Ep. 2: Vaccine IP Fight; Delicate Dem Dynamics; Deciphering CDC

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Dr. Mario Ramirez: Hi, and welcome to the second episode of *OnAir: Health Care*, a podcast by Akin Gump that brings you to the intersection of policy, personnel, and politics. I'm Dr. Mario Ramirez, a consultant with Akin Gump and a practicing emergency medicine doctor.

Matt Hittle: And I am Matt Hittle, a senior policy advisor with Akin Gump. Mario, it's awesome to be back with you for episode number two.

Dr. Mario Ramirez: Absolutely, Matt. Super excited to be here. Before we get started, I want to make sure that we thank the behind-the-scenes folks. I want to give a special shout-out to Jose Garriga, our senior communications manager here at Akin Gump who handles all the operations, as well as Sean Feely, our policy advisor who edits all the transcripts. Thank you to both Jose and Sean.

Matt Hittle: Yeah, absolutely. Couldn't do this without them, so major thanks to them. Well Mario, we've gotten a fantastic response from the first episode of *OnAir: Health Care*. Really excited for that and thank you to all of our listeners so far for all of the ideas for the podcast. Keep them coming, please. But for today, we have a full episode. First, we're going to have Mario Ramirez talk about the latest COVID science, including CDC's [*Centers for Disease Control and Prevention*] new guidance for vaccinated people, and that is an update from our previous episode.

Dr. Mario Ramirez: Absolutely, Matt. We're super excited to welcome two guests today. The first is Ed Pagano, a partner here at Akin Gump and former senior Democratic Senate aide. He's going to talk about what's on tap in Congress following the massive $1.9 trillion American Rescue Plan, particularly in light of the delicate Senate math that we have to use to get to 50 votes.

Second, we're going to have Akin Gump partner Clete Willems, a former senior Trump administration trade official, who's going to discuss the potential for the Biden administration to limit patent exclusivity for COVID vaccines, an issue that's come up for many manufacturers.

Matt Hittle: Thanks Mario. We're going to turn first to a segment we're calling “Capitol Conversation,” where we prognosticate about what Congress is likely to tackle. For that, we're turning to our colleague, Ed Pagano. Ed is uniquely suited to comment on these matters and all the goings-on under the Capitol dome, given his long tenure both as a Senate staffer and a key Obama administration official. Thanks for being here, Ed. Why don't you tell our listeners about your background?

Ed Pagano: Thanks Matt and Mario. I'm Ed Pagano, I've served as a Senate Liaison for Legislative Affairs for President Obama and before that I served as a Chief of Staff and Senior Counsel on the Judiciary Committee for Senator Patrick Leahy, a Democrat out of Vermont.

Matt Hittle: Awesome. Well, Ed, you're uniquely suited here so let's dive in. Congress is coming off of a—I think we can all agree—glorious two-week Easter/Passover recess. I hope everybody's emails were a little less the last couple of weeks. Democrats are emboldened by their win on the American Rescue Plan. They have been looking to capitalize on that success with an infrastructure effort. The first question I have for you, Ed, was posed on Twitter this week, and it became a meme: What is infrastructure?

Ed Pagano: Infrastructure is in the eyes of the beholder. I think this is going to be a long and winding road to the final package on infrastructure. This is the beginning of the debate, certainly not the end. President Biden has made a broad proposal; it's an outline and is not legislative text. Congress will now delve into the details, and I expect vigorous debate in the House and Senate in the upcoming months, defining what is infrastructure, and what can achieve a majority vote in the House—a very closely divided House. Actually, now three seats divide Republicans and Democrats in the House based on several confirmations of House members to the Cabinet. That's really going to stay very close in the House. Then in the Senate, there's a 50-50 Senate, so any senator can be the king or queen of the caucus if they really care about an issue, for or against it. So, expect a rigorous debate and many twists and turns on the road ahead.

Dr. Mario Ramirez: Let's dive into that a little more, Ed. Even if infrastructure, whatever it is and however we define it, occurs in some of the processes like reconciliation, Dems still have to get to 50 to end debate and pass the bill. Can you help our listeners understand the complex dynamics within the Senate Democratic caucus right now and maybe what the path forward looks like on infrastructure?

Ed Pagano: Sure. You are correct, we need a majority vote, so, in a 50-50 Senate, that means that Leader Schumer must unite all of the Democratic caucus, from Bernie Sanders on the left, Joe Manchin on the right, and 48 other Democratic senators in between. Infrastructure, although it's been talked about and actually became a bit of a meme about infrastructure week in the previous administration, they're really delving in now to the details, but they're really new.

Congress has not had this serious debate before. We're going to have to see how it all “sugars off,” in a Vermont phrase. It's certainly going to be, by the traditional infrastructure definition, roads, bridges, highways. I think you probably have bipartisan support that broadband access, particularly in rural areas but also in underserved urban areas, is part of the debate on infrastructure. That may

not have been the case 20 years ago, but certainly we saw during the pandemic how important broadband access is for remote work and remote school.

Then there are members of the House and Senate on the more progressive side that have talked about potential drug pricing, child care investment, climate change, housing, even immigration reform as potential parts of an infrastructure package. The key in the Senate on reconciliation—and I know it gets a little detailed—but, in general, it is about what legislation impacts on a budget process for tax and spending and less on policy. That enjoys the reconciliation protection, which, in the Senate, means a majority vote. Otherwise, you need 60 votes in the Senate to pass legislation: the so-called filibuster rule. So, we're looking at a reconciliation package that will be determined in the scope of it by the Senate parliamentarian, and she has now become probably the most powerful person in the free world. Everyone will be trying to convince the parliamentarian, “yes, this falls within the scope of reconciliation” on one side, and arguing against it on the other side.

As you saw with the debates on the minimum wage increase that President Biden proposed, the House passed the minimum wage increase, and it actually was taken out of the Senate bill that became law because the Senate parliamentarian ruled that it was not within the scope of reconciliation protection.

Matt Hittle: Ed, after this is all over, I think we're all going to be experts in arcane Senate procedure, unfortunately.

Ed Pagano: Sorry about that.

Matt Hittle: You touched on this a little bit—as our listeners know, the term “infrastructure” in the Biden-Harris context here includes, I think, $100 billion for broadband, as you noted, and $400 billion dollars for increased home and community-based services under Medicaid. That's about one-fifth of the American Jobs Plan, which is huge. This comes on the heels of the pandemic in nursing homes and decreased census rates in nursing homes; the industry is reeling. Senator Sanders talked about lowering the Medicare age to 60. Just today, House progressives unveiled a wish list including allowing Medicare to negotiate drug prices, which some Republicans would say is, essentially, price setting. So, there seem to be “poison pills” dotting the landscape here and a lot of moving pieces on the health care front in particular. We've talked about the broad strokes here. Getting down to brass tacks, what's the realm of the possible?

Ed Pagano: That is to be determined over the next several months. Very ambitious plans by some members. Can they unite the Democrats? Because, you mentioned, Matt, “poison pills” probably is the view of most House and Senate Republicans. We live in partisan times, for better or worse, so, I do think this package will go through the reconciliation route, the route of a majority vote. And that process just becomes even more partisan, so, I expect this infrastructure package to be Democratic-supported only. Republicans probably united or minimal support, depending on how the package evolves.

All the provisions that you just mentioned, these proposals are really going to have to be fleshed out, and they’re going to have to see if they can get majority support—majority support of probably Democrats only. We shall see.

Dr. Mario Ramirez: Well, it's interesting, Ed. On that point, the powerful House Energy and Commerce Committee recently had a legislative hearing on several bills that would expand and build upon the ACA [*Affordable Care Act*]. That looks like maybe a blueprint for House action on health care. If it is, do you think that a package like that could get to 50 votes? Or do you think that some of the folks really in the progressive wing of the Democratic Party are going to have a hard time supporting something like that? Is it going to be too paltry for those folks?

Ed Pagano: That is the two- to three-trillion-dollar question. Can the centrist Democrats agree on some of the more-progressive proposals? Can the progressive Democrats scale back some of their ambitions? Can Speaker Pelosi corral both those wings in a House that is so closely divided? We're talking about a 435-member House and three to four votes right now divide Republicans and Democrats. I know a lot of folks focus on the Senate because it's 50-50 and you can see that one senator has a lot of power. But I would argue, given how close the House divide is, that it's maybe even tougher a task for Speaker Pelosi to unite her Democratic caucus on these details.

Dr. Mario Ramirez: Interesting.

Matt Hittle: Well, and Ed, when we think about reconciliation, we think about the middle-of-the-night markups, ramming legislation through on partisan lines. Are we talking something that's going to happen very quickly, or what's the timeline here and when do you think that stakeholders involved should start to engage?

Ed Pagano: I would engage now. The debate is happening. Speaker Pelosi has announced that she would like the House Energy and Commerce Committee and Transportation Committee to debate bills in the coming weeks, with a goal of reporting things out of committee by May and the goal of passing an infrastructure package in the House by the July 4th recess. The Senate would then like to take something up in the July work period before the traditional August recess. It's an ambitious timeline, we'll have to see if the House and Senate can meet that. But the details are being worked out as we speak. Folks are really delving in, staff and members, and so my advice is now is the time to engage.

Dr. Mario Ramirez: Well there you have it, folks. Ed, thanks for that fascinating insight into the inner workings of Congress right now. I know our listeners appreciate your thoughtful insight.

Matt Hittle: Thanks for being here, Ed.

Ed Pagano: Thank you.

Matt Hittle: Alright, Mario. We're turning now to a segment we call "The Doctor is In," featuring you, our resident physician here at Akin Gump. Mario, in the last episode, we discussed CDC's guidelines for vaccinated people. But of course, as always happens, in the mere week and a half since we've recorded, the guidelines changed again. This just emphasizes what we talked about in that first episode, which is that CDC is pulling in so much information and trying to make reasonable nationwide guidelines. It's a nigh impossible task because the science changes every day. But it's not just those guidelines, there seems to be a lot of churn coming out of government regarding COVID information. It's all

against this backdrop of rising case counts in some places, plateauing case counts in others. So I want to start there. Could you give us a sketch of what's happening with these rising case counts? Are we actually headed for a surge?

Dr. Mario Ramirez: Absolutely, Matt, it's such a good question. I think one of the real challenges of working in public health and that CDC faces every day, is that you're trying to cast a message that is applicable to the entire country, but that at the same time is flexible enough to reflect what is happening individually on the ground, which in a lot of ways is different from place to place.

I think if we step back from the guidance for just a second and to answer your question about whether we're headed for a surge, there are really two competing trends that we're seeing. Folks may have heard about this footrace against the variants, so, let's break down what that means exactly. A couple of months ago, we preferentially targeted vaccinations towards older Americans. What we're seeing is that the number of cases and the number of hospitalizations and deaths in older Americans has continued to drop, which is all great news. But, conversely, what we are seeing is that the number of cases in younger Americans, those people who are age 20 to 50, are really starting to increase. The concerning sign is that rate of increase or the acceleration is increasing in those groups.

That's primarily driven by two things. The first is that people are out moving around more—we've started to open schools, we've started to open businesses, some of the states have removed mask mandates. But then the other part is the variants. The variants have become the buzzword in the country right now, particularly related to COVID. But what folks need to know is that these new variants seem like they attack and infect younger people much more efficiently than the original strain of coronavirus. So, when we hear these mixed messages about things are getting better, but case counts are going up, that's why. Because, for particular groups of Americans, particularly younger Americans who haven't been vaccinated yet, the situation is still pretty dangerous out there.

The good news is that we're vaccinating more Americans on a daily basis, and if we can really get vaccines into those younger folks over the next two to three months, then I think we're going to be well positioned to continue the downward trajectory. If we can't get those folks vaccinated, then it's likely that we're going to see a sizable surge heading into the summertime.

Matt Hittle: Got it, okay. With that groundwork, let's dig into what the CDC has said recently with respect to vaccinated people. As you recall, we discussed this on the last episode and since then, CDC updated its guidance. So give us a summary of what the update is and what it means particularly for travelers, because I know we're about to hit the summer travel season here.

Dr. Mario Ramirez: Yeah, you're right, Matt. I think there's three issues that are worth highlighting for listeners real quick. One of the questions that I raised on our first episode was that the guidelines really did not address travel. I think a lot of folks brought that up as well. Since then, the CDC has come out and said that if you have to travel—they're still calling it essential travel, not recreational travel—but if you need to travel for essential purposes, that travel is safe in the United States and internationally provided that all of the public health measures are in place during your transit. That means, specifically, that people are using masks, that they are

continuing to socially distance in airports, and that they're continuing to wash their hands and sanitize things frequently. That's a big change.

We know, just looking at the travel numbers from TSA and from the airlines, that people are clearly traveling for more than just essential purposes. People, I think, are pushing beyond the CDC guidelines. But this is the first recommendation we've seen that it is, in fact, okay to travel on airplanes, from the CDC. That's really a watershed moment, I think, in terms of getting the country back to a place where people feel like they're able to move around. Now the important piece, and I can't highlight this enough, is that it applies to vaccinated persons who've completed their vaccination series. That's either two weeks after your second dose, or two weeks after your single dose of the Johnson & Johnson vaccine. That's the first big policy announcement that we saw this week.

There were two other things that are worth highlighting, though. In addition, the CDC updated their transmission guidance for surfaces. An ongoing question when the pandemic first broke out was how long the virus was viable on hard surfaces and how much cleaning and disinfection needed to happen. I think this is important because this is a big piece of getting folks back to work, about getting schools reopened. What the CDC essentially said over the last week was that the virus is not viable on hard surfaces after three days, and probably much shorter periods than that. They emphasized that deep disinfection on a daily basis is probably not needed. That there is still some risk, there will always be risk present, but the majority of coronavirus spread happens through respiratory droplets. It's not happening on what we call fomites or surface contaminants that are then being spread to people. I think this is going to go a long way to shaping some of the guidance from OSHA and the EPA and other groups that have a handle on how do we clean, how do we disinfect things. That was another policy change that's coming down the pike.

The last thing that I want to highlight for folks was that the CDC edged closer, they didn't quite definitively say it, but edged closer to saying that the vaccines are actually helping to stop transmission. An ongoing question was whether or not if you have been vaccinated, are you still capable of asymptomatically spreading the virus? The CDC Director, Dr. Walensky, cited a good-sized trial of hospital care providers who had been vaccinated, about 4,500 personnel, and then also looked at data from the U.K., and looked at data from Israel and saw that the transmission dynamics dropped off considerably in vaccinated individuals. Now, it's not quite enough to say with 100% certainty that if you're vaccinated, you're not transmitting it, but we're getting closer to that point. I think the CDC and other public health folks are wary of saying that something is absolutely impossible without a sizeable body of evidence, but we're continuing to build that body of evidence.

Matt Hittle: I have to say, I'm just happy that we can end the sanitation theater, the spraying down of every surface. I remember I would wear latex gloves when I pumped gas several months ago, so I'm just happy we don't have to do that kind of stuff anymore. But CDC does have, like I said, an impossible job. They've just got to be very cautious before they make a judgment call because mistakes can potentially cost lives. We all understand that. The CDC is under incredible pressure to deliver quickly. People are getting their vaccines, saying, "Okay, I want to go take my international trip now. Please tell me I can do that." But

they're being cautious. How soon should we expect CDC to issue the next big tranche of policy news?

Dr. Mario Ramirez: Yeah, this is reading the tea leaves a little bit, Matt. We don't know for certain, but I think that we've probably seen all of the major policy updates that we're going to see from CDC for a few weeks. I think there are certain things that people are really looking for specifically. I think folks want to know when can we start to have mass gatherings again? When can we have concerts? When can we go back to the theaters? Also, when can we start going back to work in person?

But what I think the CDC has said, to my point earlier, is that they're not going to issue specific new guidance until there is a solid body of evidence that definitively says something is safe, or at least is able to quantify or stratify the risk of doing something. In fact, they only changed the recommendations about schools and the six-foot versus three-foot rule when there were a couple of big studies that came out in short order just a few weeks ago. I think we have not seen that there is a lot of data that is about to be released on some of this mass gatherings stuff yet, so I think the next set of big policy announcements are probably several weeks away.

Matt Hittle: Got it. Well, let's talk about work. You referenced returning to work and many of our listeners, I'm sure most of our listeners, are listening from home rather than the office. After over a year of remote work, people are wondering when they will get to or have to go back to the office, depending on your perspective. OSHA [*Occupational Safety and Health Administration*], which governs workplace safety, was supposed to issue temporary employee standards by March 15th. That deadline came and went, so lots of employers are now waiting and wondering when to expect it. What's your take here?

Dr. Mario Ramirez: Yeah, a lot of us were really watching this March 15th date pretty closely, and we expected that OSHA was going to issue this temporary employee standard on or before that date. There was a lot of discussion about what that was likely to include because it could potentially have huge ramifications for returning to work. I think most of us had expected that the temporary standard would be in place for about six months and might include a requirement that employees wear masks, that it might include improved guidance about cleaning, and possibly require social distancing and keep this six-foot rule as something that employers had to maintain. Then there were big questions about the responsibility of employers to report symptom outbreaks in their facilities and how they would report testing results. Also, what are the responsibilities of employers to actually conduct testing in the workplace? That was really the guidance that I think a lot of us were looking for.

Instead, to your point, they decided not to issue that temporary standard, but instead have said they're going to use something called the National Emphasis Program. In some ways I think this reflects the fact that the science is changing very quickly right now. If you're OSHA and you issue a temporary standard and then your CDC counterpart says that the science is actually different on this, it's a tough thing to go back and revise those rules in real time in a way that employers can adjust for on the fly. Instead, I think OSHA has issued this National Emphasis Program where they identified key industries where they have either seen evidence of increased spread or they believe that the conditions are such

that they're ripe for increased outbreaks. In particular, they have said that they're going to focus on industrial agriculture, as well as meat packing and food plants, because folks work together in tight quarters and those areas have been sources of increased spread.

It sounds like OSHA is directing their inspectors to emphasize inspections, particularly as we get into the summer and into the fall. But there are still many people who believe that a temporary rule could be forthcoming, so we have to wait and see.

Matt Hittle: Okay. Well, in the meantime, what are employers and employees to make of the current landscape? I guess what I'm asking here is: When should we start the workout regimen to ease the transition from sweatpants to suit pants? I'm asking for a friend.

Dr. Mario Ramirez: Well, if you're like me, you've probably put on a couple of pounds during the pandemic. I think maybe a better way to say it is: When are we going to be going back to the beach and when are we going to be going back to work and when should we start to bring some of those pounds back off? I think those changes are probably pretty soon, over the next few months. Like I said about case rates, the real question is going to be what happens with that younger population of folks and how many of those folks can we get vaccinated, and how can we convince that population to really opt into vaccination.

The message that we heard earlier in the pandemic was that this was not dangerous for younger folks. I think it's shifted a little bit with some of these new variants that have shown to be more dangerous in younger folks. The vaccines look like they work well against these variants that are out there circulating, so if we can get all of those folks vaccinated, then I think it's time to start toning up and getting ready to head back to the workplace soon. Because if we get all those folks vaccinated, then these case counts are going to drop off really quickly. On the other hand, if folks choose to opt out or one of these variants breaks out of the vaccines, then this may continue for a little while longer and we've got a little more time in sweatpants to go.

Matt Hittle: Got it. Well, before I head out on my jog, one more question for you. Last episode, we recorded a piece about the guidance and it changed quickly so we had to quickly record a caveat. For our editor's sake, how settled is this guidance for vaccinated people right now?

Dr. Mario Ramirez: I believe it's pretty settled, Matt. I think that our editors can rest assured that there won't be late nights. I think maybe another way of asking your question is: How much confidence do we have that these vaccines are going to keep working and that the guidance isn't going to change? Like I said, right now all of the studies that we have show that the vaccines work really well against the variants. I think there's going to be two key things that we're looking out for that might potentially shift any guidance.

The first is whether we see any of the variants that we sequence show the potential of breaking out against the antibodies that the vaccines produce. If we see something like that, we'll conduct the mixing studies in the lab and we'll take a look and we'll see if there's something that looks concerning. But then like I said before, the other thing is whether we start to see vaccinated persons getting

sick and being put in the hospital. Some of these vaccines, particularly the single-dose candidates, don't prevent all infection, they prevent serious infection. At some point, the conversation is going to shift away from just raw case numbers and it should specifically focus on how many people are being hospitalized and how many people are dying, because those are really the most important metrics.

I think if we see changes around those, then we might see some of the guidance change. But for now, things like those recommendations are here to stay.

Matt Hittle: Got it. Mario, thank you very much. We're calling our next segment, “Patent Pending.” We're talking about a recent push by some countries, led by India and South Africa, to waive patent exclusivity for COVID-19 vaccines. To dive into this today, we're turning to Clete Willems, a partner at Akin Gump and former senior trade official in the Trump administration. Welcome, Clete. Tell our listeners about your background.

Clete Willems: Sure, thanks so much for having me on today. As you mentioned, I'm a partner now at Akin Gump. I joined Akin about a year and a half ago from the Trump administration where I was the Deputy Director of the National Economic Council, and I was also part of the National Security Council. Prior to that, I worked during the Obama years at USTR, the U.S. Trade Representative's Office. I started my career on the Hill with Congressman Paul Ryan, who's my home district congressman from Wisconsin.

Dr. Mario Ramirez: We're glad you could be here, Clete. I've got a question. Last fall, several countries, particularly led by India and South Africa, petitioned the World Trade Organization [*WTO*] for suspension of intellectual property protection around COVID vaccines. I think we are all aware of the inequitable access to vaccines around the world, but can you give us just an idea of what this would look like and where the issue stands? I know there's a lot of hot button issues here and would love to get your thoughts.

Clete Willems: Sure. This is the issue that we call the TRIPS waiver. TRIPS is an agreement under the World Trade Organization. It actually stands for Trade-Related Aspects of Intellectual Property Rights and it's a multilateral agreement to which the United States is a party, India, South Africa, Europe, China; all WTO members basically signed up for this and it requires the signatories to protect intellectual property in their markets. It lays out different conditions for how you're supposed to do that and it covers the whole gamut from patents to copyrights, industrial design, and everything in between.

What India and South Africa proposed starting last October, was basically that a broad range of provisions throughout the agreement should be waived because intellectual property protection was serving as an impediment to the distribution of vaccines around the world. That's been their argument. A couple interesting things about it: a lot of people when they think about this issue, they think about patents. But India's proposal actually applies to a whole bunch of other stuff not related to vaccines, like copyright. The other point that I think is interesting is they made this proposal before there actually was a vaccine that was being distributed.

So, there are some interesting aspects to it and we can get at why that is. But long story short, they made this proposal in the fall, they've tried to get support for it. The United States, Europe and others, certainly during the Trump administration, were very opposed to this and really saw it as an effort by these countries to undermine IP, which has been a longstanding interest of theirs. But now the Biden administration is thinking about what it's going to do.

Matt Hittle: Let's dig into that, Clete. As I understand it, the administration plays a key role here. Describe what that role is for our listeners and—you mentioned there's a shift over time—describe the shift. Please put it in the context of the political dynamic, because as our listeners all know, everything is dependent on the politics.

Clete Willems: Right. Well, sure. We shifted from the Trump administration to the Biden administration and one thing the Biden administration has said is that it wants to try to be a more constructive player in international institutions. I think at the same time, the Biden administration feels like it's under pressure in what I would call the debate over vaccine diplomacy. You have China and others sending vaccines around the world and the U.S. wants to show that it's doing its part to try to vaccinate people outside of its borders as well.

You have this dynamic that exists. I think you're getting pressure from Congress as well, on the Democratic side in particular, saying, "We need to be a good actor at the WTO and we should consider this waiver." So they're looking at it. There's been a robust inter-agency process that's underway. There's a lot of key players here, but I'll highlight a few. First, there's USTR, who really is the lead on this issue because they represent our interests at the WTO. There's the National Security Council, who is really focused, I think, on the diplomatic elements of this, along with USAID [*United States Agency for International Development*]. Then you get other agencies like Commerce and in particular, their Patent and Trademark Office, who really cares about how U.S. intellectual property is treated within these international organizations. They're just some of the key players that have been talking about this, debating this issue, and trying to come up with a path forward.

Dr. Mario Ramirez: Clete, I heard you mention China in there. Let me expand that to Russia, as well. Where do China and Russia fit into this equation? Would they benefit from the waiver or what's their position on this?

Clete Willems: Well, now you're getting down to the substance. I think I've been trying to give a high-level overview of the issue itself. But when you turn now to the substance, and the question of whether or not we should do this, the argument again that you hear in favor of this is that the U.S. has to do its part and that this will somehow increase vaccine distribution around the world.

Now, the counter argument that you hear to that, and this is where I'll bring up China, but let me start with the first counter argument and then the second argument on China. I mean, the first counter argument and the one that I happen to believe, is that that's just false, that this will not actually help with vaccine distribution. The problem is not IP, the problem is just the lack of distribution channels around the world. Let me give you two examples on that. First, you have the ability for countries to license this technology. The United States has licensed its technology to Indian companies, in fact, who are producing this in

India. India has a Serum Institute, which has worked with AstraZeneca. Gilead has also worked with manufacturers in India and basically licensed their technology to them so that they can produce this.

If you can't get an agreed-upon license arrangement with a U.S. company or a European company, there are also provisions in the TRIPS agreement called compulsory licensing, where if you try to get a license on reasonable terms and you're not able to achieve that, you're able to do what is called a compulsory license where you basically do it by force. Now, the problem then with India's proposal, is it's basically trying to ignore all that stuff, circumvent all that stuff, and say, "You just need to give away this technology for free." Again, I think my view very clearly is that U.S. intellectual property protection is part of the reason we have the most innovative companies in the world who are producing this. Further, that that intellectual property protection is not an impediment, because as I mentioned, you can have licenses or you can even have compulsory licenses.

To me, it looks like this is just part of India's and South Africa's longstanding efforts to undermine intellectual property rights through the WTO and really doesn't have anything to do with COVID—that's just the latest excuse. Now, I promised I'd talk about China and I know it took me a little while to get there, but I thought this other context was important.

When it comes to China, the issue is really this: China has identified the pharmaceutical sector and advanced techniques of manufacturing these drugs as part of its Made in China 2025 plan. It wants to dominate these industries, wants to be the world leader in them, and wants to surpass the United States. This sector is a core part of its ambitions for dominating industries in the future. What we also know about China is they utilize a lot of "tools"—unfair practices—to achieve those goals. One of the things that they utilize is a policy called forced technology transfer. Many of you know who follow U.S.-China trade relations, that's there's basically a whole trade war fought over this issue. It's something that both Democrats and Republicans have widely condemned.

The problem here, of course, is that basically what you are doing is if you endorse this TRIPS waiver, you are endorsing a system of forced technology transfer in an industry that China is trying to dominate in the future. So you're basically aiding and abetting China's Made in China 2025 ambitions, if you endorse this TRIPS waiver, by basically breaking down the international rule set that is intended to protect these kinds of things from those kinds of practices. I think that is a political dynamic to this that I think initially when the Biden administration started looking at this, they didn't fully appreciate. I think now, especially from the national security types, this has really gotten them to be a little bit more nervous about what endorsing this would really mean.

Matt Hittle: Clete, it seems like this fig leaf of reducing patent protections to assist poorer countries is covering up this deeper substance that you just went into, which I think is really important. But you're not the only one who's identified this cover. *The Wall Street Journal* recently released an editorial suggesting that vaccine manufacturers are already, to your point, sharing intellectual property and stated, "Even if the WTO suspended patent protections, India and South Africa still couldn't make vaccines without cooperation from developers." The associate director for innovation at the Duke Global Health Institute said the proposal was "more symbolic than practical."

Do you think that it would even be worth it to entertain this, given the really serious implications with respect to the non-IP issues that have been bubbling up for some time? Is the fig leaf here even worth it?

Clete Willems: No, I don't think that it is. I think you said it well. You have a proposal on the table that's going to undermine decades-long U.S. policy that promotes the protection of intellectual property rights through the international trading system and recognizes that strong IP rights are the best way to lead to innovation in a given industry. You're going to undermine that principle and you're not going to get anything in return. I think what the U.S. had started to look at, and that I think is a much more preferable approach, is what are the ways that we can actually create distribution channels and facilitate the sharing of vaccines with poorer countries around the world, with countries that don't have the same access that we do in the United States?

I mean, don't get me wrong, that is a laudable goal and one that we should be trying to achieve. I just don't think this proposal is the way to do it. Bill Gates actually has said something similar about that and about the need to basically fund the distribution. A lot of folks have looked at past examples where we've done something like that. PEPFAR [*President's Emergency Plan For AIDS Relief*] was an example way back when in the Bush administration, when we were distributing drugs throughout Africa to deal with health issues that they were having. We put a lot of funding behind that; we put a lot of money into building up distribution channels instead of totally undermining IP because we recognized it wouldn't actually solve the problem.

Now, one thing this administration has done that I like, is it did enter into a partnership with the Quad [*Quadrilateral Security Dialogue*] countries. Which interestingly, includes India, along with Japan and Australia. Basically, this proposal would put U.S. money behind trying to distribute vaccines to the developing world. It doesn't deal with the IP, recognizes IP is not an impediment, but it does recognize that money is an impediment and distribution channels are an impediment and tries to use that as a way to achieve this. I think that's a much better approach, looking at what we did through PEPFAR is a much better approach. We should try to achieve this goal, let's just not do it in a way that undermines longstanding U.S. policy without actually achieving what they're trying to achieve.

Dr. Mario Ramirez: Okay, I want to drill down on that just a little bit more, Clete. I think we can all recognize, and the economists and other groups have brought attention to the fact, that the vaccine in underdeveloped countries is pretty slow-going at this point. Personally, one of the things that I've supported has been the U.S. re-engagement in the COVAX [*COVID-19 Vaccines Global Access*] effort, which is a pointed effort to try to distribute vaccines to those countries. But if relaxing patents isn't part of that, is it strictly distribution or are there other issues that are also at play here? I know indemnification and some of these other things around injury claims are also out there circulating. What else do our listeners need to be thinking about here?

Clete Willems: Well, I think you hit the nail on the head with indemnification. That has been a problem, as well. I do think that maybe there are ways that the U.S. government could try to provide some of that assurance to U.S. companies if the countries

themselves that are going to be the recipients of the vaccines aren't able to do so. But at the end of the day, I would hope those countries could get there on indemnification because if you do want to have access to this, you're going to need to do everything on the ground to facilitate your ability to receive that drug.

I would also say another issue that we haven't yet touched on is the issue of export restraints. There are a lot of countries around the world who are putting in place export restraints on their ability to send this stuff abroad. So if it's produced in Europe, can it then be distributed or sold in the U.K.? That's been a hot button issue. India itself, interestingly, has actually put in place export controls, as well. As I mentioned earlier, India has licenses from U.S. and European countries to produce this vaccine and they have now put in place export controls to prohibit those vaccines from being sent abroad until June. I do think it's a little bit ironic that the U.S. is feeling pressured and feels like it’s being portrayed as the bad actor here, when a lot of other countries around the world are also taking actions that seem very much focused on protecting their citizens and really not looking at the global picture.

I do think this is a little bit more of a complicated issue than is being portrayed, as though the U.S. just needs to do its part. We all need to do our part and like I said, distribution, export restraints, indemnification, these are all part of the solution.

Matt Hittle: Clete, what is the timeline here? We've talked about the substance of the issue. I want to get to the nuts and bolts. You mentioned some of the relevant agencies within government that are considering the waiver. What has to happen going forward? When do you expect it to happen? When will the Biden-Harris administration actually make a decision and what do you expect that decision to be?

Clete Willems: In terms of the timing, there isn't a specific action-forcing event, in the sense that the WTO meets regularly, it discusses this and other issues and the next meeting of the TRIPS committee is going to be in June. They could always call an emergency meeting, which would force the U.S. to decide whether it is going to maintain the same position that they did under the Trump administration in blocking this. There are also conversations in Geneva. The new director-general of the WTO has been convening meetings to discuss this with manufacturers. I think she's been trying to be productive here. She hasn't come out and endorsed the waiver, she hasn't come out and opposed the waiver. She's basically doing what she's calling a third-way solution where she's trying to figure out is there a better way of cooperation and facilitating these exports without having to necessarily require the forced technology transfer of this sensitive IP.

My point is, there's no action-forcing event, so it really just comes down to how much pressure does the Biden administration feel to get to an answer here based on what it's hearing from Congress and based on what it's hearing from the international community? They've been discussing this for over a month now, they've been holding inter-agency meetings. USTR is now hosting meetings, they call them the TPSC, it's the Trade Policy Study Committee, that hosts interagency meetings to come up with solutions. That process will take at least a couple more weeks to work itself out, until they'll come to an answer.

In terms of where they land, again, I think there are different agencies with different opinions. I think USAID is pretty forward-leaning on this. I think elements of the NSC [*National Security Council*] may be forward-leaning on this. I think agencies like Commerce Department and PTO [*United States Patent and Trademark Office*] would be inclined to be opposed to this. I think the career folks certainly at USTR understand that this would reverse decades-old U.S. positioning on IP and I think they would be inclined to be opposed to this. They're going to have to work all that out.

I personally think at the end of the day that it would be a huge mistake for them to come down in any way other than opposing this. If you just think of, as I was talking about earlier, the global competition with China, to come out and basically endorse technology transfer of mRNA—very sensitive technology—to China would be a huge mistake. One thing I haven't mentioned, is a lot of this technology was funded by DARPA, funded by our Defense Department as a national security strategic priority and that was part of the way that they came up with this technology that produced these vaccines. So for us to give DOD-funded research over to China just doesn't make a lot of sense. I think that as that becomes more and more clear to the Biden administration, I predict they'll ultimately do the right thing here.

Dr. Mario Ramirez: Interesting. Well, that's super fascinating, Clete. Clearly this is a complex issue with a lot of different nuances that I'm sure our listeners are interested to learn more about. Thanks so much for coming on the podcast today.

Clete Willems: It's my pleasure.

Dr. Mario Ramirez: Well, that'll do it for this second episode of *OnAir: Health Care*, your podcast here with Akin Gump. I'd like to give a special thanks to our guests, Ed Pagano and Clete Willems.

Matt Hittle: Absolutely. It was a fantastic episode, chock full of information. Be sure to like and subscribe to get more. And as always, if you have ideas for episodes or, of course, if you'd like to compliment us on our radio voices, our email addresses are in the description.

Dr. Mario Ramirez: Signing off, I'm Mario Ramirez.

Matt Hittle: And I'm Matthew Hittle. Join us next time on Akin Gump's *OnAir: Health Care*.