

# Borderless COVID-19, Restricted Vaccines: Assessing the global pricing of vaccines and treatments

April 28, 2020

OK. Hello, everybody, and welcome. Thank you for joining us for this webinar entitled Borderless COVID Restricted Vaccines. This webinar is organized by Global Access in Action, a project of the Berkman Klein Center at Harvard University. GAIa, as some of you may know, focuses on promoting access to medicines for vulnerable populations to policy and regulations.

My name is Ash. I'm an affiliate of GAIa and Berkman Klein Center. Before introducing our speakers, I want to remind you that you should be happy and free to use the checkbox to interact with other participants, but also most importantly to drop your questions in the Q&A box and to vote for the question which you wish the speakers to answer first.

So I now have the pleasure to introduce our two speakers for today. Quentin Palfrey is the co-founder of Global Access In Action. Quentin currently serves as president of International Digital Accountability Council, an independent watchdog created to improve digital accountability through international monitoring, investigation, education, and collaboration with online applications and platforms.

During the Obama administration, Quentin was the senior advisor for jobs and competitiveness in the White House Office of Science and Technology Policy and deputy general counsel for strategic initiatives at the US Department of Commerce. In these positions, Quentin played a leading role in efforts to develop baseline consumer privacy legislation centered on the idea of a consumer privacy bill of rights.

He also served as the lead White House staffer in connection with passage of the American Invents Act, the launch of the Patent for Humanity Initiative, and the relaunch of the Privacy and Civil Liberties Oversight Board. Prior to his time in the Obama administration,

Quentin served as the first chief of the health care division in the Massachusetts Attorney General's Office, where he oversaw multimillion-dollar litigation and investigations against insurance and pharmaceutical companies and played a key role in decisions relating to the implementation of the Massachusetts Landmark Health Care Reform Law.

Quentin also served several nonprofit organizations, including JPow North America, where he worked to improve the efficacy of social services in the areas of health care, economic mobility housing and education, and the voter protection corps. Quentin was most recently the 2018

democratic nominee for lieutenant governor of Massachusetts. Quentin is a graduate of the Harvard University and Harvard Law School. So thank you for joining us, Quentin.

Our second speaker will be John Stubbs. So John is familiar to many of us who are connected to the Berkman Klein center. He's a Washington DC-based affiliate of the BKC where he works to connect scholars and experts to policymakers in the Washington, DC area on issues related to international trade in addition to supporting GAIa's work on innovative medical technology.

John is also the managing partner of Romulus, a Washington DC-based consulting firm that helps executives and corporate boards develop and manage a proactive, productive global public policy agenda. From 2001 to 2007, John worked for the W Bush administration, including a senior advisor to the US state trade representative.

He is currently a board member of the National Foreign Trade Council Foundation, board member of the National Association of Urban Debate Leagues, and a founding member of the Krewe du Kanaval supporting the work of KANPE Haiti and the Preservation Hall Foundation in New Orleans.

So thank you both for joining us. It's a pleasure to have you both on this panel. So Quentin, as of date, the COVID-19 has infected more than 3 million people and killed at least 210,000 worldwide. The US alone has more than a million cases, and several European countries remain hot spots.

On other continents, public health experts continue to be concerned about the increasing trends in all regions as cases of death might be underreported. So there is definitely an international community pledged to coordinate for a global trial on the safety and efficacy of therapeutics for COVID-19.

And where I come from-- so I come from Africa, as you know-- the CDC Africa and the African Union have also stepped up to call for coordination of responses, but also to rethink how procurement and supply chain would look like to address the COVID-19.

And while Africa faces a lot of health challenges, including inadequate supplies of medicines, that's now being made worse by international hoarding and overpricing, a lack of health professional, inadequate infrastructure. Everybody is converging towards the fact that vaccine efforts should be guided by three imperatives-- speed, manufacturing deployment, and global access.

But while this global race for COVID-19 vaccine intensifies, there is a question that keeps popping into many of our minds. When a successful vaccine emerges, will the market power be allowed to dictate access, and will most vulnerable nations be able to afford it?

Thank you so much for your kind introduction, Ash, and hello to all of you. I see in the attendee list a lot of familiar faces and some good friends of our program over the years. And I hope everyone is doing well and is safe in these really extraordinary and troubling times.

I think I can share my screen and share some slides that we've prepared. And the key question that I think that we're struggling with is as the COVID-19 epidemic, pandemic has overwhelmed some of the most advanced health systems in the world, the pandemic has been slow to arrive in Africa.

But if the health systems of some of the most advanced countries in the world have not been able to cope with this, when it does explode in some of the poorest parts of the world, there is significant potential for great misfortune. Unfortunately, we're starting to see an uptick in cases in Africa. Just in the last week, there's been a 43% increase.

And the fundamental question that I think that we need to ask ourselves is as the world community scrambles to develop not just vaccines, but also diagnostics and treatments, how do we make sure that everyone around the world has access to these medicines, no matter where they live? So let me sort of start with a baseline in terms of global access to medicines, and therapeutics, diagnostics, and vaccines.

And there are shameful disparities. So a child born in Cambodia, 18 times more likely to die by the age of five than a child born in Iceland. There are 22 million of the 37 million people living with HIV globally didn't have access to treatments. And many drugs are not available at any price in some of the poorest parts of the world. That's the bad news.

The good news is that as a result of global social contract beginning with the Millennium Development Goals in September of 2000, we've made extraordinary progress as a world community in addressing some of the health disparities and the health conditions that are facing the globe. So the rate of deaths of children under the age of five have fallen by half between 1990 and 2013.

New HIV/AIDS infections have declined by 38% between 2001 and 2013. So working together as a community has been a very successful strategy for alleviating getting some of these problems. Unfortunately, this global social contract has begun to unravel recent years.

There's a rise of populist nationalism, development assistance by members of the OECD. Some of the world's richest countries have fallen. We've seen increasing trade tensions around the world. And we've seen equally increasing foreign direct investment for a number of years in a row.

So as we sort of come together as a world community, we see some of the most important players in the world community trying to tackle the challenges of COVID-19 as they're emerging at a breakneck pace.

Last week, we saw the World Health Organization, European Commission, some of the leading philanthropic voices from the Bill and Melinda Gates Foundation, CEPI, and GAVI, and Wellcome Trust, and Unitaid, and Red Cross coming together to make a global commitment to try to take on some of these challenges.

We also hear voices, some of them in the United States and some around the world, that suggest that it is more important for countries to deal with their own challenges. And at the bottom of that is sort of this notion that maybe we should have drugs and vaccines cost the same all across the country.

So President Trump is one of the main voices for this sort of America-first or populist nationalist approach. And in last year's State of Union, he said it's unacceptable for Americans to pay vastly more than people in other countries for the same drugs if they're made in the same place.

And I think that one of the things that this brings up-- and we've seen these voices not just on the right, but also on the left. And I think that one of the things that I'm trying to articulate is the importance of the global social contract as a mechanism for ensuring access to medicines across the globe.

And one of the ways to think about what's wrong with this notion of America first is to think about progressive pricing of pharmaceuticals as something that's analogous to progressive pricing in taxation. So in nearly every country in the world, including the United States, we tax our residents on a sliding scale.

So if you make more money, you pay not only more taxes, but you pay a higher rate of taxes as your income increases. And insisting that fairness demands that Mozambique or poorer countries pay the same prices for vaccines as treatments as, say, an OECD country would mean more hardship. It would also decrease the amount of innovation.

And what we've seen is over the last few decades, the use of progressive pricing as a mechanism for increasing access to medicines has had an extraordinary impact on the availability of medicine. So if you take the example of HIV/AIDS, those medicines tend to cost between \$35,000 and \$40,000 a year per patient in the United States, but only \$75,000 in Africa.

And this has caused an extraordinary increase, this aggressive pricing approach has caused an extraordinary increase in the access of medicine to some of the world's poorest countries. And this notion of global solidarity is embedded in some of the international norms that underlie some of these international efforts.

So the Goal Access in Action Project at Harvard under the Berkman Klein Center has looked at a number of strategies for increasing access to medicines. And some of what we do is direct country advising to African country governments to work with their legal systems to enable some strategies for increasing access to medicines.

And some of it is to look at some of the mechanisms for making drugs available in a way that allows for incentives to develop the next phase of medicines. So access to medicines, availability of affordable medicines is not just a question of the world's poorest countries. We have lots of access challenges within the same jurisdictions.

And so as you're developing strategies for increasing access to medicine, you also need to look at how you can charge different prices in the same countries. And you also have to think about

some ways that we can have global collaboration and incentives for global collaboration on solving new challenges.

We're starting to see this with COVID-19 vaccines and other treatments that as the world sort of comes together to research and try and come up with new [INAUDIBLE] new count, new solutions to some of these challenges, we want folks to be working together on these solutions and not just for [INAUDIBLE].

So I think at that point, I'm going to let John take the next piece, and then we can sort of talk about [INAUDIBLE].

I think that overview was very comprehensive and gives a good background on some of the work that we've been doing at GAIa, and challenges that we're facing currently or that COVID-19 has illuminated, challenges that have existed for a long time in the access to medicine space.

I think one of the things that has been getting some attention is the pricing of vaccines, should one become available. I'd like to talk a little bit about some of the other challenges that exist, though, with respect to vaccines. I think that price is perhaps a visible component of this. And everybody is curious how such a thing would be-- how do you create a price that is equitable and fair?

And I hope that in the discussion we can get into a little bit more detail about different strategies that provide greater net social utility than a flat price, for example, would. But there are other challenges ahead of us as well, and it wouldn't matter what the price was or if the drug were freely available.

We have challenges in many parts of the world where there's not access to hospitals or health care professionals. Education is an enormous barrier. I think there is some discussion in this country about vaccines and whether people even believe that they are something that we should be using therapeutically.

Harris Poll found that last year, 45% of Americans don't believe that vaccines are safe. And in many parts of the world, you might have deep-seated religious objections to the use of vaccines, the use of human tissue cells to create vaccines. Some parts of the world believe vaccines are a Western plot to sterilize or infect societies.

I think you still have fallout from reports such as Edward Hooper's *The River* claiming that HIV/AIDS was started in Africa as a result of transitioning from monkeys to humans via the polio vaccine. These are challenges that we still confront in daily practice with existing medicines.

And the creation of new medicines is certainly a place where there's a lot of tension and a lot of skepticism. And I don't think we've made progress in the area of dampening susceptibility to fake views. So that challenge continues to grow, I think, every year.

Perhaps the most, the biggest determinant, frankly, of access to medicines is perhaps the most obvious, and that is financing. So numerous studies demonstrate that if financing is available, medicines are available where medicines are perhaps not as obvious. Where medicines can be priced higher in some parts of the market, those medicines are more likely to be available.

And so I think it's worth noting that the pricing of medicines and access to medicines is a complex issue, one that it usually doesn't involve the patient as the end consumer. But rather, the government has some kind of program or some insurance mechanism that isolates the rational consumer model from working in the health care context.

And you then are left to look at what the governments are doing or what the public sector is doing. And if we look at those numbers across the world, the US, as you would expect, is a leader. So we spend 2% of GDP on pharmaceuticals, which is near the top of the OECD statistics.

Japan spends about the same, also 2%. And Canada spends about the same, 1.8%, 1.9%. Korea, Switzerland, Germany, Spain, around 1.6%, 1.7%. But there are a few Western outliers. You can look at countries like the UK only spends 1.1%. Denmark and Luxembourg, 0.6%.

And so I think it's worth asking whether there is some, as Quentin referred to, a social contract, where Western governments that are-- not necessarily Western governments-- governments that have more resources should be paying more than those with less resources.

I mean, an example would be that in Ethiopia, if the Ethiopian government paid half as much as Americans pay for drugs, that would be 60% of GDP. So, I mean, obviously, that makes no sense at all. And there should be a difference in how we price medicines in the US for the system that spends money on pharmaceuticals, here and how we price medicines for Ethiopia in the system that spends money on medicines.

And I think one more point I just want to make before we open it up to questions, because I'm sure there are a few of them, is one that Quentin made kind of in the middle of the presentation. And that is we've been thinking a lot about how to explain what this process of pricing medicines differently.

And in the US, I think most people don't perhaps realize that you would have dozens of prices for the exact same medicine, just within our market. And you have a lot of discount programs that are available to some population segments or to large purchasers that aren't available to all patients, or patient groups, or insurance groups.

And that that system ends up delivering greater access more widely than a system that would price the same for everybody. Another way to think about it, as Quentin noted in the middle of the presentation, would be income taxes. So we tax people in the United States differently based on-- it's based on their income.

I mean, is it unfair that some people pay 4% income tax and others pay effectively 27%? I don't think that we would think that it's unfair. It raises a lot more revenue. It allows us to do all kinds

of things. But there are some that have argued that it is unfair. I think it was a populous Republican talking point for a while, and Newt Gingrich and others were-- Pat Buchanan-- arguing that we should have a flat tax in the US.

So it's not something that's completely off the rails. But I think in terms of thinking about medicines and how in some cases, it's actually more equitable for there to be price differentiation, it's useful to think about some of the practices that we've learned from taxation.

Sure. Thanks a lot for the comments, John. So I'm going to play a little bit the role of the devil advocate here. And the arguments that are a lot being launched in the public domain is the same ones that we have seen before when we talk about a price mechanism for the greater good. So the COVID vaccine is estimated to cost something like \$2 billion.

As of now, CEPI has managed to raise I think just about under \$800 million. So the conversation is very much, how do we get the funding? How do we make sure that the investment that the industry is making or governments are making does have some sort of return on investment? So on one side, that's one school of thought.

On the other side, we can only be as healthy as our neighbor. So for the first time probably in history, at least since the 1918 pandemic, we can't really say if another country really far from us does not have access to the vaccine, it's totally fine because we have it. Because the way the connection works today it will eventually get to any nook and corner of the globe.

So how do we, from both your experience-- John, from your experience from working with the industry and having been on so many of those conversations of the balancing act between the industry and society, and you, Quentin, from especially of the conversations that you've often brought up in terms of IP pool. What are the possible solutions that would be a win-win situation for both stakeholders?

You want to take that first?

Sure. Now, this is kind of a very interesting case study, as you have enormous demand, a race to develop a vaccine with dozens and dozens of participants. You will have a variety of vaccines potentially that come out of this, which creates some form of price competition.

You'll have a variety of treatments. You'll have a variety of diagnostic tools. So I think it's important to note that there's not going to be one end-all-be-all solution and everything else will kind of fall away. There is already a ton of competition which creates a lot of market dynamics that we're all familiar with.

The question of how-- and I think Ash rightly pointed out that this like many other infectious diseases, it's one that affects all of us. So everyone has a vested interest in making sure that all patients in need everywhere in the world, regardless of their ability to pay or their government's ability to pay, receives access to care.

I think that there are a lot of opportunities to put into practice some of the things, some of the lessons that we've learned over the last 20 years. One would be to create an environment where the companies that are providing treatments are providing them to least developing countries or so-called recipient countries in this case on a lower cost or a free basis.

Free would mean, I guess, licensing. And we could license technology through something like the Medicines Patent Pool, which has been used effectively in the past in HIV and other cases to spin up manufacture and distribution in least developing countries or other parts of the world. There are lots of prices that could be set in advance based on volumes.

There is some potential use here for advance market commitments. I don't think there's a lack of investment on the R&D side. But in terms of the distribution and manufacturing, there is certainly going to be a need to spin up a lot of market participants there.

So I think that this is really just an interesting opportunity to deploy some of the lessons that we've seen be effective in other cases of infectious diseases like HIV, and perhaps also to look at some of the cases that didn't work. I think there are other examples where you had a lot of the elements in place. But because there wasn't financing available, you didn't really see the same uptake in distribution, and that can be instructive as well.

Yeah. I think that you're right, Ash, that there that there is a self-interest in on the part of a number of the wealthier countries to make sure that the pandemic is contained as quickly as possible all over the world because of the interconnectedness of the world. I think theoretically, you're trying to do sort of two things at once.

One is we want to have incentives for the research and development to happen and had an extraordinarily compressed time scale. So normally with drug research and development, you have a time period for both the development and then the safety and efficacy testing that spans often decades.

Here, we have to do everything in a period of a year or 18 months. And so you need to kind of incentivize that kind of collaboration, that extraordinary rapidity of the research and the testing-- and not only for the vaccine, but also for a series of tests and therapeutics. And so you need resources to do that.

And some of the traditional mechanisms don't work very well because on the back end, there's going to be an extraordinarily large market. But there's also going to be a lot of need. On the other hand, you also want to make sure that once we reach the finish line, all of those categories of therapeutics, and diagnostics, and vaccines, that we can actually effectively deploy them and not price people out of the market.

And so what I would suggest is one of the goals that the charitable organizations, the intergovernmental organizations, the government organizations should have as money comes into the system is to have some strings attached to that financing that will help smooth out some of these problems on the back end. So John mentioned advance market commitments.



And advance market commitments are a mechanism that has had a lot of academic support. And where there have been a couple of practical examples of trying to design them, particularly in the pneumococcal space, but much more theoretical interest than practical application.

Advanced market commitment, in my view, could work in this situation. Last, though-- I mean, typically the reason why you do an advanced market commitment is because there are insufficient resources being devoted to R&D. Here, I don't think that's the case. I think that there's going to be an enormous, enormous amount of energy and resources focused on that.

Maybe we need to increase those incentives. But there's a lot of reasons for folks to get involved in this. What there isn't as much is price certainty on the back end, and some ability to make sure that beyond the initial push, that there is price fairness.

And so I think one of the things that the world community or one large government could do is try to tie some of the resources that are being provided in the advanced market commitment to an obligation to increase access on the back end for everyone. And I think that kind of a quid pro quo would work pretty well under these circumstances.

It's very hard to design it, and it probably requires more resources to be effective than are currently on the table. But I think if you could create some kind of advanced market commitment where you promise a certain amount of purchases at a certain price for a certain period of time in exchange for a commitment beyond that period of time to charge a fair price in the poorest countries, I think that could work very well.

Yeah, absolutely. So I think now it's time, as I see the questions popping in more and more, maybe to bring the first question to you. So I'm going to go to a friend of GAIa, but also someone who is from CEPI who has asked one specific question. And so the question is from Richard Wilder. Can you discuss the role of patent tolls in the field of vaccines more specifically?

And I see a similar kind of question from the Q&A as well. So maybe a little bit more on the technical point, probably from the legal aspect of it. How feasible is it now to pool resources, and to have one IP, and to have access to this IP from the rest of the world?

You mentioned this. Do you want to start here, and I'll chime in?

OK, yeah. I'll be brief. Since you're the attorney, I'll let you take the legal part. I mean, I think there is kind of an interesting ex ante ex post question here where most of the medicines that we put in things like patent pools have been developed, and they're on the market, and commercialized, and available in some parts of the world.

And this is a mechanism to distribute them more broadly. Is there an ex ante opportunity here as we're looking to forecast what those treatments, diagnostics, or vaccines might look like? And are there some programs that would be effective in helping to scale up for distribution to the developing world?

The one I alluded to would be something along the lines of getting commitments from companies to license their technologies that were approved for use for COVID into something like a patent pool which could then be tied to a fund.

And then you would have some kind of tender offer program managed by the fund to encourage manufacture and distribution in parts of the world that would not be able to create the demand for that technology on their own, right?

So if we're talking about least developing countries where you have GDPs of less than \$1,000 a year, and what kinds of funds could be created to assist those countries in delivering, and in manufacturing the vaccine for distribution, and then and actually distributing the vaccine in those parts of the world?

And probably the easiest piece of that to figure out in that case is, how do we get the rights to that technology, basically based on some of the groundbreaking work that Quentin and others have done over the last two decades to develop some of these kinds of programs? So I'll let you--

First of all, I just want to give a shout out. So one of the most significant developments in the field of epidemic preparedness coming out of the ebola crisis was the development of a new organization, the Coalition for Epidemic Preparedness, that has played a really significant role in the COVID response.

And one of things that we learned from the ebola experience was that we need more resources focusing on epidemic preparedness and focusing particularly on the research and development side of that. So CEPI is sort of having a moment of particularly profound importance, and this is exactly kind of what it was created to do.

So when we were talking about patent holes, I think you kind of have to disentangle two pieces. One is that anything that relates to the patents is one of things that you're trying to figure out is how do you make sure that folks and inventors or companies that have vested time and money in the development of a commercial product are able to recoup their investment over time?

In the field of medicines this creates a particular challenge, right? What you do in order to allow patent holders to recover their investment is you allow them to restrict output and raise price in other contexts. That's something that we as a society have decided is mostly a good incentive.

But in the world of medicines, it does mean that you are, practically speaking, pricing some folks out of the market. And so you need then as a downstream measure to try and figure out how you manage those access and equity issues.

And so in a lot of cases, patent holders with life-saving medicines develop various kinds of programs either to contribute their medicines to some poor countries, or to license them to generic manufacturers, or to market to parallel markets within the same jurisdictions to increase the access.

You've always, when you've got patents with life-saving medicines, you've always got this push and pull between wanting to reward the inventor, and incentivize the next wave of innovation, and at the same time, making sure that people have access to that, that they don't get priced out of the market for things where getting access to it or not can be a matter of life for death.

But in the context of a patent, you've got another layer of complication, which is that in a lot of these medical innovations it is not just one patent that governs the stream of research that needs to come to the therapeutics or to the vaccine. Many cases, you've got a number of different entities that have patent rights.

And patent pools have come into being in part to make it easier for governments, and charities, and intergovernmental organizations to negotiate with a larger pool of patent holders without as much friction, without as many transaction costs, and to come to arrangements that will allow for what will rapid distribution medicines [INAUDIBLE] keep them on their terms.

And I think that you're seeing some of that. You've certainly seen this in the context of HIV/AIDS. You've seen it in the context of tuberculosis and malaria. And I think that we're going to see some need for that within the context of COVID. There's a lot, there's a race to develop some of these medicines.

And I think that the most likely outcome is that in order to provide needed medicines to a lot of different countries, you're going to have a hodgepodge of different patent rights. So having some mechanism that allows both for fairness and takes out some of that friction to the transaction costs I think would be very effective.

Thank you, Quentin. So let's go now to the US context with a question from Evan.

He says, "As far as I understand, many drug companies spend more money on marketing than on R&D, and most research funding in the US comes from the NIH and the NSF. Why focus on getting people to accept progressive drug pricing across countries rather than reducing the prices across the board by reducing the patentability of drugs based on public funding." So maybe Quentin?

So there are a number of different inputs to some of the innovations that are most impactful. And I think that there is good research to suggest that there is very high efficacy to the public investments that NIH and NSF have made. And it's very clear that there are very significant access challenges, and we've seen some very bad practices that have garnered a lot of headlines in the United States around patent gouging.

And so those are definitely issues that we need to take on. I think a lot of those can be taken on at the national and subnational level. So we've had a lot of conversations with state legislatures. We've had some conversations at the national level, although our Congress is broken.

But in the international arena, I think that you're also talking about huge, massive public investments of resources. This effort that's coming together under the leadership of the WHO,

and of charities, and IGOs and countries around the COVID involves a massive infusion of public and charitable money.

And I think that that's where a lot of the resources are going to come from initially. I think on the back end, we want those charitable entities and those governments to be able to recoup some of their investments in some of that research. And so you want to come up with mechanisms for some of that revenue flow to come back to the original IGOs, investors, [INAUDIBLE]. John, do you want to take any of this?

I think that this is a challenge. What is the right-- there's a necessary tension here. We're trying to create incentives for market activity. And a patent is a market disrupting device. It is a public policy tool used to try to incentivize innovation in specific areas.

We might do things like add years on for data exclusivity or add other regulatory benefits if we want to drive investment in certain categories. Most of the medicines, the new medicines that are produced globally come out of the US system. So the system is one that works, does attract capital, a lot of risk capital.

I mean, you could argue perhaps we're not driving enough incentives to the sector. You have a lot of investment in developing finely tuned targeted ads for the internet. And people do make a lot of money doing that, too. So I think that there are a lot of ways to come at this problem.

Public financing would certainly work if it were at the levels required. I don't think it is. I mean, as we were discussing, the US in the current environment, even with market pricing in some cases, spends 2% of GDP on pharmaceuticals. We spend a lot more, a lot more, on other categories, defense spending, or even health care more broadly, which is 90% of GDP.

So within the health care context, pharma spending is about 10%. So I think that there are a lot of ways to look at it. But the most important is, are we creating the proper incentives to generate the kind of innovation that we want? Do we want innovation to come faster?

If so, what are some of the mechanisms that would create an environment that pushed more money and more smart people into working on those problems when they can choose to work on anything? And I think that's something we should be constantly debating and discussing. And so I think it's a great question. It's hard to answer.

I think it's a terrific question. I'm very open to more patent reform. So when I was in the White House, we were engaged in a large patent reform conversation. It led to the passage of the American Invents Act, which is by no means perfect, and helped us to rationalize some of the differences between the US patent system and the international system.

It allowed us to take on some of the backlog issues. But when we were done with that process, we very much thought that there was a series of additional reforms that we would like to see happen. And as I was leaving the White House, we announced a sort of second wave of reforms that we were interested in pursuing.

Some of that was discussed through the second term of the Obama administration, and again, make progress in a Congress that is not functional at this point. So one of the things I would say is just it's very, very hard to move federal legislation.

One of the things that I would do or think if I were looking at another wave of patent reform is that trying to deal with some of the challenges that come up with what's called a unitary patent system. So one of the things that becomes difficult is that patent innovation, patent incentives are very one-size-fits-all. They're very blunt methods.

And in a lot of ways, the kinds of innovation that you're trying to incentivize is very different from one invention to the other. So if you think about a cell phone, there are, say, 3,000 or 4,000 patents just in my iPhone. And if you think about one of the drugs that you're developing maybe for COVID-19, that's probably a single main operative active element.

And treating those two problems the same way creates a lot of structural friction within the system. One of things that we experimented with and thought about a little bit was trying to give more rulemaking authority to the US Patent and Trademark Office. The US Patent and Trademark Office has procedural rulemaking authority, but they don't have substantive rulemaking authority.

So one way to deal with that would be to try to figure out how to create different categories for patents and play with the various amounts of incentives to deadweight loss that you create within the system.

But another way to do it would be to push down to the agency level some power to tweak individual pieces of the incentive structure maybe in little ways that would allow us to sort of smooth some of the differences between the kinds of incentives that you're trying to create and the kinds of deadweight loss that is created as a result of that [INAUDIBLE]. It's very, very hard, and is not something that sort of had problems.

So a lot of questions regarding patent at the moment. And I would like to come back to that, because they are a really interesting one. But before that, let's zoom out and talk a little bit more from the developing countries' perspective.

So we have a very interesting question from Paula Byer who is saying, the small economies of the Caribbean are very concerned about access now, even beside pricing. We saw early on in March that there were insufficient PPEs available for us to purchase.

How do we ensure that there is sufficient production of vaccines, and treatment, and diagnostics, et cetera for all persons and nations, and that this will be made available at a price that-- what is it going to look like? Will it be only a commercial process or is there going to be something else that they can look forward to?

I mean, that's a fantastic question, and it's important in a few respects. One, this is not just about the vaccine or whatever treatment ultimately people will determine is most effective for the

widest use of people to take. It's about everything from the Personal Protective Equipment, to diagnostics, to treatments along the way for people that contract the virus, to the vaccine.

And in all cases, we have the same problem, which is an enormous delta between countries that have resources and those that don't. And so I think that there needs to be more work done in this specific challenge, this pandemic that we're all facing, that we're all connected.

It presents an opportunity for us to try to calibrate some of the redistribution that has to happen between richer nations and poorer nations. And I think the important takeaway is really what Quentin highlighted in his presentation. And that is there needs to be a restoration of the social contract.

I mean, this is very basic stuff. Kantian, or the golden rule, or however you want to think about it, it is those who can should. And it's not much more complicated than that.

So I want to build on something that John said earlier, which is that pricing barriers [AUDIO OUT] access problem. Sorry, am I muted? [INAUDIBLE]

No, we can hear you.

So we talk a lot about the pricing mechanisms because they're very important. And it does feel like there's a real world burden not to let price be the thing that prevents somebody from accessing ongoing technology. But there are a lot of other challenges as well. An your question about Caribbean countries springs to mind in a lot of instances, it's about getting the thing to the place.

And there are a lot of medicines that are not available in a lot of countries at any price. You talked about PPEs. There are also shortages of trained health care workers. So I spent a little bit time in Mozambique. And the coastline of Mozambique is like the coastline from Miami to Maine, where Miami is the sort of main city Maputo.

You can drive essentially the same coastline as the East Coast of the United States completely on dirt roads. And I got there, and I said, what are some of the challenges in terms of access to meds? And I thought everybody was going to be all upset about pricing. And they said, we've got these medicines, and they're in a box. And the box is too big to fit in the truck. I can't get the trucks up the coastline.

And so there are a lot of unique straightforward kind of blocking and tackling kinds of problems. But also, you think about trained health care workers. So the ratio of trained health care workers in some of those northern hill towns in Mozambique to the population of about 200,000. So having anybody with medical training be in a position to diagnose and get good treatment to you is a real challenge.

And so as we think about some of these pricing mechanisms and we talk about how we're going to have equitable access on a price basis, also we think about health system capacity is about

getting the manufacturing capacity we need trained health care workers who can actually get the stuff to the people. And those are real challenges.

Yeah, absolutely. I think one of from the developing countries' perspective, there's more than one issue. And a lot of those issues were already in this health system before the COVID-19. So faced with the international pricing and hoarding at the moment, it's adding on to the complications of those countries.

And that brings me to another question on patent, going back to competition. So we have a question from Sanna, who is asking, patent force often lead to anti-competitive behavior. Pharmaceuticals involved in developing a vaccine may collude, hence defeating the very purpose of making the vaccine accessible. How do you propose one deal with this drawback?

So it's a really interesting question, the relationship between the patent law and the anti-competition or anti-trust. So if you think about what in general in antitrust law, we don't let trade associations facilitate cooperation or collusion across otherwise competitive entities. In some cases, we do have governments step in or intragovernmental organizations step in to try to facilitate cooperation.

But sometimes, cooperation becomes collusion, then price comes up. So you have to be very careful when you supplant the ordinary rules that encourage people to work in true competition at truly arm's length, that if you're breaking those walls down to encourage cooperation, that you actually cause the price to go down as opposed to going up.

And I think that that requires rigorous structuring of the patent rules and good oversight. I do think that there are some circumstances, though, where it is important for folks to work together. I remember when the ebola crisis hit, and there were a number of different research streams of different solutions to the problem.

And people got together in one room and started to share their research, and it did accelerate a lot of the resolution, some of these problems. So I think that the lesson is not don't cooperate. The lesson is have oversight during those periods of cooperation to make sure that you're accomplishing your public policy.

John, do you have any take on the question?

No, I think he handled it.

Yeah. I think there were a lot of comments that ties well to your reply, Quentin. We have, for example, Zain who's commenting on Johnson and Johnson estimates that it can produce a billion doses annually if the vaccine is effective, and that that's a fraction of the global population, meaning billions will go without timely access.

And her question is, do you support that requiring companies to share know-how and manufacturing technologies? I think you covered that pretty much. Do you have anything specific to JNJ?

Yeah. My instinct is to say that the entities that are coming forward to help with finance-- so that may be the World Bank. That may be the Bill and Melinda Gates Foundation, or CEPI, or GAVI, or some of the European countries-- should think very seriously about what strings they attach to the contributions at a moment where they do have some leverage.

And we should be very careful that the requirements that are tied to that funding actually get to some of the challenges that we're likely to see downstream. So one is we want to gear up manufacturing capability to the level that's going to be required-- not necessarily profit maximizing level, but, like, solving the problem level.

But we also want to make sure that when we have that capacity, there is actually an effective mechanism for distributing the medicines, and the tasks, and the vaccines at prices that can be afforded by countries that are buying it. And as John says, in many cases, the end user is probably not the purchaser, so we're thinking about those purchasers.

But I do think that this is a moment where borders could play a really important role in helping donors condition their investments on very specific follow-through mechanisms to make sure that the contracts require things that are actually helpful. And it just takes good lawyering to do that well.

I can provide two examples of how that plays out in reality. So one-- and they're both from the same experience, which is essentially the work that Gilead did pioneering these licensing agreements with generic drug firms to scale up production of HIV. In this case, you had funding. So you had funding coming from PEPFAR and the global fund.

But one of the really interesting things that happened as a result of the licensing agreements was the reduction in price and the innovation that occurred in the manufacturing supply chain. So when Gilead was producing HIV medicines 10 or 15 years ago before really ramping up the licensing program, it thought it could produce net 100.

And that was the cheapest price that the Gilead had manufacturing could produce. Once the patent licensing agreements were created and there was competition created within the supply chain from generic companies around the world, and you had a structure which essentially did not say, OK, JNJ, we want you to do a billion.

And Company X, we want you to do a billion. And Company Y, we want you to do 200 million. And then here's a contract for that. There were bids put out. And with these very large bids, generic companies had to stretch. And there was fierce competition, because these were incredibly large contracts.

That competition led to innovation in the manufacturing of these products which drove down the cost of those products significantly. The price of a hundred 15 years ago is now less than 10, or less than 15. So you had a greater than 85% reduction in the cost of the same products. I think that's extraordinary.



I mean, when you start to think about how you need to scale up treatment, it's not about raising a bunch of money and doing it to one company. It's also thinking through, how do we create market dynamics which are in some cases very powerful and will lead to more innovation beyond the thing?

The thing is just the first innovation. And then we need to think about, how do we produce the active pharmaceutical ingredient cheaper? How do we scale up the manufacturing so that it can deliver millions of more units per month?

And there are lots of things that continue to happen after the thing exists. So not to forget about those things, and to create structures that will continue to incinerate innovation, as it will take years for us to reach everybody around the world once there is something available.

All right. Thank you, both of you. We are slightly over the hour. So thank you very much to everyone for your great questions. I think they were all very interesting if we had enough time to go over each one of them. But unfortunately, we could only accommodate a few.

So Quentin and John, what is the one thing, as a concluding remark, that is critical for the world to look at to make sure that we increase access to the COVID vaccine of the whole world population, including those who for the vulnerable groups?

Yeah. I just think that this is a time for us to come together. I don't think this is sort of an every country for yourself kind of an experience. And I think that we need to push back against this sort of populist nationalism. And I think that's true not only here in the United States.

But unfortunately, it's something that's sort of creeping into this space. And I think that we need to reinforce the notion that it's in both our moral obligation and in our collective self-interest for us to be thinking particularly about pandemics as a global problem with global resolution.

I would just say, echoing Quentin's closing point, that now is the time for leadership. Those who can lead need to step up and do so. And those with resources and the ability need to participate in a leadership capacity. There are needs around the world.

And this is certainly one of those moments where as Clinton was saying, we're all in this together. So hopefully we can get back to that social contract idea, and the US and many other governments around the world will have to play a leading role.

Thank you very much for this great conversation. It was a pleasure having you both on the panel. Thank you to all the participants for your great questions. I have my email in the chat box. If you want to send me further comments, feel free to do that. And we hope to see you again on BKC platform or future GAIa webinars. Thank you, everyone.

Thank you so much.

Thank you.