CONVERSATIONS WITH MIKE MILKEN

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Mike Milken: Esther, thank you for joining us today.

Esther Krofah: Thank you for having me.

Esther, in the series of podcasts we've been doing, as you know, they varied from CEOs of the world's largest employers to the leaders in medical research to government leaders focused particularly on the coronavirus. But one of the interesting ones I had was with a military leader and a good friend, and the discussion turned to how great leaders in peace time might not be great leaders during war. You came to lead *FasterCures*, which had been founded as an outgrowth of my lifelong effort spanning almost five decades to try to figure out how we could accelerate medical science with the idea that time equals lives. This organization with a long history of trust – that had dealt with philanthropists; disease-specific organizations; academic research centers; government agencies; and healthcare, biotech, and pharma companies all over the world – you took leadership of the organization in, but in peacetime. And now you have been thrust to lead an organization during a war, a war against COVID-19. I did call you in February and told you that this was going to be maybe our greatest challenge, and you and your team have risen to that challenge. How are you operating in such a stressful environment?

This interview has been lightly edited for clarity and readability.

Thanks, Mike. We've had a great legacy with the work that *FasterCures* has done over decades, and when all of this started to emerge, we responded by creating a rapid-response team, if you will. We brought together our advisory board that you chair – which includes former FDA commissioners, former pharmaceutical executives, Nobel laureates, leaders from technology, and others – to help inform us of how can we be the most effective. They helped us identify four areas where we have focused our attention: (1) tracking where treatments and vaccines sit in development; (2) identifying critical policy initiatives to make sure that our government agencies and others have the resources that they need; (3) identifying where we can accelerate medicines more specifically in working with specific promising organizations and companies; and then, finally, (4) what do we do after all of this? What is our response from a surveillance perspective so that we make sure we don't repeat what has happened to date and that we're better prepared for addressing what that pandemic could look like in the future as we transition out of COVID-19?

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So our team has been restructured. We've gotten a lot of great input, and the work that we have done over the last six weeks has made a tremendous difference in the landscape in providing trusted and foundational information that's guided efforts from government agencies to private sector efforts as well as to NGOs and multilateral organizations who are at the forefront, on the front lines, of developing medicines and vaccines.

Let's talk about a few specifics: We receive three to five new testing strategies a day; more than 100 vaccines are now proposed, with a number of them already in humans; antivirals, antibodies, immunology; coordination between philanthropy with government agencies and numerous large biotech companies, small biotech companies in need of capital, and large pharmaceutical companies; and the efforts of CDC, FDA, NIH, HHS, BARDA, CMS, VA, DOD[†], and so many others. With all this information swirling around, I think of your development of the tracker – to have one place in the

[†]**CDC**: U.S. Centers for Disease Control and Prevention. **FDA**: U.S. Food and Drug Administration. **NIH**: National Institutes of Health. **HHS**: U.S. Department of Health and Human Services. **BARDA**: Biomedical Advanced Research and Development Authority. **CMS**: Center for Medicare and Medicaid Services. **VA**: U.S. Department of Veterans Affairs. **DOD**: U.S. Department of Defense.

world people can go to look at what is currently happening and updating it every day. What has been your experience, and how has this idea worked for the world?

Mike, we spend numerous hours a day updating that tracker because what is critical is real-time information that researchers and scientists can respond to. And our team – who's working on looking at preprint materials and looking at clinicaltrials.gov, the Chinese version of clinicaltrials.gov, publications, media resources, speaking directly with these companies, biotechs, and individual investigators – has been able to aggregate all of that readily into this platform. As I've been speaking to colleagues, ranging from NIH to these large companies, they're using that daily in their prioritization exercises to determine what they can accelerate and what the potential opportunities are. From my team's perspective, it's not just a tracker. It is a research acceleration protocol.

Esther, there's a company called Moderna. You and I spoke to the CEO. I've done a podcast with Tal Zaks, their chief medical officer. BARDA eventually made a commitment of $483 million in a grant to build manufacturing and to build millions of doses, even though we don't know if it works today. How did that work? For our listeners, how might it work in other situations that we're currently working on?

BARDA is at the front lines of identifying what are emerging infectious threats and diseases that can threaten our society. They very much so have been at the forefront of funding technologies for therapeutics, for diagnostics as well as for vaccines. They made the $483 million investment into Moderna recognizing that we need to simultaneously accelerate the clinical trial and give companies like Moderna the capacity to ramp up manufacturing, which is going to be incredibly needed to be able to shorten the time period between having a potential for a vaccine or a therapeutic and then having individuals who can get access to that. We need those kinds of organizations.

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Likewise, they're taking a lot of funding applications for organizations and companies that have compounds that can be accelerated. What we have done, Mike, is provided to them critical information around leading companies that have promising compounds that could address some of the most severe effects of COVID-19. I would just mention as an example a small company out of North Carolina named Biomarck that just recently completed a phase 2 study for ARDS, which can address acute respiratory distress syndrome, which a lot of patients in

ICU are affected by or dying from as a result of COVID. Those kinds of companies and the compounds they offer are promising. Having BARDA have conversations with them to learn more, determine what's needed to get those medicines immediately to patients is exactly what we need to do.

Beyond BARDA, we also see the work of CEPI, which is the Coalition for Epidemic Preparedness Innovations that have been funding a lot of these big efforts as well and also ramping up in manufacturing for these vaccine candidates while they're in development. We've been engaging with them, making different connections to ensure that their funding as well as their efforts are well-supported and we can get a vaccine as quickly as possible and that resources are the issue in order to do so.

One of your directors, David Feinberg, who today is the head of Google Health – I know he's been a great resource for you. As you said, you've had the last two heads of the FDA, Scott Gottlieb and Peggy Hamburg, in addition to Mark McClellan on your board. Also David Baltimore, who we did a podcast with, Nobel Prize winner, and who did work on viruses. How is your team using this board, and how is it making you more effective?

Our board, as you mentioned, Mike, provide extreme expertise. They provide high level of insight into how we can accelerate medicines. That's exactly what we need at this time. One of the big recommendations that both Scott Gottlieb and Mark McClellan have proposed is a task force – a therapeutics task force as well as a diagnostics task force – to respond to COVID so that we're reviewing in real-time and prioritizing in real-time what is promising from both of those perspectives and can get them quickly through FDA review.

Peggy Hamburg was there at the very beginning of the response to HIV and has had tremendous leadership from the New York state health department as well as her time at the FDA. Her voice has been quite helpful in us identifying – I'll give you an example – how do we leverage the FDA alumni and the bench that have had experience with review of therapeutics? How can they be integrated at a time like this to ensure that we have the capabilities, we have the staff, we have the resources to be responsive? So the board has been quite critical. We need their leadership. They've been guiding us and our team on a daily basis and will continue to help us as we think about the post-recovery space as well.

We saw immediately that the Gates Foundation appointed a person to interact with you at *FasterCures* and that the NIH appointed a person to interact with you at *FasterCures* as we've set up these activities. Talk a little bit about the level of cooperation and collaboration, and how is it speeding our efforts today?

We have had that high level of collaboration within our Milken Institute family, if you will. That includes the Prostate Cancer Foundation. It also includes the GW School of Public Health. Having the leadership of Dr. Jonathan Simons and Dr. Goldman to speak with and review these ongoing and current research efforts and then direct these researchers accordingly to where they can plug into either a BARDA effort or an NIH effort or a Gates initiative has been quite critical.

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So everyone is really working a breakneck speed not only to identify the compounds, working with individual investigators, working with potentially large clinical trial sites and working with philanthropy in a comprehensive way. No stone is left unturned in this effort.

Well, as you know on these podcasts, the goal was, you and I are talking every day, multiple times, but this gives people a chance to see our interaction and listen to some of the things we're focused on. And the podcast have included the head of CEPI and Lynn Goldman and Jonathan Simons and Peggy Hamburg and David Baltimore, and many of the people that are on your team at *FasterCures*. So our listeners can listen to each of them individually. *FasterCures* was when you took over and remains today a nonpartisan, nonprofit organization. It was there and put on the first cancer summit. It was there and put on the March, which ultimately doubled the NIH budget and tripled the NCI budget with help from half a million people that participated, and more than 400 billion in incremental funding for medical researchers. NCATS, which you work with, the National Center for Advancing Translational Science, was created with support from *FasterCures*. And as you said, 21st Century Cures – we even lent them part of our name on that creation. This history, this element of trust – obviously today, trust, data accuracy – may be more important than ever from the world's standpoint. We talked about a peace-time and a war-time effort, but in effect there was always a war-time effort for the individual with a life-threatening disease and trying to accelerate research. But this is really a *world* war-time effort. Has this history and this credibility and trust served you in helping to bring diverse groups together, particularly as a nonpartisan organization, to speed medical research? How have you used these relationships built and forged over decades, from Partnering for Cures and other events that *FasterCures* put on?

We've built tremendous relationships with nonprofit disease foundations through your leadership, Mike, and the Prostate Cancer Foundation's work early on. There's a tremendous amount of trust between us and government, business – with large pharma companies and smaller biotech companies – from academic and research institutions. The foundational legacy of work we did over many years, 10+ years with Partnering for

Cures convening – they really believe in our mission to accelerate medicines and cures for all patients because we recognize that we don't have time for patients who are suffering from life-threatening diseases.

As you have said in the past, Mike, we believe time equals lives, and so these organizations, these institutions, have been part of our journey over the last almost three decades. And as we come to a time like this with COVID, we need that foundation of trust so that we can provide reliable information. When we put out resources, for example with our tracker, it is picked up in such high numbers because we're building on that foundation of trust. We reported not long ago that we've gotten almost 1.3 billion impressions on the tracker. Whenever I go into it, I see at least a hundred multi-users of it at the same time. Even from the media, getting questions about what is promising to you for patients because of the work that we're doing. There's that recognition that individuals, families, patients is what drives us day-in and day-out, and that really speaks to leadership you've provided and that foundation of trust that we built over many, many years.

So Esther, you've spoken about your plan on how we're going to carefully and thoughtfully reopen parts of our economy. I know you've been working with our Center for Public Health. I know you've been working with the Center for Financial Markets and the Center for Global Market Development and others. How are you thinking about this and what challenges do we face?

As I mentioned earlier, one of our pillars – that final pillar for us – is surveillance, which includes the short-term question of what do we need to reopen the economy and the longer-term question of how do we ensure that we have learned sufficiently from this experience that we are better prepared going forward in the future? As we think about the post-recovery in the short-term and our collaborative efforts with the Center for Public Health and others, it's really focused on what kind of diagnostics and testing capabilities need to be stood up? Whether serology tests that can give individuals information on whether they have antibodies that have developed, either they're recovered from COVID-19 or testing continued, rapid testing, PCR tests to confirm if you've had the virus so that we can very quickly be able to put the right mitigation strategies in place like contact tracing, which will continue to be critically important as we identify what the emerging hotspots are going to be around the country.

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We have interacted with the Centers for Disease Control, the CDC, alongside the Center for Public Health and the leadership there working on strategies

like contact tracing and provided to them organizations that have technologies that could be helpful at the local and state public health departments to facilitate those efforts in the short run.

In the long term our attention is going to turn to what are the technologies that we need for ongoing surveillance of emerging infectious diseases that are well-funded and well-supported so that we can, at the moment we see hotspots start to emerge around the world, we're quickly deploying that technology and the network that needs to be brought to bear to develop the immediate response and mitigation for that potential pathogen.

So those are the ways that we're thinking about the post-recovery space, but certainly in the short term we are quite focused on how we can support CDC and HHS and their leadership to ensure that the right strategies are in place for individuals to feel confident in going back to work.

So Esther, I remember when you told me you're going to update your tracker daily, and I had told you it reminded me of this old *I Love Lucy* episode where she was putting candy in a box and it's coming down the conveyor and it's backing up, and do you want to put that pressure on yourself and your team? What about every other day? What about three times a week? How has your team held up? How are they doing? How are you holding up with this pressure that every day you have to update the tracker and you and I both know we might see a dozen or two dozen new things every day?

I have to say there have been sleepless nights and there have been long days. We are working and updating that tracker daily because that information is so critical that we have a team organized to scan and review hundreds and hundreds of sites and information and papers and it takes a toll. But Mike, we feel as though we are doing a human good and we need to save lives. So we are willing to do that and we will continue to do that through the duration of the crisis. But we are holding up and continue to hope that we do so over the weeks and months ahead.

In addition to a job that could be 24 hours a day, seven days a week, you also have responsibilities with your own family and kids because they're not going to school. They're at home. And both you and your husband have come from West Africa. Tell us a little bit about your journey of you and your husband and your family today.

Well, Mike, I represent the immigrant story, and as you mentioned I grew up in Nigeria and immigrated to the U.S. at a young age, at eight years old, in fact. My husband grew up in Ghana and came here at 19 and went on to Howard University. I moved to Ohio, grew up there and went on to great institutions of schooling, from Duke University to Harvard for graduate school, and my career trajectory I believe has in fact prepared me

for a time like this. I would not have known that, but when you look back in retrospect, the experiences I've had in government and out of government, at the state level and the nonprofit level, at a large pharmaceutical company like GSK – that journey has led me to a time as this where we need all of those multifaceted aspects and approaches.

Coming from West Africa and having my family come from West Africa and my husband as well has also oriented me to be a global citizen. And that's exactly what we also need at a time as this, to look at circumstances and situations from many different vantage points and to understand who are the most vulnerable among us and whatever technologies we develop that can be deployed easily to areas of the world that may not have the same kind of infrastructure. So I'm very sensitive to that. I'm a mom as well of three young kids – 5, 7, and 9 – who are elementary and pre-elementary age that we're guiding through this pandemic as well. They may not understand everything that is happening around them. You have to give them a solid foundation to know that whatever's happening, they're safe and that they're well cared for.

So being a leader at this time requires a comprehensive view of the world and also keeping a nice healthy family balance to make sure that you have the energy that you need every single day to do what we can on behalf of patients who are suffering. I've had extended family, Mike, who have had COVID and have now recovered and we're grateful for that, so we're also experiencing this disease at a very individual and family level as we're responding to it from a professional perspective,

Esther, I can't thank you enough for your service, your management capabilities and the role you are playing. In many ways it substantially reduced my burden by not having to take any responsibilities for this tracker except making sure you know and your team knows everything that I know, and you have done an amazing job of taking of an assignment that I thought was not even doable – that daily updating. I wish you health, I look forward to seeing you in person again, and I look forward to spending some time with your three kids and maybe getting them into Mike's Math Club. All the best. Thank you. And please give my best wishes to your entire team.

Thank you so much, Mike.
