 15000 people to COVID. Do you think that actually decentralized manufacturing is going to be the fastest way we get doses? You know, actually fill that supply gap. And there's two specific reasons why I'm asking this question. The first is, for any vaccine, right, they're not like small molecule drugs like HIV drugs. In order to get even a licensed version of a vaccine, that's not under the originator's control. Actually proving that it actually works, and approved and ready to distribute, you've got to do bridging trials. And those bridging trials are thousands of people. They take months to do so. Even ignoring for one second the possibility that we can get the manufacturing online really, really rapidly, if we're going to have to launch bridging trials for each one of these independent producers of the vaccine, isn't that going to be a lot of time before we actually get those doses into arms? And then the second question I would have is just looking at how tech transfer has actually gone with mRNA vaccines, right? You know, the only example we have really is Moderna to Lonza [vaccine manufacturer with sites in Portsmouth NH, Visp, Switzerland and elsewhere]. And we saw something really interesting, that every chemical and process engineer we talked to told us would happen. Lonza was able to launch in about two months in New Hampshire, right? Which is about a 40 minute drive from Moderna's facility in Norwood, Massachusetts. But it took about nine to 11 months to actually get there Visp Switzerland line online, not because Swiss people are any dumber than people in New Hampshire, of course, and not because there's not the same resources as in New Hampshire. But because when doing tech transfer on a technologically complicated product like an mRNA vaccine, having that ability to be really close to your originators line and actually drive down and see what they're doing here and drive back up made a huge difference. So even though the Visp facility is Lanza's flagship facility is actually better equipped than Portsmouth, it was able to go about two or three times faster to actually get drug substance online than what was going on in Switzerland. So I would love to hear your perspective on those two issues.
Stephanie Nolen [00:38:59] My perspective, which could be summarized as, yeah, I don't know. This is like, this is the America's Top Model aspect of this little thing where it's like, 'Oh, you can convince me of one thing. Well, you can now convince me too. And then I would call Zain, and he'd convince me of a different thing. So there is this proposal for Rwanda. This deal that Rwanda supposedly signed with BioNTech. Is that they're going to take a shipping container in Germany, and they're going to set up the production in the shipping container, and then they're going to airlift the same people and equipment and ingredients and all the things, and put it down in Rwanda. And then they'll just keep making the drug. Maybe they'll never even stop while they're being airlifted. And so then they won't need to do regulatory approvals because it'll be all this same. You don't need to do trials because you're still making the same vaccine. I feel like maybe that's not going to work as well as they think it is, but maybe I'm just a skeptic. The trials thing is a huge problem, and in terms of setting up production somewhere, I think that the hub, the hub in South Africa, the hub with the cooperation of Moderna, would be the thing that gets you through the largest number of those hoops, the most quickly. Failing that, yeah, you absolutely have to go through whether it's Genova or Chula, or it's the reverse engineered (not with the cooperation of Moderna) being produced in Cape Town and Dakkar, you, you absolutely have to do the whole trial process, and it's and it's going to be really slow. I don't see a solution to that besides actually just starting to do it. Will it be faster? Will vaccines come from somewhere else faster? Yeah, like conceivably. But again, what happens in six months when there is a new variant? And so now we're all getting some new tweaked Moderna booster and we're going to do all children and every person of every age in the entire global north before we do Malawi. Looking around right now, ues, the process of doing huge trials, starting with a whole new separate mRNA vaccine with huge trials going could take an incredibly long time. And does it seem like there should be something more efficient than that? Yes. And then I also just think, you have to look at the events of the last 20 months and think, we just also need to do this. We also need to just try this. And the proximity tech transfer question, I think is really interesting. Again, I think it
was Zain who told me about, so it's Novavax who flies people. They have a little team of people that they fly around the world, right? But AstraZeneca did it all on Zoom, which I think is kind of fascinating. I don't think it's easy. I think having the physical people there is going to be important. I think it will take a long time unless you're going to try the shipping container in space model that BioNtech is proposing. I'll say it seems like nobody that I talked to, nobody was this sort of undiluted cheerleader, right? Nobody said it's going to be super easy. People were very realistic and very sober about the fact that it was going to be complicated. A quote that I had to cut from the story, Patrick Tepo, who is the sort of chief scientist at Biovac, who is a partner in the WHO hub, Patrick said, 'here are all of the things that I can think of that are going to be hard and a problem and take a long time. And then there's all the ones that I don't even know about, right? ' He's like, 'I can't even tell you what I don't know, because I don't know it. It's going to be hard and slow and take a long time. And there's not, we don't have another solution except to just do it because nobody's coming to help us.'

**Mitchell Warren [00:43:19]** And I think there are a couple of questions that came up about tech transfer and the human resources and your table. And for those who have seen the article, there's a table of the various manufacturers. It shows the issue of production, facility, human capital, the regulatory piece, and the money. But of all those, where did any of these come out at the end, what's the price point? Do we assume that simply by moving to one of these 10 manufacturers in Latin America, Africa or Asia, is the actual price fundamentally different? Did people comment on what comes out the other end?

**Stephanie Nolen [00:44:04]** Nobody was willing to put a dollar figure for me on it. Which frankly, I didn't push too hard on that. Because I think that's fair. Because there's a million variables at this point and we don't what they are, right? I will say that for both Chula and Genova- Genova is owned by MCURE, which is a big generics manufacturer, and they really have access kind of baked in. I mean, whether it's access from a social justice perspective or just access as in 'if we're making the drug that's
viewed as accessible, this is a good business practice." Whatever. Affordability is very much at the forefront of what they are planning to make. A company like MCURE, supplies drugs to the Zambias and Chads of the world, right? They know what kind of a price point they would need to be talking about, to be affordable. And then obviously, that idea is also central to what's being proposed for South Africa, right? We are going to make this as cheaply as we possibly can for COVID and for everything else.

Mitchell Warren [00:45:18] And you mentioned that in your interviews across the board, you also talked with a bunch of venture capitalists, who often know what's on the horizon. You mentioned in the article that Aspen, the South African company, felt that for $100 million they could begin to manufacture and supply all of Africa, as you reported. In the scheme of the COVID response, $100 million is nothing. So I'm wondering if any of the venture capitalists or potential angel investors said, 'Oh my God, for $100 million, we could equip.' I mean, that seems like such a bargain to me. And I'm wondering did anyone say 'Stephanie hook me up?'

Stephanie Nolen [00:46:05] No, no oddly they did not. Yeah, it's funny. Hey, 100 million dollars. It's nothing. No they did not. I would say the venture capitalists were most interested in what's going on in India. This also ties into a couple of other different stories that I'm working on. There is now, I would say, an ecosystem of people whose job it is to broker deals in global health. They are finance people, like real City in London or Wall Street finance guys because there's so much money sloshing around in COVID. I've been working with some colleagues on figuring out who's behind some of these things. And I found it, I guess, funny, but I retain the capacity to be surprised, but I do. And it just has been very interesting to find out who's in the room when a lot of these big deals are being discussed about who's going to get what support, from where. Nobody said to me, 'Hey, give me Stephen Saad's phone numbers so that I can set Aspen up tomorrow with 100 million bucks.' The last time I talked to Stephen, he didn't have 100 million bucks. Again, the place where I sense that that money is really moving around is India. So Indian venture capitalists see huge possibility in this. And companies that we
didn't include on our list, like Panacea and Stelis, are having no trouble finding investors. And the Serum Institute, which is setting up its own mRNA facility, is just doing that out of its own incredibly deep pockets. So there's money moving around. I think most of it's moving either to or within India.

**Mitchell Warren [00:48:09]** Yeah, a super interesting and I think for a lot of us on the line from an advocacy perspective, making sure that, when we think about global capacity, it's not just the global north and India. We need to really be thinking more broadly. And I'm glad I see Zain's hand up. I was going to invite Zain into the conversation. Zain Rizvi from Public Citizen, another of the huge thinkers on access to medicine generally and particularly around COVID vaccines. And you mentioned him earlier, Stephanie. Zain, I'm not sure what you were going to ask, but I was going to actually turn to you to think about how it's not just responding to COVID right now. It's looking more broadly, I think, at capacity and access for the long term. But feel free to respond to that or the question you were going to put on the table.

**Zain Rizvi [00:48:56]** Yeah, thanks so much, and so sorry, I'm late. So first, let me make Stephanie uncomfortable by saying how amazing this article was. There's two things that struck me. One is reflecting on the past few months, and then one is more forward looking. What does it say about global vaccine manufacturing and kind of the ecosystem we have where the New York Times has to send out this reporter who fearlessly tracks down all these vaccine manufactures? Figures out their capabilities, assesses them, talks to a bunch of people and we have this blueprint on: what is available, what can be done and on what timelines? I think it's an amazing piece of work, and at the same time, it is distressing in a way that 1) it took so long and 2) that a journalist has to do this and governments have not already done this, at least publicly. Or tha the people who knew about some of these things were just not speaking up public, necessarily. Right? One of the really fascinating things about this article is it speaks about some of the advantages of mRNA. How mRNA can be useful for things in the future, how you can modify mRNA and suddenly it's useful. The other big thing
was about the production process, right? About how it's more enzymatic than it is kind of dealing with living cells. And frankly, just the size difference. mRNA manufacturing is thirty-seven liters and normal traditional vaccine manufacturing is two thousand or 20,000 liters. And I think the article does an amazing job of highlighting the promise of mRNA, including for future technologies. I was disheartened by the fact that it took almost a year since the Pfizer vaccine came out that we finally had this kind of really public and rigorous analysis of what is possible. That's my first instinct. The second thing I would say; ties back to your question, Mitchell, is that mRNA has a lot of promise. We don't know exactly what it will look like. We don't know if this is actually going to pan out, might just the hype. But there is reason to believe that this could be a whole new class of medicines for TB, for malaria, for cancer or HIV. And of course, you know, mRNA is a delivery mechanism, and those diseases have very complex kind of biological characteristics. So we still have to figure out biology. But if it is the case that mRNA vaccine manufacturing is established all around the world in a distributed way, then we're talking about vaccines for COVID, but we're also talking about vaccines for other diseases in the future. And what makes this especially promising, I think, also is that it's the world's investment against future pandemics. Right? If we have mRNA vaccine manufacturing all around the world in a distributed way, then we can actually stop or at least reduce the impact of pandemics very quickly. You know, I always go back to: it is November 11. Pfizer vaccine was authorized December 11 by the FDA. I think it's more than three million people. It might be more than four million people now who have died since the Pfizer vaccine was authorized. And so we knew what it would take to end the pandemic, and we still know what it would take to end the pandemic. I don't want to say it's a foregone conclusion, but governments around the world simply have not acted. And so I think it's really, just so powerful to look at quotes from developing country manufacturers saying, "Yeah, give us the tech and give us a hundred million bucks and see what we can do". You need to kind of validate that and assess that, and do the technical stuff on it, but (I tweeted this, and I stand by it, and I have liked every time I've seen this article pop up on Twitter) I really do think it is one of
the most important stories of the pandemic. And I'm so grateful for Stephanie to have written it.

Mitchell Warren [00:53:40] I don't know if that makes her uncomfortable. I endorse everything you said and I see her smiling. So I hope you're

Stephanie Nolen [00:53:49] Quietly mortified.

Mitchell Warren [00:53:50] Quietly mortified. You love it. This has got to be better than a journalism award to have advocates and activists say your piece is— and I think we have just a few minutes to the top of the hour, your piece is taking a brilliant, reportage in the New York Times to changing global health architecture. And there’s a great comment just that came in from Melinda Moray, a longtime expert in these areas of product development and manufacturing. She says advocates tend to be in disease verticals, and how do we change our advocacy for multi disease platforms? And I wonder in many ways, just as that came from Melinda, if that's very much at the heart of this, because this actually, it seems to me, isn't about COVID vaccines, and it isn't even only about mRNA. The old saying, history may not repeat itself, but it rhymes a lot. You were clearly hearing that rhyming in the beginning of the pandemic of what you experienced in HIV from drugs. And I guess the question is maybe to both of you, since you're on screen in the last couple of minutes, is what do we do now? What next? How do we take this analysis and all that's behind it to really retool our advocacy not only around COVID vaccines, because we need them desperately and we need them equitably distributed now, but what does it mean for the long term? And I am happy that to see if either one of you want to pick up on that.

Stephanie Nolen [00:55:28] My bits done. Over to you folks? I would just say one thing, which is that, I am interested in global health and I was drawn always due to HIV because it's fundamentally it's an equity issue, right? It's a justice issue. We can talk about mRNA being good for lots of platforms, but like ultimately, or lots of diseases,
ultimately where we're talking about is access right? And is there going to be a great new technology that continues to solve or starts to solve different health problems for people who have money and is, like so many others, out of the reach of people who might need it? So I think this very much is still about COVID because I think we're still going to be, we might get to stop talking about COVID in six months that would be nice, but there's still going to be a COVID problem in Zimbabwe, right? And so I think it's still going to be relevant for COVID for a long time. And then also, it's just going to be relevant for a lot of other things. You know?

Mitchell Warren [00:56:49] Absolutely, Zain, did you want to pick up on it?

Zain Rizvi [00:56:51] Yeah, just finally quick thoughts. It's about the technology, right, it's about the technology and getting the technology out there. We know developing countries want to make the vaccines. We know some of them are ready to make the investments, but it's about the technology. And so I the Biden administration should be pushing the companies to share the technology with manufacturers around the world. The Biden administration has the tools, it has the Defense Production Act, it has contractual rights and it has other IP. And it's the most powerful government in the history of the world. And this is why this is a pandemic. Thousands of people are dying. We need to get vaccines as quickly as possible to people all around the world, and we need to do that in a way that solves this crisis, but also leaves us better prepared for any future pandemic threat because this is the first pandemic in memory for a lot of us. But it is certainly not going to be the last.

Mitchell Warren [00:57:53] There's one last comment that came in from a colleague of ours in Kenya Dasiy Ouya about homemade vaccines and the acceptability when something might be made locally. And I'm reminded of a statement that John Nkengasong, the head of the Africa CDC and now nominee to lead PEPFAR, said recently, that Africa doesn't have vaccine hesitancy. We have vaccine scarcity and this idea of manufacturing locally not only accelerates equity and simplifies delivery, but to
Daisy's point actually gives people a sense of confidence. And again, and I didn't mean to say we're done with COVID at all, but it's not if we build it, it's not just for COVID, it is for so many other things down the road. Stephanie, early in your talk, you mentioned, had we done this back in November 2020 in anticipation of an emergency use authorization or had we done it in March or April. And it reminded me of the great story, when is the best time to plant a tree? And of course, the answer was 20 years ago, because now it'd be able to bear its fruit. It would give us shelter in shade. And the second best time is now. And I think your article and I don't think your work is done. By any stretch. On behalf of many of us on the line, the work of Public Citizen, the work of PrEP For All, the work of the COVID Advocates Advisory Board 9 that a number of people on the line are on) you know, it's great to read, it's great to see the multimedia pieces and we need to pick this up and articulate what do we do now? Because if we're still talking about this in three or six months and haven't seen the hub take off, even if the hub is not going to get a vaccine in arm in three months or six months, it is going to get a vaccine in arm a year from now, or two years from now. Or if we do have an mRNA vaccine for malaria or, in the longer term, potentially HIV. So really, really helpful. Stephanie, thank you. Any and you are about to make your first reporting trip in a pandemic experiences any any last thoughts on this call?

Stephanie Nolen [01:00:21] Well, I would just say as a question, I didn't get a chance to answer, but I saw in the chat about what's going on in Rwanda and Senegal. I'll just say as a teaser, I've been working with colleagues on a long investigation that relates exactly to this. And yeah, I just pick up the Times from time to time because there's a lot more coming on this topic. If I can in fact, navigate the incredible hurdle of the COVID tests, airport transfer, quarantine, vaccine passport, blah blah, blah blah and actually get there, we should have a great story to tell.

Mitchell Warren [01:01:03] We look forward to that. I do want to pick up on just one great [question] Bill Snow raises. He's asking about broadly neutralizing antibodies, which are obviously being explored for lots of things. We're expecting soon an FDA
decision on cabotegravir, the first nano formulated injectable for prevention that's already approved for treatment. The future of this is not just small molecules made in tablets by generic companies, which is the HIV experience we know. But I'm just wondering, we're quickly mRNA, broadly neutralizing antibodies, nano formulated injectables; is there a larger story if you're thinking about manufacturing, what are likely to be more complex biomedical products across all disease areas, maybe that's the platform and the focus about a multi disease advocacy. I don't know. Quick thoughts on that.

**Stephanie Nolen [01:02:29]** You probably thought more about it than I have Zain.

**Zane Rizvi [01:02:33]** In so many ways, we are just telling the same story over and over again. Right? This is the story of public funding contributing to huge scientific innovation, contributing to really breakthrough advances. And yet the fruits of that public funding are largely monopolized. Private corporations end up getting control over technology or being able to exercise unilateral authority over production and pricing decisions. And so many of the technologies you have mentioned. And let me say definitely in the case of mRNA. It started with the NIH. It started with the National Institutes of Health in the US. It started with US public funding. It started with European public funding. And so I think one of the real structural challenges and structural opportunities is making sure that we make the US government funding agencies make the NIH really understand that its mandate is about access as well, and particularly global access. Because when the U.S. government was handing over a billion dollars here and a billion dollars to J&J over there, that was the opportunity to really concretely and clearly identify how they were going to make this vaccine a global public good, how they were going to make sure the technology was shared and how they're going to make sure that people around the world had the capabilities of making this vaccine as soon as possible. And so I think a key priority has to be the really upstream stuff. And I can be candid in saying that sometimes it's difficult to focus on that stuff, because it feels so upstream, right? It feels like we're talking about 10 years from down the line.
But the problem is that the decisions that are being made now will have impacts 10 years from now, and then 10 years from now we wish we had intervened like here and now. And so that, I think, is really crucial. And as you look at things like gene therapy and CRISPR and access, this is, right now, we are in vaccine apartheid. But what does CRISPR apartheid look like? What is that? It's a lot to think about. It's really when we get into genetic modification and gene therapies, it's going to be a whole new world. And so we need to be ready as advocates to kind of meet the moment.

Stephanie Nolen [01:05:09] One thing that I would say about that. So when I was starting to report on therapeutics access for COVID and who would get it, I wanted to, I didn't end up using this reporting, but I wanted to talk a little bit about what that has already looked like for people elsewhere. I spoke to doctors in rural Ghana and I said, you know, did you manage to get remdesivir? Did you, back when we thought hydroxychloroquine was a thing? 'Could you get it? Like, No, no.' And I said' monoclonal antibodies', and they burst out laughing, and they said, 'if you could get monoclonal antibodies, you would rather just charter the plane and just get out of here, right?' Like that was the equivalent price, the flight for the price of monoclonal antibodies in Ghana. You can just fly to Europe on your own plane. And I have been working on a really interesting initiative. It's quite a good project working on monoclonal antibodies in Latin America. But what makes it interesting is that it's the one project that's looking at what you can make and how you can make it affordable. There's one little project in Ecuador, right? So [these issues of access and affordability] it's not baked in from the beginning at all. It's like here are these amazing technologies that are offering so much help to people in North America or, the possibility of hope in North America and Europe. And it's great that there's a little project in Ecuador, but there's a little project in Ecuador, right? And so it just, you know, Zain is thinking much more than I am about what you would need to do the upstream stuff. But I can tell you from trying to report it on the ground, it's just, we are having this conversation right now about COVID vaccines, and probably we will imminently be having them about therapeutics. But for everything else that's coming it's really not. It's it's not baked in from the beginning,
**Mitchell Warren [01:07:00]** We all learned that in HIV and it didn't get baked into COVID. And I guess that's the real metric of our collective success. Will we do better with CRISPR and gene therapy in a nano formulated injectable for PrEP? From HIV advocacy perspective, will cabotegravir for PrEP look like COVID vaccines, that people who want it and will benefit from it in the US get it in January, and people in low and middle-income countries talk about it and say, 'Well, I might as well just charter the plane.' And I think that's the test. And I know we all are really good at documenting the lessons over and over again. But the successes is when we actually apply the lessons. And I think that's the challenge for all of us. Huge challenges as someone put in the chat and lots to ponder.

**Stephanie Nolen [01:08:28]** Hey but the upside is now everyone's a COVID reporter. And let me tell you, from being in meetings people are aware of some of these things and aware of access issues in ways they never were. So there has there has been an upside. The Times created an internal channel so that science reporters could start answering questions from the entire rest of the newsroom early on in the pandemic because suddenly everybody had to understand epidemiology. And it's just interesting to watch the way the traffic to that channel has really trailed off because people know now, right? People have much more familiarity with it, with a scientific study. And obviously some of that's been problematic, right? Everyone's an epidemiologist. But also, I think people, I think globally, people have a new understanding of some of the ideas around the interconnectedness of public health that they didn't see.

**Mitchell Warren [01:09:17]** This is this is our moment. I mean, for those of us who do research advocacy, who talk about data safety and monitoring boards and and prequalification, those were, you know, the six of us. Now, you know, my mother knows about a DSMB.
Mitchell Warren [01:09:36] It's strength in numbers, but there is a rising science vaccine and research literacy, and we need to capture that for both R&D, but also for access going forward. So I am excited that you are back on the beat with the times that you're about to head out and really looking forward to pieces.

Stephanie Nolen [01:10:40] Thank you so much for having me. Thanks, everyone for coming.