Francis Collins
Director, National Institutes of Health
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This interview has been lightly edited for clarity and readability.

Mike Milken: Good morning, Francis.

Francis Collins: Good morning, Mike.

One of the things we learned many years ago is that to accelerate science, one of the keys was collaboration. Could you talk a little bit about how you feel collaboration is working today?

Well, it is critical, especially at a time of global pandemic with COVID-19 that we see around us.

For me, having come up through scientific experiences like the Human Genome Project and various things that followed after that, all of which are intensely collaborative, it's natural to look at this situation and say, are we doing enough to bring together all of the best and brightest; all the talent; all the resources from every sector; from academia; from NIH; from industry, both pharma and biotech; from philanthropy; from stakeholders of all sorts;

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from the regulators? Are we really doing everything we can in this moment of global crisis to knock down barriers and accelerate progress?

So that's where my head is this morning, sequestered as I am in my home office trying to behave the way we all should be in terms of distancing, but trying to light a fire under any kind of opportunity here to speed up the process of identifying effective treatments and vaccines and making sure our clinical trials are ready and tuned up, to try out virtually all of the good ideas that come along.

That's what we really have to focus on right now at this moment of crisis, maybe more than we ever have before

Many years ago, when we started hosting Partnering for Cures, those groups you've just spoke about came together, but not with the sense of urgency we have today. As the director of the world's largest medical research organization, how have you attempted to redirect the efforts of the tens of thousands of people that work for the NIH?

Everybody who works for NIH is incredibly energized by the opportunity and the responsibility to bring the resources that we have given by Congress to turn to this particular challenge. We have on our campus the vaccine research center that's working 24/7 to accelerate the progress with as many of these different vaccines as possible, but particularly one that's already in phase one trials.

We have multiple other scientists both in our intramural program and out there in universities who weren't thinking of themselves as coronavirus scientists before, but they are now trying to figure out how their skills and insights can be brought to bear. And we at NIH are being very flexible in allowing people to repurpose some of their resources now for this particular challenge. And we are very definitely trying to see how we can do this collaboratively with other organizations, be they private sector philanthropy or industry to make sure that those linkages don't get missed.

I will say, Mike, your formation of the Partnering for Cures effort really did provide what is now turning out to be a very useful network. I got to meet a lot of the people who I now am working closely with now through those frameworks so we know each other because we've had that opportunity to talk in real ways but sometimes hypothetical ways about partnerships and now those all have to be really real and those personal interactions have helped a lot.

Francis when we think of accelerating clinical trials, how do you do that, and what's happening in that area?

NIH supports a whole bunch of clinical trial networks. NIAID, our Infectious Disease Institute, led by Tony Fauci, has their own set of global clinical trial capabilities, much of which of course had been devoted to things like HIV/AIDS but which now can be repurposed for looking at coronavirus.

We have other networks. The Heart, Lung and Blood Institute has a very important network that looks at lung disease. And since we know that the big threat of coronavirus is what happens to the lungs, those also can be brought into this.

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And then we have our whole network of CTSAs [Clinical and Translational Science Awards program], 60-some centers across the country that are set up to do clinical trials on a rapid turnaround with a single IRB [institutional review board authorization]. They can be brought to this as well.

Similarly, industry has their clinical trial capabilities, sometimes through CROs [contract research organizations]. We need to figure out how every patient who turns out to be positive for COVID-19 would have the opportunity to be approached about a clinical trial.

You guys have set up this tracker database, which I think is a really useful way to keep track of all of the ideas that are out there, because they're coming at all of us fast, and try to see how we prioritize which of these are ready now to be pushed forward – ideally things that we think are safe because they've already been in humans but they could potentially be repurposed for coronavirus. We don't want those sitting on the shelf and we don't want them in a long queue waiting for their turn.

We want all those clinical trial networks to be linked up in a way that we can do multiple massively parallel clinical trials on therapeutics that might turn out to be just the thing we're waiting for. So, yeah, lots of things that we need to link up there that we've never quite had to do before.

One of the ideas that's been put forth is that things that look like they're positive in some sense like the Gilead drug, we should be producing them in large quantities

now before they're approved so that if they do work and they are approved, we don't have to wait weeks or months for production. What is your view on that idea?

I think that's critical and it would be tragic indeed if we had a clinical trial that showed, "Oh my gosh, we have the therapeutic we've been waiting for, but oh we'll have to wait now four or five months to be able to produce enough product to get it to the people who need it."

So, we have to take a chance in doing the production runs before we know whether something's going to work. In the U.S., BARDA (the Biomedical Advanced Research and Development Authority), which is part of HHS, does have a lot of funds and they just got bumped up to over $3 billion from the latest congressional supplement for COVID to be able to make those bets.

And that is a place where I think more than ever, we should be carefully looking at how those bets are being made and making sure we don't end up in that circumstance where something works, but we can't actually deliver it.

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Same thing for vaccines. There are at least 20 different vaccine programs. Some look more promising than others, but you never know. And you wouldn't want to get in the circumstance there either where you have proof of effectiveness of a vaccine, but you only have enough of it to give to a few people. BARDA can help there, but we all have to think about that.

This is not a time to have things go in the usual pace where it might take three or four years after the successful trial, before everybody has access. We do not have that time.

Francis, when you think back to the early '90s when you launched your effort to sequence the human genome and the technology available to us then versus today, take us through the difference.

It seemed at that time that this was pretty radical. Nobody had really tried a big science project in biomedical research. Sure, the physicists were doing things like that, but biological science was still pretty much individual-investigator-driven, hypothesis-based, small scale. Laboratories maybe had a few people.

The Human Genome Project simply couldn't get done that way. It required bringing people together. Ultimately it was 2,400 scientists working in six countries, all of whom had to agree to a certain set of milestones and deliverables and hold themselves accountable and not worry too much about who got the credit for it. That started something, and that has really been a change in the dynamic and something that I have had a significant hand in as we've seen more and more instances where those kinds of team efforts are going to be successful in empowering everybody.

Now here we are with COVID- 19 and if there was ever a time where we need to bring all those teams together, not that we're going to run over those small labs that have great ideas, but we're going to empower them with access to data that all has to be open access and freely accessible.

This I think is a moment where you can stand back over these last 30 years and see in a certain way we were preparing for something like this without fully realizing it. I'm sorry, we have to be tackling something as serious and dangerous as this, but in a certain way we are better prepared than we possibly would have been before this hit.

Francis, you spoke about, for example, the Moderna trial, where the vaccine was given to individuals on March 16th. But I think realistically we all realize – whether it's antivirals or antibodies or things that have dealt with the immune system – those will probably come first in controlling this virus. Where do we stand today on those areas?

Where we stand is having a couple of potentially most-promising therapeutics, and I would put in that space hopes for Remdesivir, this Gilead drug, which is still in the process of being tested in appropriate randomized, controlled ways. And until you have that data, let nobody imagine that we really know.

And also the antibody approach, something as straightforward and sounds like last century as convalescent serum, but also then moving that into the production of monoclonal antibodies that you know are going to be highly effective in attaching themselves to coronavirus and preventing it from entering cells.

Those are extremely promising. They're being pushed really hard, but right behind that, Mike – and again your tracker documents this – there's a long list of potentially other important interventions.

When it comes to the serious lung disease, is the ability to block the cytokine storm that seems to be part of what really causes the greatest risk for death – is that something that's going to help us in terms of those people in ICU who are most in need of a pretty

radical intervention? Sounds sort of promising, but we don't have the data yet either. Again, let me come back to, that's why we need all these clinical trial networks to be linked up and ready to test all of these things as quickly as we can.

Francis, four decades ago we began this interaction with a young man named Steve Rosenberg of the NCI [National Cancer Institute] on this concept of immunology and the cytokine storm you spoke about. We have thought that what's occurred in cancer might have some answers to this cytokine storm. How do you view that?

There are a lot of similarities for people who have been studying cancer immunotherapy like Steve Rosenberg. Particularly, when that works, you get such an enormously large amount of tumor lysis that you release all of these substances that the immune system reacts to and sometimes overreacts and releases a lot of cytokines, particularly IL6 six. We have learned with CAR T-cells and how to approach this, that you can in fact reduce the likelihood of somebody ending up very sick and even potentially dying of the treatment because the immune system overreacted.

Could the same approach work in this situation? Now, it's tricky, Mike, because this is an infectious disease. There is an active virus involved. By blocking the immune system's response, trying to keep it from doing damage to the lungs, are you unleashing the virus to be more readily able to replicate? It's going to be a tricky balance. That's why we've got to do the trials and find out what really works.

Francis, in 1957 you and I were young students in school. Sputnik went up and young generations were focused on science. DARPA [the Defense Advanced Research Projects Agency] was formed, NASA was formed, and maybe BARDA is the equivalent today. It encouraged you and many other young people to follow your dream, which eventually led to you young scientists leading the Human Genome Project. Are we at an inflection point today that might lead a resurgence of focus – in this case on bioscience?

Well, we certainly need that resurgence in terms of the way in which young people today see biomedical research as something they'd want to get interested in and the way in which we are teaching this in K–12, which unfortunately in many schools is still way behind.

Sputnik woke us up to the need to put our scientific educational process in much better shape a way back in 1957. Are we at a point now where we need to have that same wake-up call in order to prepare the next generation for what is going to be an incredibly exciting and important time scientifically?

I sort of hate it that we have to have a global pandemic in order to achieve that wake-up call. But I guess if we're always trying to look for something good that could come out of a crisis, that might be one of them. And I certainly don't think there are very many people in the United States or around the world right now of whatever age that have not had their eyes opened to how science can be the way in which we can actually save lives in a hurry for a very serious condition. Maybe that will inspire some longer term change. I certainly hope so.

I believe what we're going to need at that point is to have almost universal testing of our population, community by community

Francis, I know that these are hectic days for you. I want to thank you for joining us today and that tracker that you spoke about, you can get at milkeninstitute.org **and there's over a hundred different therapies, from immunology to antiviral to antibody and vaccines, that are listed there. One last question about your thoughts on antibodies – getting people back to work, getting people that might be immune, getting our health care workers and people who would not spread the virus nor would not affect them. Do you see that as our first response here?**

Mike, I'm so glad you asked about this because this is also an area of intense focus right now. We're so of course dominated by what's happening in terms of the peak of these terrible infections across the country. But we will get through this over the course of the next weeks or months and we will find an occasion where the number of new cases has begun to drop maybe all the way down to zero. And then the question is, is it safe for all of us to re-emerge, and what do we need to know in order not to have a second or a third wave of this same horrible infection?

I believe what we're going to need at that point is to have almost universal testing of our population, community by community: Who has the virus? Okay. Those folks still need to be sequestered. Who has antibodies indicating they've had the infection and recovered from it and are now relatively immune? It'd be really nice to know that part too. And there are serological tests coming available very soon. And we also probably need to know, well, where is everybody? So we'll require some kind of digital technology keeping track of all of this information in order to make rational decisions about how to get us all safely back to where we were before this hit.

That is a big focus right now at NIH, although we have to obviously work with lots of partners at CDC and with other parts of the government to be sure we do this in a way

that doesn't tread on people's privacy but gives everybody a chance to get back to something like a normal life and not have this risk of a big recurrence of the same pandemic all over again. That is going to be a big thing to be talking about.

Francis. Thank you. And obviously your experience in leading the Human Genome Project, leading the NIH allows me to sleep a little better at night. So thank you.

Thank you Mike. As we begin our fourth decade of working together, I really appreciate your partnership in this and so many other things. Let's keep doing everything we can together to move the ball forward.
