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Marianne O'Hare: Welcome to Conversations on Health Care with Mark Masselli and Margaret Flinter a show where we speak to the top thought leaders in health innovation, health policy, care delivery and the great minds who are shaping the health care of the future. This week Mark and Margaret speak with Dr. Peter Hotez, Dean of the National School of Tropical Medicine at the Baylor College of Medicine, Dr. Hotez's team has developed a low cost vaccine, partnering with India and other international entities to allow poor and developing countries to produce their own vaccines to address the lack of global vaccine access. Also a pediatrician, he's concerned about the low vaccination rate in the U.S. let around the world, allowing for the spread of more variants.

Lori Robertson also checks in, the Managing Editor of FactCheck.org. Looks at misstatements spoken about health policy in the public domain, separating the fake from the facts, and we end with a bright idea that's improving health and well-being in everyday lives. If you have comments please e-mail us at chcradio@chcone.com or find us on Facebook, Twitter, or wherever you listen to Podcast. Now stay tuned for our interview with Dr. Peter Hotez here on Conversations on Health Care.

Mark Masselli: We begin 2022 with a grim statistic, the seven day average for new COVID cases in the United States has increased 82% compared with the previous seven days. The dominant variant is Omicron. We're told more variants will be on the way until the world can deploy additional vaccines. Our guest has an intriguing approach that promises hope.

Margaret Flinter: Dr. Peter Hotez of the Texas Children's Hospital Center for vaccine development has been called a global health warrior, the center is in its third decade as one of the leading vaccine development centers in the world. And now Dr. Hotez and his colleague have developed Corbevax. It's a low cost open source alternative to the mRNA vaccines, which we're using here in the United States, but which have been slow to roll out in developing and under vaccinated countries around the globe. But the Indian government has granted emergency approval for its use.

Mark Masselli: Dr. Hotez, we appreciate you joining us again on Conversations on Health Care, especially at this critical time and so many questions to ask about the new vaccine. Where the trials were done? What age range does it cover? How does it work compared to the mRNA vaccines that we are so familiar with in terms of the Moderna and Pfizer and tell us about its efficacy?

Dr. Peter Hotez: Well, this is a recombinant protein vaccine that's similar to the Hepatitis B vaccine that's been in use for 40 years. It's made through

microbial fermentation in yeast, and most parents in the U.S. have given it to their kids or the parents have gotten it for themselves when they were kids.

So it's got a great safety track record. And the level of neutralizing the antibody looks pretty exciting in terms of and comparable to the mRNA or adenovirus vectored vaccines, but at a fraction of the cost and ability to scale it up. And because this technology is already in place, in places like in terms of the Recombinant Hepatitis B vaccine, technology is in place already in Indonesia, Bangladesh, Vietnam, Brazil, and India of course. And so they can easily adopt our approach.

So what we do is we develop the prototype vaccine because we developed the vaccines for neglected diseases of poverty, we have been doing that for 20 years, and then transfer the technology with no patents, no strings attached. Now to India, Indonesia, Bangladesh and Botswana. India's the furthest along, they have 150 million doses already ready to go with plans to scale it to a billion doses this year. And we have just got released for emergency use authorization. So everything is really moving pretty well. We could have gone faster had we some support from the G7 countries. But that's life. But in the meantime, we're hoping to make up for some lost time.

Margaret Flinter: Well, Dr. Hotez thinking back to our last conversation with you. I imagine this has been an incredibly intense year. Not a lot of sleep, a lot of work pushing this forward. We want to thank you, as always, for your work, but tell us more. This is major news, obviously. And for India, and the other countries that you've described to have access to a new vaccine supply, obviously, a huge step forward. But I remember reading back early in the epidemic responses to vaccines around the world and India had some of the same issues, the United States did around vaccine hesitancy, resistance to vaccines. What are your people on the ground in India telling you about the willingness of people now using India as the country where you're launching this takes up the vaccine and really moving forward to get people vaccinated now that they might have a reliable supply of vaccine?

Dr. Peter Hotez: Well, we're hoping hesitancy will be lower than some of the other technologies. Because, you know, people of India have already been getting a vaccine of this technology for four decades. So they're familiar with it, they know its excellent safety profile. So hopefully, that will mitigate it against that somewhat. The other issue is making certain that India will donate doses to the COVAX sharing facility, that's going to be also important.

So it's going to be a mixture of vaccines used within India, but also exported to the world, and India has that track record as well. And as I say, where India's the first out of the starting gate, we're hoping to make similar progress with Indonesia, Bangladesh and in southern

Africa. And if we can get additional support from the U.S. government or others, we can make this arrangement with still other countries as well. And the advantage of the technology we're not constrained like we are with mRNA and/or adenovirus, where there's limits on the amounts you can make, the sky is the limit for this technology.

Mark Masselli: You know, we recently had Dr. Haseltine and Dr. Topol on who were complaining about the lack of sort of global leadership, that's sort of fallen apart, you just mentioned the G7 countries were sort of an obstacle, talk to us a little more about the difficulty that you encounter or the what needs to be -- what road needs to be cleared. So that we can start disseminating what sounds like a very easy to produce vaccine. And again, we're, I know, it hasn't had a peer review article been published on it yet, but talk a little bit about the global partnerships or lack of?

Dr. Peter Hotez: Well, actually, by the way, we've had about seven publications on our vaccine. So all of, we've put everything in the public domain. So every aspect of its production, its features, its characteristics is out there, and you can just go to the PubMed index and put my name in and you'll see a fair amount of details about the vaccine.

The clinical data has not been published yet. And that's because we, we provide the vaccine with no strings attached. So it's owned by the company, Biological E in India, just like it's owned by Biofarma in Indonesia, and Incepta in Bangladesh. And they work out the publication plan with the Indian regulators. And they say it should be forthcoming very soon. And actually probably will happen faster than the pharma companies did after their vaccines were released for emergency use.

So their vaccines had a three to seventeen week lag before the publication came out after emergency use, I think it'll actually happen faster. So that's moving forward. But and I think that's an important point that we don't, there's this concept in global health that we practice everyone talks about, called decolonization, and that we're not trying to own the technology. We're trying to give it to the countries to empower the country so they can, they can be out in the lead. So it's looking really exciting. And all that information itself what's coming.

Margaret Flinter: Dr. Hotez, I think that, you know, for those of us just kind of on the frontlines trying to respond to all of our communities and our patients. It's a little bit of whiplash this year with COVID. We think we're doing better we think we're doing worse. Delta arrives. Omicron comes in, I will tell you just on the front lines, we're seeing just such dramatic increases in infection. I know that just mirrors the national data. But maybe you could just tell our listeners is the vaccine that you've developed another tool in the toolbox of vaccines, but one

that we believe can be more readily available and distributed because of how you've approached this in terms of the ownership at the country level? Or is there? Is there anything fundamentally different in terms of effectiveness or effectiveness based on the number of doses? Or is it one more good tool or something fundamentally different? Just help our readers get a handle on that, if you would?

Dr. Peter Hotez: Well, the differences is it's produced locally, and meant to empower the low and middle income countries to produce their own vaccine. And it can be scaled locally and can be distributed locally. So and if you, and in terms of the nature of the technology, since there's already widespread experience locally to manufacture it. We think this is one that could be made in the billions of doses very quickly. And so if you're talking about vaccinating the southern hemisphere, the Global South, we think this, this could move quite quickly. I mean, that the truth is had we a fraction of the funding that Moderna had or Pfizer had from public sources, who knows the country, the world might have been vaccinated by now. And we would never have heard of something called Omicron. And so that's where the lack of leadership comes is the G7 countries and the U.S. government have not had that commitment to vaccinating the global south. And as a result, Delta arose out of an unvaccinated population in India earlier this year, and last year, and now Omicron out of Southern Africa. And we're going to have other variants of concern arise until we make that commitment to vaccinate the world. And this will be an important first step.

Margaret Flinter: Got it. Oh, that's a pretty important addition to the tool box. Thank you for clarifying that.

Mark Masselli: President Biden just spoke to the American people about the surging Omicron variant and the need to beef up our supplies of therapeutics. He announced that the government was buying 10 million more doses of the Pfizer, anti viral. I'm wondering if you could tell us why this therapeutic is so necessary in our toolkit to contain the severe disease into lower hospitalizations from COVID.

Dr. Peter Hotez: Well, you know, two of our three monoclonal antibodies appear not to work against Omicron, the one from Regeneron, and the one from Lilly. So that's a problem. And all we have in terms of effective therapeutics right now is the monoclonal antibody from GlaxoSmithKline/Vir. And that's only available in limited quantities in hospital formularies. And the Remdesivir, which has to be given parenterally. So having Paxlovid, the Pfizer medication will help a lot. And if we could get that sooner rather than later, that can also make a big difference. And so that is also a priority. But a reason why this Omicron epidemic is so dangerous, we have knocked out some tools that we have in our toolbox for treating it. A lot of health care

providers are getting sick and can't attend to the patients that are going into hospitals and the hospitalizations are rising. So even though on average, Omicron, may not be as severe as some of the previous lineages that aggregate effect of knocking healthcare providers out of the workforce of not having adequate treatment tools creates a very dangerous situation for the country.

Margaret Flinter: Yeah, we're certainly seeing that on the frontlines here in the United States every day. But I wonder if I can ask you the strategy of how this really becomes available throughout the world. Are you working with the World Health Organization, is that part of your strategy, as you think about how this vaccine could really get to all corners of the globe and try and bring this pandemic to an end?

Dr. Peter Hotez: It is and also the developing country vaccine manufacturers. In fact, they call themselves the developing country vaccine manufacturers network are now working with the World Health Organization for emergency use listing globally. So while we have started those discussions with the WHO were also in on some of those discussions. Because to get this pre qualified by the World Health Organization makes it much easier to for Biological E to export the vaccine to other countries. And so we're moving forward on that as quick as possible.

Mark Masselli: You know, we're entering 2022, Happy New Year, but it's the third year of the pandemic. We have had a million cases, positive cases the other day, I wonder if you can give our listeners a sense of, of the arc of this COVID virus, pandemic that's going on? What's your sense of what to be hopeful about? And what keeps you up at night?

Dr. Peter Hotez: Well, I do think this will subside and, and based on the kinetics of the, or the, the curve of this Omicron wave in the UK, in South Africa, hopefully it starts to go down as quickly as it's gone up. And whether or not it plateaus for a while remains to be seen. But eventually, this will pass and then we've got to decide what the world looks like post Omicron we know, the all likely Omicron is probably not going to produce much in the way of durable protection, people will still need to get vaccinated. So that's got to be a priority. It means defeating this very aggressive anti vaccine activities that are causing people to needlessly lose their lives by being defiant of vaccines. 200,000 Americans since June 1, who refused vaccines lost their lives. So anti vaccine, anti science activities are a top killer in the United States. So we've got to figure out how to conquer that. And lastly, we've got to vaccinate the world to prevent the new variants from emerging. If we can do those things we can get out of it, but it's still a pretty high bar.

Margaret Flinter: Dr. Hotez, I think as the world knows you are a pediatrician, you are a professor in the department of pediatrics in molecular virology and microbiology at Baylor College of Medicine. And I would imagine that at least once or twice a day, people are asking you what's going to

happen with schools? We're post the New Year's holiday, certainly seeing huge spikes, there's discussions about whether schools should close, stay open. Certainly seeing increases in numbers of hospitalizations of kids, although probably associated with just the dramatic increase. What are you saying to school superintendents and people there on the ground in Texas who want to know whether we need to close schools again, and take the kind of draconian measures that we did earlier in the pandemic that really thought we had moved away from?

Dr. Peter Hotez: Well, and in fact I was just asked about the mayor of New York's decision to keep schools open and I said, look, it's a choice between a bad decision and a bad decision. There's no good decision here. If you go back to virtual learning, we know about the harmful effects over the last two years on kids, on the mental health of kids and the Surgeon General came up with his report at the end of the year. On the other hand, trying to do this at the peak of a variant which is so highly transmissible almost to the level of measles, it's, that's going to be really, really tough to manage.

So is there a benefit to delaying the opening of schools another couple of weeks and tacking it on in the summer treating almost like two weeks of snow days. And as I say, I have a tremendous empathy and sympathy for administrators making those tough decisions. And I could argue it either way. And I think a lot of it has to do with the wishes of the community and the school boards, and but either way, it's going to be a very tough decision to make.

Mark Masselli: And another tough decision certainly for parents of young children, right, still no vaccine on the horizon, or maybe there is one of the zero to five birth to five years old. And this is particularly troublesome for young people, the Omicron variant, maybe walk through some advice for parents, what should they be watching out for, in terms of dealing with a variant. I don't simply know what parents can do with children in terms of who have no vaccine. But what's your best advice now for parents?

Dr. Peter Hotez: But, you know, I think the key first of all is kids, five and up are eligible to get vaccinated. And nationally, we're not doing very well, vaccinating the 5 to 11 year olds, only about 15 to 20% of kids are eligible are getting vaccinated. So I think there's room there, even among the teenagers, we're not seeing good vaccination rates in the northeast, a little better about 75%, but only about half that in the south.

So I think maximizing out the use of vaccines for five and up is going to be of paramount importance. And then for the little kids trying to keep them safe and you know, under five years of age, I don't think we'll have vaccines in the U.S. available anytime in the immediate

future. We're trying to do that now from India and globally with our vaccine. So this is the reason for being conservative and, and trying to make sure your kids wear masks in school so they're not bringing the virus home to the family.

Margaret Flinter: Dr. Hotez, congratulations on the development of this new vaccine. We'll be following its path from your lab to India and beyond. You can follow Dr. Hotez's work by going to bcm.edu/NationalSchoolofTropicalMedicine or follow him on Twitter at @PeterHotez. That's H-O-T-E-Z. Dr. Hotez. Thank you so much for joining us once again on Conversations on Health Care. Good luck.

Dr. Peter Hotez: Thanks so much. And thanks for all your great work and all the best to you.

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Mark Masselli: At Conversations on Health Care, we want our audience to be truly in the know when it comes to the facts about health care reform and policy. Lori Robertson is an award winning journalist and Managing Editor of FactCheck.org, a nonpartisan, nonprofit consumer advocate for voters that aim to reduce the level of deception in U.S. politics. Lori, what have you got for us this week?

Lori Robertson: With the release of its pediatric COVID-19 vaccine, Pfizer switched the buffer used in its formulation to increase the stability of the product. This allowed the vaccine to remain at refrigerator temperatures for longer. The Food and Drug Administration okayed the change and the change is also being made to some doses for teens and adults. Social media posts however, have misleadingly suggested that the ingredient swap is dangerous or was added to prevent heart attacks in children. There's no evidence to support that.

The ingredient in question is Tris or Trimethylamine, which is used as a buffer in the children's vaccine and will soon be available in some Adult and Teen formulations as well. A buffer keeps doses at the correct pH, neither too acidic or too basic. The original iteration of The Pfizer-BioNTech vaccine used phosphate buffered saline or PVS. Pfizer and the FDA have said the switch was made to improve the stability of its mRNA vaccine, which previously had to be kept ultra cold for long term storage and lasted a month in a refrigerator once thawed, the newer version can last in the fridge for up to 10 weeks.

Other experts back that up. Tris has safely been used in other vaccines and other products. Less stringent cold chain requirements are especially helpful for the pediatric vaccine, which is being administered more in doctor's offices. As for social media post claims about Tris being dangerous or a drug for heart attacks. In large quantities Tris can be used as a drug. But here as in other vaccines

and medicines, the compound is present in only a very small amount as an inactive ingredient to keep the vaccine stable.

Dr. Kawsar Talaat, an infectious disease physician and vaccine scientist at the Johns Hopkins Bloomberg School of Public Health, told us the infinitesimal amount of Tris in vaccines has absolutely nothing to do with the much larger volumes and higher concentrations of Tris being given to people who are having heart attacks. The Pfizer-BioNTech COVID-19 vaccine is not known to increase the risk of a heart attack in any population. Instead, the cardiac concern that has been identified for the two mRNA vaccines is an increased risk of myocarditis, or inflammation of the heart muscle, and pericarditis in inflammation of the lining surrounding the heart, particularly in young men. But these adverse events are rare and as a buffer Tris would not be expected to modify the risk in either direction. And that's my fact check for this week. I'm Lori Robertson, Managing Editor of FactCheck.org.

Margaret Flinter: FactCheck.org is committed to factual accuracy from the country's major political players and is a project of the Annenberg Public Policy Center at the University of Pennsylvania. If you have a fact that you'd like checked, e-mail us at www.chcradio.com. We'll have FactCheck.org's Lori Robertson check it out for you here on Conversations on Health Care.

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Margaret Flinter: Each week Conversations highlights a bright idea about how to make wellness a part of our communities and everyday lives.

Daniela Tudor, had a revelation a few years ago waking up on the cold floor of a jail cell, she could ask for help for her drug and alcohol addiction or she could die. She chose the former. Tudor then launched not only on her own recovery journey, but on a broader quest to develop tools that could help all people grappling with addiction recovery to avoid relapse, which is so common, especially in the early days of sobriety, she realized that there needed to be more readily accessible tools for those in recovery to stay connected to their treatment goals. Beyond the 12 step meetings and the talk therapy sessions,

Daniela Tudor: I am in long term recovery. And I went through a four-week inpatient treatment program, where at the end of that four week program, all I received was a piece of paper that listed an enormous amount of things I'm supposed to do on a daily and weekly basis for the rest of my life to stay in recovery. And I knew that building something on our cell phones that are with us 24/7 regardless of where you're from and who you are, would be a way to bridge that gap and keep people accountable through an app to those activities.

Margaret Flinter: So she founded WEConnect a relapse prevention on the go mobile application that can be downloaded on a smartphone. The platform is designed to keep people engaged in their recovery plan using daily reminders and a reward system for when you perform the tasks that are essential to recovery.

Daniela Tudor: The individual along with the support of our certified peer recovery support specialists are able to input those activities into the app. And when it comes time for that activity to start, you simply check into it. You see at the top of the app, how you're earning your incentives. And by the way, this incentive program is based on evidence based research called contingency management. So it's actually proven to show that it keeps people accountable to their recovery plans or their care plans. The way that we've digitized it in the immediacy of that incentive, keeps people accountable to checking into those activities on the go.

Margaret Flinter: And the digital platform also allows everyone who's connected to the person's health care ecosystem to see in real time activities that are enhancing recovery. And also when one might be at higher risk for relapse.

Daniela Tudor: We have trained peer recovery support specialist all across the country. And they get to leverage a tool that we developed called a data dashboard, where they can see in an instance if someone needs additional support or outreach, and that is built through the app with keeping them accountable to those activities and the peer having insights on how they're staying accountable to those activities in real time. So it really allows for this connection of support 24/7 and visibility so that when someone needs that added support, you know, not days or weeks go by which is without this program is what happens, but rather gives insight and gives the option for connection in real time.

Margaret Flinter: Since the pandemic hit Tudor says the WEConnect platform has been a lifeline for those in recovery. Those now often cut off from meetings and in-person sessions during the shutdown.

Daniela Tudor: Actually, when the pandemic hit, immediately, my heart went out for Wow, none of us have support meetings to go to any more in-person. So we immediately stood up with a set of partners, these mutual aid meetings that are online that are led by certified peers. And within just a couple months, over 200,000 people joined from all states and several countries.

Margaret Flinter: WEConnect, a downloadable app designed by people in recovery for people in recovery, to help maintain sobriety with a support system in the palm of their hand, keeping them on track with health goals, staying connected to a care team and avoiding relapse. Now that's a

bright idea.

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Mark Masselli: You've been listening to Conversations on Health Care. I'm Mark Masselli.

Margaret Flinter: And I'm Margaret Flinter.

Mark Masselli: Peace and Health.

Margaret Flinter: Conversations on Health Care is recorded at WESU at Wesleyan University, streaming live at www.chcradio.com, iTunes, or wherever you listen to Podcasts. If you have comments, please e-mail us at chcradio@chc1.com, or find us on Facebook or Twitter. We love hearing from you. This show is brought to you by the Community Health Center.

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