CONVERSATIONS WITH MIKE MILKEN

Margaret Hamburg

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April 9, 2020

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

It's my pleasure to be with you.

Peggy, I'd like to take you back to the day we met. You were running the Food and Drug Administration, the FDA, and I came to see you. And after about five or six minutes you got a call from the White House and you told me we would have to reschedule, and I fully understood that. If you were still running the FDA and the President had called you to the White House, what would you suggest?

Well, I certainly would have listened to what we knew about what was this emerging new infectious disease agent. But no matter what the infectious disease threat was, FDA would have to mobilize to respond in a couple of critical ways. First of all, how to make sure we had the medical countermeasures to respond –

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This interview has been lightly edited for clarity and readability.

the diagnostic tests to be able to identify people who were infected with this new virus so that they could be isolated; there could be contact tracing so that they could get the medical care that they needed, and so we could have some way of actually tracking and understanding the unfolding contours of this epidemic as well. We would want to start thinking about what kinds of therapeutics might be available or could be developed to treat a new infectious disease threat. And then of course the long- term goal of trying to develop a vaccine.

Now all those things might not get started at once until we really understood the nature of the threat that we faced, but we'd be starting to think about it. And of course a very significant part of medical products used here come in part or sometimes in whole from China. Also food products come from China. So the dislocation of supply chains with a serious epidemic of disease could also have significance for the United States and its consumers.

Peggy, as I think back, it's almost 30 years since you became in charge of health in New York; it's almost 25 years since you first went and worked at HHS [Health and Human Services]; and it's 11 years since you became the FDA Commissioner. Technology has changed so dramatically over these decades. What would be available to you today to deal with this that would have not been available in, say, 2009?

The ability to sequence the genome of this virus quickly and then have it posted by a Chinese scientist for all the world to see did make it possible to move much more quickly towards the development of diagnostics and vaccines and to help us better understand the nature of this virus for the development of drugs. The ability to use information technology to do more sophisticated disease surveillance and modeling and tracking, I think, gives the opportunity to really understand more the enemy that we're confronting and how to best prepare and respond. That, I think, has been very, very important.

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We have spoken about when you were the New York Health Commissioner and you learned about the first World Trade Center bombing. Take us back there. How did it change the way you think of health leadership and your job as the health commission?

Well, it was certainly a wake-up call for me and I think for many others. It was the first time that I really took domestic terrorism seriously for our country and thought about all of the vulnerabilities and threats that, as health commissioner for New York City, I

needed to be thinking about, preparing for and deepening my understanding about a range of concerns.

I've worked on pandemic preparedness, both a naturally occurring pandemic threat or a deliberately caused biological threat, for now many decades. And I always said it was a question of *when*, not *if*, we would have to combat a global pandemic. But somehow, doing all those tabletops and thinking about all the different scenarios, I actually have to admit I never really thought I'd be watching it play out in real-time.

To get back to normal, whatever the new normal might be, ultimately we need to have a vaccine. But the first vaccine for widespread use is not in 2020. We have to find a way to accelerate the process.

It does take time to develop and test these products to make sure they actually work and to make sure that the benefits of these products, whether drugs or vaccines, will outweigh risks to patients, which we cannot discount. Efforts are underway to accelerate this process as much as possible. There are a lot of candidate vaccines that are now being developed, more than 50. In fact, one vaccine has broken all records, going from the first posting of the genome by the Chinese scientist to an actual injection of a candidate vaccine into a person in just a little over nine weeks.

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So that is very exciting and very encouraging about an accelerated path. But we have to really look at every step of the process to make sure that we can move forward as swiftly and as surely as possible. The regulatory authorities need to be working with the product developers from the very beginning to make sure that there aren't unexpected things that come up, and the regulator says, "oh, you have to go back to the drawing board." That would be disaster.

We also have to think about how to do our clinical studies of the candidate vaccines in innovative ways. We normally do vaccine studies in a very systematic way. They are expensive and high-risk undertakings. It will have some more risks in terms of potential failure because we didn't recognize something earlier on, but with a lot of good minds focused on it, I think we can do some of the phases of vaccine testing in a somewhat more collapsed way. There are a lot of scientists working across sectors – industry scientists working with academic scientists and a lot of international collaboration that's critically important, including collaboration amongst the regulatory authorities, which again can help to streamline the ultimate access. So all of that is very encouraging.

Peggy, you're a member of the Coalition for Epidemic Preparedness and Innovation [CEPI] as well as the Global Alliance for Vaccines and Immunization [GAVI]. Now, if I recall, you got involved with both of these organizations long before we heard about the coronavirus. When did you get involved with these organizations, and how can these two organizations help us accelerate a solution?

When there is an unexpected crisis, we don't have the luxury of sort of starting at the bench to figure out what kinds of products might be useful. To identify what are some of the pathogens of pandemic potential and concern, and then investing to do the important early research and development and study of the vaccine through proof of concept in the early phase 2 studies in people so that we would have vaccine candidates if a serious epidemic, potential pandemic, in fact emerged.

Some questioned the value of this when it was first announced just a few years ago, but I think it has proven its value as we've watched this global pandemic of a novel coronavirus emerge. And also recognizing that once we have a proven vaccine that's safe and effective against this novel coronavirus, we're going to want it in huge quantities. We're not talking tens of thousands of vaccines, a hundred thousand vaccines – we're talking billions of vaccines potentially for the global community. Because with a virus that knows no borders, that has already shown us its ability to spread around the world causing devastation and death, all of us have a vested interest in making sure that the world has an appropriate supply of vaccine to actually protect against this virus and hopefully stop the continuing spread from the current pandemic and to hopefully prevent future pandemics of this virus.

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Will our experience with this virus build or diminished trust in the FDA and other agencies? How is the public going react, do you think, when it's over?

Well, there's no question that the FDA is very central and essential and uniquely positioned to help our country and countries around the world respond to a pandemic like the one we're currently experiencing. I think it's often underappreciated. There's an assumption that FDA is a dreadful, outmoded bureaucracy that only is a drag to the system, but in fact a well-funded FDA with the right kinds of expertise, the right resources really, I think, benefits everyone.

People don't realize, but FDA actually regulates products that account for somewhere between 20 and 25 cents of every dollar that consumers spend on products, whether it's

toothpaste or your drug to prevent heart disease or to treat your diabetes. FDA is there in your life every day making a difference. It's essential that FDA has what it needs.

The other point about trust and confidence is a key one because there is no doubt, whether we're talking about FDA or the Centers for Disease Control (CDC) or the National Institutes of Health (NIH), that we have the most sophisticated and expert scientists and medical and public health professionals of any place in the world. And when you're talking about responding to a pandemic like this one, you want to harness all of that expertise as fully as you possibly can.

We need the best and the brightest leading this effort, and I'm confident that with that we will come out the other end.

Once we have a vaccine or once we have an antiviral or serum from antibodies, demand for it is going to spike. Assuming at the beginning there's some degree of scarcity as we ramp up manufacturing and distribution, how would you prioritize and roll out these antivirals, antibody treatments or vaccines? What are the issues you'd be thinking about and addressing from a governmental level?

We know there's going to be huge demand and we know that there may be competition amongst individuals and amongst nations for access to drugs or effective vaccines that will be in limited supply. One strategy, of course, is to make sure that we have enough. That's why when we were talking about the vaccines, the issue of being ready and able to manufacture in very large quantities very quickly is going to be key because the more we have, the less destructive competition may occur.

But I think this is going to be a challenge for all countries because every country is going to want to protect their citizens and that is a very appropriate and necessary kind of a response. On the other hand, we also have to recognize that with a global pandemic, we are truly all in it together.

Peggy, I think you've outlined the enormous importance of the FDA and the role it's going to play in stopping this pandemic. That is underlined as we see the importance of the FDA with having three former directors of the FDA on the board of directors of FasterCures. I want to thank you for your service to our country and to the world. Thank you for joining us today.

Thank you, and thank you for the support of *FasterCures* to FDA over many years now.