BIOCENTURY

Pfizer's MacKenzie: Other diseases deserve the same acceleration as COVID-19: a BioCentury audio interview

BY STEVE USDIN, WASHINGTON EDITOR

Pfizer's Rod MacKenzie says the collaborations and accelerated timelines taking place during COVID-19 are causing introspection in pharmas for how they operate, and for how they can push for regulators to continue the pace of interactions they're setting during the pandemic into its aftermath.

Pfizer Inc. (NYSE:PFE) administered the first dose of the COVID-19 mRNA vaccine it's co-developing with BioNTech SE (NASDAQ:BNTX) two hours after FDA approved the trial, MacKenzie, EVP and chief development officer at the pharma, told BioCentury.

In an audio interview that was part of a series of conversations with industry leaders for BioCentury's Back to School 2020 package, MacKenzie described steps companies and regulators have taken to speed the development of COVID-19 medicines.

These efficiencies must be applied in the future to all drug development for serious unmet needs, he said. The COVID-19 experience "has taught us what we're all capable of when the chips are really, truly down."

At the same time, MacKenzie said, it raises the question: "Why just COVID-19, because there are so many other people in dire need from other serious diseases. It is not that their conditions are any less deserving or their needs any less urgent."

The speed of interactions with regulators must be maintained, he said. "It would just be extremely difficult to go back to waiting months for a meeting with a regulator after what we've had here."

Aspects of drug development that have been accelerated by the COVID-19 response include the "use of wearables, electronic diaries for real-time data capture image collection, using smartphones," and telemedicine, MacKenzie said (see Cover Story: "The Imperative of COVID-19").

He also discussed the importance of overcoming vaccine hesitancy. To bolster public confidence in the COVID-19 medicines it is developing, Pfizer has said it will not describe results in press releases before data are made available to the scientific community.

While the development of medicines to prevent and treat COVID-19 is breaking speed records, advance planning would have saved months — and many lives — MacKenzie said. "If we had worked from a putative virus like this years ago, we could have been much further ahead. In fact, we may even have [had] vaccines in place."

He added that this level of preparedness is a "very expensive proposition that requires a huge commitment of governments, particularly, because they will be the ones to coordinate all this and then ultimately taxpayers would have to fund it."

A transcript of the interview follows.

[00:00:00] *Steve Usdin*: Hello, I'm Steve Usdin. Welcome to BioCentury's Back to School Audio Interviews. In this interview, Rod MacKenzie, chief development officer and executive vice president at Pfizer, says that COVID-19 has shown what biopharma companies can do when the chips are down and how this raises the stakes for developing medicines for other conditions.

[00:00:23] He also discusses how the pandemic has accelerated Pfizer's embrace of digital technologies and preparedness for future pandemics.

[00:00:30] Dr. MacKenzie, let's start with Pfizer's collaboration with BioNTech on the COVID-19 vaccine. What's the status of the vaccine candidate? And how does it fit into visors COVID response?

[00:00:41] *Rod MacKenzie*: It's good to be with you. Thank you, Steve, for the question. Let me start by just telling you what we're doing more generally for COVID-19. I think as far back as March 13th, we outlined a five point plan to really do everything we can possibly do for COVID-19 and involved, making sure that we share all of our tools and insights with people who are researching COVID-19.

[00:01:02] We brought our own team together to work 24/7 on all of the aspects and we made our own drug development expertise available to anyone who was willing to listen to us, on a free advice basis. We offered up our manufacturing capabilities to other companies who maybe developing medicines or vaccines.

[00:01:22] And we're committed to improving our future response times for any subsequent pandemic. On the medical response, we've started, by identifying some antiviral compounds we have in our libraries that may have the potential to treat COVID-19 and we hope to start our clinical trials on those very shortly.

[00:01:39] But of course, as you allude to, we also need to protect our communities and a vaccine is going to be key to that. So we started with BioNtech. It's a German biotech company that we've been collaborating with for the last couple of years. And we've been using our in depth expertise as a vaccine developer and working with them on their technology.

[00:02:00] *Steve Usdin*: So COVID drug and vaccine development has become highly politicized. Large numbers of people in the United States and Europe say they won't take a vaccine once it's authorized or approved. And they don't have confidence in the regulatory authorities.

Is there anything that Pfizer and other companies can do to increase trust in the regulatory system and the bigger picture in science itself?

[00:02:19] *Rod MacKenzie*: Yes, you're right. I'm troubled as well by what we see as a growing level of vaccine hesitancy and distrust in science.

[00:02:28] And that is a real problem, I think, for society to grapple with, and certainly the scientific community needs to take it head on because otherwise society is going to suffer as a whole. I think there are many things we can do in order to make sure that people have confidence in the vaccine. The first one is the one that you mentioned, and that is people should take great confidence from the fact that we're working in this country certainly closely and in other countries in the world, whether the regulators, the health authorities, whose job it is to make sure that, nothing gets licensed, nothing gets authorized, that isn't safe and effective. And so far, I would say that in the Food and Drug Administration in all of their guidance, they've been extremely robust about their requirement for efficacy with a vaccine, if it's going to be approved.

[00:03:17] And I think we should all take encouragement from that. The same is true from health authorities around the world. That's the first thing I think we should say. I do think the industry and those who are working on vaccines have a responsibility to be transparent about the study and how we're getting on, what's happening, what the data are. We made a commitment at the beginning that we would not go ahead with press releases about our studies and our vaccines and antivirals unless at the same time we were publishing all the data so that the scientific community were able to look at it and gain confidence in it. But the scientific community as a whole has to talk, I think, in language that the lay public can understand to build their confidence, because what worries me a little bit is that if we're silent, there's only one voice for people to hear. And that's the people who are anti-vaxxers or they're anti-science in general.

[00:04:11] *Steve Usdin*: Moving on to a broader topic, COVID-19 product development, not just vaccines, but also drug development has broken all speed records. Collaboration among companies and with regulators has played a big part. But so has the intensity of the effort. Putting everything aside and working 24/7 to solve a single problem isn't a viable long-term strategy. That's not going to continue after the pandemic has been tamed. Are there elements of the COVID-19 experience that will endure, and that will change and shape the way that drugs are developed in the future?

[00:04:41] *Rod MacKenzie*: I think many things will change across the board actually. You make the point that the COVID-19 response has certainly taught us a lot of lessons already. But one of the things has taught us is what we're all capable of when the chips are really, truly down. And so it does though immediately create another question for us, which is why just COVID-19 because there are so many other people in dire need from other serious diseases. It's not that their conditions are any less deserving or their needs, any less urgent.

[00:05:10] So I think for all of us that are involved in clinical trials, all the sponsors, the research clinical sites, health authorities, it's a very important time to reflect and also to take some actions to improve trials, that better serve all patients. And I think there are plenty of things that will sustain themselves so long as we take some actions.

[00:05:30] There are all kinds of areas where, for example, in regulatory response times, where we've turned months into weeks into days, and sometimes hours to get feedback, to have scientific advice. There's no reason why for life-threatening conditions with very little treatment out there that can't sustain.

[00:05:49] In fact, I think it would just be extremely difficult to go back to waiting months for a meeting with a regulator after what we've had here. I think also internally within sponsor companies, this has really changed the way we think about our programs. For our vaccines, I think by the time we had permission to go ahead from FDA to the time we dosed our first subject was two hours., And the only reason that happens is because we had an intense focus on operational excellence. It's very difficult then to go back to a time for say a cancer study, where we might wait days for that to happen.

[00:06:24] So a lot of internal processes are changing within sponsors at the same time. And then the other thing I would highlight is that in the interface between people who are developing medicines and vaccines, and those who are regulating them -- and actually policymakers -- I think this has highlighted some real gaps in our infrastructure, particularly in our digital capabilities, that haven't really been fully accepted and need to be accelerated by what we're seeing with COVID-19.

[00:06:52] *Steve Usdin*: That's really interesting. Can you go a little bit more into that? What are the kinds of digital gaps that you're seeing and what would be the kind of things that governments and industry need to do to respond, to fill those gaps?

[00:07:04] *Rod MacKenzie*: We've been forced, if you like, by the advent of COVID-19 to embrace a lot of the digital infrastructure, because we had no choice. Many sponsors had to stop new recruitment in existing clinical trials because the clinical research sites were fully engaged in patient care for COVID or they just weren't willing to have people come visit them for obvious, good reasons.

[00:07:27] So a lot of things have happened that were beginning to happen, but really have been accelerated. Things like use of wearables, electronic diaries for real time data capture image collection, using smartphones, things like telemedicine engagements, which had been nascent before. And particularly remote quality and safety monitoring which uses advanced analytics and then electronic health records in order to reduce the amount of on-site data verification. That was going on and I think that has been a proven success. Also, you see regulatory inspections of sites and sponsors using secure video data-sharing technologies has been forced to happen and has been largely successful so that you can have inspectors interviewing people, reviewing standard operating procedures, validating source documents, that type of thing -- and still be able to comply with all the privacy laws. Even things like

routine communications using secure emails, portals, or dedicated digital vaults, that type of thing. All of these kind of existed, but they weren't really the traditional way things were working. So I think it's just incumbent upon all of us to let go of these familiar ways, but embody ways of working and come together to broadly implement these common digital solutions.

[00:08:45] *Steve Usdin*: And do you think that can happen or should happen on an ad hoc basis? Each company doing its own thing or is there a need for a kind of overarching structure where companies and regulators come together and agree on standards and operating procedures?

[00:09:01] *Rod MacKenzie*: The latter is far preferable, and I think there is a growing recognition that much of what we're talking about here is really in everybody's interests.

[00:09:10] There's nobody really against it. What we're talking about is non-competitive -- we don't compete on -- and you'll see, and I think we are very big supporters of institutions like TransCelerate, which is largely focused and trying to provide common solutions to existing problems. They help everyone by instead of, for example, having every single sponsor have a different protocol template, we have one that we all use. That makes life easier for everybody.

[00:09:38] And there are many examples of that. So I think groups like TransCelerate and other bodies like CTTI [Clinical Trials Transformation Initiative] which encompasses FDA and NIH, and also, the sponsors, I think these kinds of groups need to play an increasingly forward role in bringing us together and getting us to common solutions.

[00:09:58] *Steve Usdin*: So one of the other things that's been accelerated as a result of COVID-19 response is efforts to collect real world data and to turn that data into real world evidence. How much progress have you seen in that in the last eight months since the pandemic has hit. And is that another area where you see a need for collaboration among companies and governments?

[00:10:18] *Rod MacKenzie*: Yeah, I think it's a growing area of interest generally. I think it predates COVID-19. I wouldn't say that it's really one of the areas that's been accelerated by COVID-19. I actually think that all of us are trying to grapple with where it's most useful, most appropriate. My own personal view is that it has a place within the clinical trials of innovative medicines and vaccines, but it's not probably the central place for it because I don't personally think that we want to throw out all the advances we've made in randomized clinical trials. I think they are good experiments. People can trust the outcome of them.

[00:10:56] And particularly when you're talking to about the licensing of new medicines. I think they're still going to be the dominant experiments that we run. But definitely later on, postmarketing studies, I think they have a much bigger place to play there. And, so we'll continue to see that. I don't think that it's particularly accelerated by COVID-19 though.

[00:11:17] *Steve Usdin*: What do you think that policymakers, governments, and again, industry collectively, should do to prepare for

the next pandemic? I've been reporting about these kinds of things for over two decades and I've been writing stories about fantastic reports that government bodies and academies of science and medicine have been writing for 20 to 25 years about all the different things that should be done to prepare for pandemics and none of them get put into place -- very few and do. So if the world's gonna look at this one and say, we're going to be different this time, we're really going to do it. What do you think should be done?

[00:11:49] *Rod MacKenzie*: Yeah, that's a very good question. And it reminds me a little bit of what happened to me every time when I lived on the East coast, we used to have a hurricane and I lost power. I was determined to get a generator for the next time and the minute my power came back on, the energy went straight out of that. I think the same is somewhat to pandemic response. Once the pandemic is over the big danger is that people don't really take the steps necessary in order to be prepared for the next one.

[00:12:16] And I think it's particularly pertinent now with COVID-19 because the coronaviruses could generate other pandemics somewhat easily. Now the interesting thing is that there's nothing about these viruses that we can't address. We understand the sequence, we know what to do. I have no doubt whatsoever there'll be vaccines and antivirals that will take this particular virus, SARS- CoV-2 off the table as a threat. But the question is how fast will we take to respond to the next one? And we're I think somewhere in the region of north of 600,000 dead globally before we have a vaccine or a really effective antiviral.

[00:12:57] So you've got the circumstance where the science and the technology is there to address something, but how do you get ahead of it? And so it's going to take a government level -- I would say -- collaboration with policymakers and people in industry who have the capabilities to put the resources in place, in order to be able to pre populate, if you like, vaccines and antivirus for viruses that don't exist as pandemics yet.

[00:13:23] There's no escape for that. If you want to be prepared and you have to be able to stockpile something like this. So for example, with SARS-CoV-2, if we, in January, I think it was, or, maybe it was December, when we had the sequence, that was the gun going off. But if we had worked from a putative virus like this years ago, we could have been much further ahead.

[00:13:45] In fact, we may even have [had] vaccines in place, but that's a very expensive proposition that requires a huge commitment of governments, particularly, because they will be the ones to coordinate all this. And then ultimately taxpayers would have to fund it.

[00:13:59] *Steve Usdin*: And we did have that putative virus. We had SARS-CoV-1 -- was not that different from CoV-2. If 18 years ago all of the R&D that started for SARS had continued, we'd be in a much better position now.

[00:14:14] *Rod MacKenzie*: There's a place in the middle, I think, where anticipating a lot of the preparatory work could be done first, earlier than that it currently has. I think we could have for future pandemic,

even with a little bit more preparation, we could take weeks and perhaps months off the ultimate timeline that we will have to get a vaccine.

[00:14:33] So there is somewhere in the middle, I think, where you just rev up, if you like, the response times, even though these response times look terrific with respect to traditional, clinical development timelines. They, don't look terrific when you think about the number of people who have died and the number of people who suffered an economic consequences in the last eight to nine months. So somewhere, if you could take two or three months out and that timeline, I think that would make it a huge difference too.

[00:15:03] And the other thing, I think, which is not to do with R&D so much is we really have to learn the lessons of what to do to protect ourselves against virus spread, asymptomatic spread. So my hope is that if one of these things comes back, we won't have a slow response as we had this time.

[00:15:22] *Steve Usdin*: There's another issue which is manufacturing capability. For the vaccines, it seems like there's tremendous manufacturing capacity that's being revved up for COVID-19. But for other kinds of therapies, for monoclonal antibodies, for antivirals, there's still capacity constraint. Do you think that's an area where there needs to be infrastructure investment to create the kind of surge capacity that we would need for the future?

[00:15:46] *Rod MacKenzie*: I do. I think we've learned quite a lot about how supply chains, relatively obscure parts of supply chains can be rate limiting in situations like this. And I do think we need to look at the overall supply chain for medicines and vaccines and make sure we have the kind of capacities that we were going to need in a pandemic. This goes to all of the known clinical supplies: needles, vials, rubber. It's amazing just how you can rather quickly become constrained when you look at the kind of volumes you need within a pandemic.

[00:16:19] So I think the big difference between a pandemic and every other time is that supply chain becomes under instant pressure and I think that the key to it probably is really the response time and the ramp between the kind of capacities needed in normal life and the kind of, what you might call war-footing levels of production and capacity that we are going to need in a pandemic. People need to look at that. You saw it with PPE in the early phases of this.

[00:16:47] And it was disappointing how slow it was for us to ramp up the kind of production we needed. And so I think all aspects of the supply chain, really needed to be looked at hard.

[00:16:57] *Steve Usdin*: Another thing that occurs to me that I haven't seen anybody else address except a little bit in the context of the possibility of having a flu season and COVID-19 at the same time is that there's no reason why you couldn't have two quite different pandemics at the same time. And if you think about the constraints of R&D and manufacturing and the supply chains that you talked about being difficult in responding to one pandemic, can you imagine what would happen if there were two? It seems to me that's the kind of scenario planning that's needed if we're really going to take the threat seriously.

[00:17:30] *Rod MacKenzie*: Yeah. I agree with you. I don't really want to contemplate two pandemics at one time, but ironically you mentioned the flu and that was what we were working on because flu vaccines -- they have to be created long before we know the exact nature of the flu vaccine in that season and so therefore they tend to have variable effectiveness. What we were trying to do with BioNtech was, using a messenger RNA platform, create something with much more rapid response so that once you know the sequence of the virus, you can be up and running with a potential vaccine extremely quickly.

[00:18:04] And in fact, I take some encouragement from that. Obviously we're very focused on COVID-19 right now, but if this messenger RNA platform is seen to be successful with this virus, it does hold out the opportunity and the potential for much more rapid responses to other viruses as they appear. Even of course, if they appear at the same time as one another.

[00:18:27] *Steve Usdin*: So just one final question, because I think we're running out of the time that I agreed on. Another whole set of concerns I think is around the equitable distribution and allocation of vaccines. The U.S. and many European countries have struck deals with companies like Pfizer to secure vaccine supplies.

[00:18:45] CEPI and COVAX are trying to create some kind of availability for developing countries, but that doesn't seem to be fully realized. What are your thoughts about how the world outside of the wealthy countries should get access to COVID-19 vaccines?

[00:19:01] *Rod MacKenzie*: Clearly we believe everyone should have access to the vaccines and that's going to take a huge effort globally. Countries, of course, are taking their own actions to protect their own citizens. I think that's understandable. Our vaccines are going to be available in increasing volumes. Clearly, getting a safe and effective vaccine is basically just the very first step that we need.

[00:19:25] We've said that we might be able to produce up to, but certainly not beyond a hundred million doses, in 2020. That's why it's important that we have more than one vaccine as hopefully we'll have multiple vaccines all with our own different supply chains. And we may get to 1.3 billion or so during 2021.

[00:19:43] But even that of course is not sufficient to vaccinate the entire world and so we definitely are going to need to think hard about how we get this vaccine everywhere it needs to go, assuming we have one that's safe and effective. There's no good solution to this, the question that you're asking. I think, in the end, governments procure what they can. We certainly don't want to be involved in decisions about who exactly gets the vaccine. My personal hope course is that they initially go to people most at risk of COVID so that we can stop the mortality in its tracks. But, it's going to take a while.

[00:20:20] I don't have a good solution. I don't think anyone has a perfect solution to this. Otherwise we'd already have it in front of us. But for me, my head is well and truly down trying to help our team get to the end of this Phase III study and see whether we have a safe and effective vaccine. And my fingers are crossed.

[00:20:37] And so let's all hope that we are successful, Moderna's successful, everyone else is successful who's working to bring a vaccine to the world.

[00:20:45] *Steve Usdin*: Thanks very much. I think that's a good way to end our conversation and I really appreciate your time and thoughtfulness.

[00:20:51] *Rod MacKenzie*: Alright, thank you very much, Steve. Appreciate it.

[00:20:55] *Jeff Cranmer*: Music for all of BioCentury's podcasts is provided by Kendall Square Orchestra, which connects science and technology professionals, and other members of the greater Boston community; to collaborate, innovate, and inspire through music, while supporting causes related to healthcare and education.

[00:21:14] All of BioCentury's back to school content, including 19 other audio interviews, can be found at biocentury.com

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