Transcription:

Pramod: Hi everyone! Good day to you and welcome to another edition of Perspectives, our podcast and video interview series with thought leaders in Healthcare and Life Sciences industry.

My name is Pramod Pratap and I drive marketing for Healthcare and Life Sciences at Infosys. It gives me great pleasure to introduce today's guest, Ed Francis, Global Marketing Partner - Healthcare and Life Sciences at Infosys.

Welcome Ed, we are glad to have you join us to share some of the perspectives and views that you have.

Ed: Thank you, Pramod. I am very excited to be here.

Pramod: Wonderful. Let's quickly jump into the questions, Ed. I think it's a great time to ask this question. It's a very, very serious concern in terms of what we are seeing around. In today's podcast, we will primarily discuss the one topic that has gripped almost every nation and everyone - COVID-19. This pandemic is calling for all the governments to act in different measures, whichever way they can flatten the curve, and obviously, this is keeping a great pressure as well on the Healthcare Systems across and not to mention the patients as well. Now with that in mind. I know it's difficult to put you in a spot and I don't want to do that. But how do you think COVID-19 situation will pan out? What do you think looking at the immediate situation and how we need to handle this, especially from Healthcare and Life Sciences industry?

Ed: Thanks, Pramod, great question. To contain this growing threat we really need to create contingencies for the short-term and the long-term. About a month ago, I predicted that there will be recognized treatments leveraging one of many existing drugs in an off-label manner. I think this is coming true today. It is evident by just last week when Remdesivir was given approval by the FDA for an emergency use. This is huge.

I will give you another example, doctors in Australia who reported the combination therapy of HIV drugs lopinavir-ritonavir paired with anti-malaria drug, Chloroquine has had a significant positive effect on COVID-19 patients. Although this is a small sample and still early, this is also important. Additionally, in New York, the federal and state governments are putting considerable resources behind a drug combination of hydroxychloroquine and an antibiotic Zithromax expediting a reported 10,000 doses for use in seriously ill COVID-19 patients. We've also watched the mega trial of the four most promising coronavirus treatments. It's the WHO who did this. Finally, also a group of researchers identified 31 existing broad-spectrum antiviral agents that may be potential candidates for repurposing against this infection. So, these multiple threads I think are important to creating a number of different contingency plans to solve this problem.

Pramod: Absolutely great insights, Ed. Obviously, ending an outbreak of this size can be difficult to cope with as you yourself said that, you know, there must be strong contingencies in place to deal with any potential situation. And may believe whether we play some crucial role in the

transmission of the coronavirus and I know that different varied reports coming through on this How strong do you think the climate would really affect the spread of the virus and indeed affect the different regions as well?

Ed: Yes, Pramod, as you rightly said within the next eight weeks we will see seasonal changes and that in conjunction with social distancing will likely slow the rate of transmission. I understand this information is somewhat controversial and the data is not absolutely clear. But I think, I do think that there seem to be reports and evidence suggest warm weather will help mitigate the transmission. The evidence stems from the analog virus studies such as SARS correlation analysis of the spread of COVID-19 and laboratory analysis of temperature and humidity effects on COVID-19. So, evidence generally has not been peer-reviewed and in the case of COVID-19 temperature analysis, the data can be questionable due to the detection challenges and lack of testing overall. I do believe despite all of this, the consistent studies point to the direction, summer will mitigate the virus transmission break particularly if you couple this with other social distancing strategies.

Pramod: Great! I know it's constantly changing, and we see those reports coming in day in day out. It's very fluid the situation is and as you rightly mentioned and use it pointed out that's a couple of clinical trials are being done across some of the new discoveries on the top side. So what do you think, do we have visibility in terms of effects of these trials? I know there's something that's come in Italy and now very recently in UK as well, but yet to see a concrete, you know, solution or drug approved yet?

Ed: First of all, let me say I am really amazed at the speed with which these clinical trials have been launched for new vaccines. The partnership between the FDA and Life Sciences companies I believe is amazing and will be a model going forward. This last month on March 16th, Moderna began Phase 1 clinical trials for COVID-19 vaccine. This is amazing how fast this occurred! I believe within just a few weeks; we will begin to see the initial safety results from these trials. That trial plus there are a whole host of others that are being done as we speak. I would say within the next 12 months; we should be seeing the initial safety results. I believe there will be positive results from a number of new drugs. I believe the FDA and the government will be something unique here. I believe by the Fall they will certify some of these vaccines for emergency and humanitarian use. I believe there will be plenty of safety data regulatories to think about and feel comfortable that this can be done and I think that will begin to see that in this age of a pandemic and a fast-moving virus that we will see emergency use, compassionate use clauses used to administer vaccines to the most at-risk populations and perhaps beyond. After that, say within the next six months, we should begin to see the deployment of approved COVID-19 vaccines based on new laws and policies. We know the crisis will change how we deal with pandemics and within a year, we should see a transformation in clinical trials in general. As you know, the US and China began the first clinical trials on March 16th and 18th respectively, and there is now an increasingly streamlined expedited clinical trial processes with heightened collaboration between pharmaceutical companies and the FDA. It is clear that now agile clinical trial processes are needed to combat any potential pandemic threats we see in the future and I believe we are on our way to this more agile approach.

Pramod: Absolutely, correct. I mean, I can't believe that's the best. I know we are seeing a lot of collaborations not just within public-private enterprises but between countries as well, hopefully, we'll see a lot more action coming through that. I know you mentioned Chloroquine as a potential remedy for COVID-19. If you have a visibility on this in terms of this treatment being used all over the world and what about the accessibility of this drug being available to nations across including US as well.

Ed: Well, interesting! You mention Chloroquine - that drug has recently fallen out of favor, but I do think it is still very illustrative of what we're going to see. When initial statements were made and some initial results seemed to appear that chloroquine was effective, we saw a shortage of the drug globally. We even saw the UK hinder the export of that drug to other countries, and so I do believe that manufacturing will become more vital than ever and that you will begin to see thoughtful deployment of the drug to the most at-risk populations. I think the situation is extremely complicated when you get to a drug like Remdesivir being a biopharmaceutical. Biopharmaceutical manufacturing is far more complicated than you will see in a drug such as Chloroquine. In this case, many of these drugs are still on patent and even the manufacturing processes are often considered trade secrets because they themselves are extremely more complicated than for example small molecule manufacturing. I think the key to this pandemic will be once we begin to find biopharmaceuticals be successful and be effective against COVID-19, that how we scale biopharmaceutical manufacturing will become important to whether or not we succeed in solving this problem quickly.

Pramod: Great! I know you've raised very interesting points regarding the clinical science, but let me put the focus back on the governments. What do you think is the best way to do in a situation like this and to fight this battle against COVID-19? And I know governments across the world, including the US are facing the very, very peculiar situation in terms of just lockdown and social distancing, yet trying to make behavioral change in people and how we do it. And there's no fixed method to do this. All we have to do is to be cautious yet wait for the drugs but by and large, I don't want to put again the spot on you, but what do you think is the way to go about in terms of containing this virus at the stage?

Ed: Now great question, Pramod. First of all, I believe governments should take a greater lead in advising on current off-label drug use and new drug emergency and compassionate use. It's interesting in this situation where we have a fast-moving pandemic and information is coming in from many sources both within the United States and around the world. Things we know today are different than even a month from now. Largely, that's because much of the information that's coming in is from small sample sizes with different degrees of rigor around how that information was sourced, but I believe the government has, probably, the best view of all of the information and their role as an advisor to the provider community is more important than this type of situation. Presently, in the US, it's doctors making decisions and while that is absolutely appropriate and I would in no way suggest that that should be changed. I believe that this is where the government's advisory capacity can be very helpful and lessen the burden and risk when providers are prescribing off-label drugs to their patients and many of these providers are backing off from this

burden and letting patients not receive prescription drugs at all. And I believe that in the state of Illinois recently instituted a law where they have taken liability away from doctors, but I don't believe that is true across the United States and so that could be helpful as well. So, with government providing guidance and consistent decision-making, a lot of those concerns could be eased. Secondly, the government should rework on unapproved drug policies better to facilitate the use of unapproved pre-emptive vaccines. They can also deploy a saturation strategy. This is basically proactively administering drugs and a high enough percentage within a population to create herd immunity.

You've heard herd immunity is usually at levels of 70-80 percent. We know that any potential vaccine could face the challenge of short supply. This will be especially true with regards to vaccines because they are biopharmaceuticals as I mentioned earlier. This manufacturing process is complex and often considered proprietary either patented or kept as a trade secret. So, what the governments can do is play a pivotal role in helping scale global manufacturing of possible vaccines. If the government can reduce the risk through initiatives, like funding and guarantees, it would dramatically speed up our ability to respond to the threat. In the insurance sector, many people are facing challenges in getting insurance approvals for off-label drug use. The testing costs of these experimental drugs are often borne by the pharma company itself. The easiest situation the government can play a short-term role in brokering a public-private solution problem. We've already seen nations giving their citizens top priority for protection. Establishing a global governance body can bring level cooperation and collaboration that'll accelerate recovery and benefit the population.

Pramod: Absolutely. I totally agree. There is no fixed one single bullet solution for all this and the situation is so fluid. I know as a matter of fact health care itself as an industry, as a vertical has been changing dramatically over the last couple of years and the situation is, even more, augmented as some of those changes need to be immediately integrated to. And I know technology plays a huge role so you know specific technologies like telehealth and telemedicine. Do you actually see, some of these actually becoming more prominent now, their applications being more relevant in this continent context and in general? Do you see that actually, we are paving the way to a different kind of transformation in the industry during COVID-19 and post-COVID-19 era, if I have to say so.

Ed: Yeah, I do and that's a great question. You know, one of the interesting aspects of COVID-19 is that the vast majority of patients are being treated at home and remotely. The other unique aspect is at the current moment, many of the existing treatments that are being used or being used in off-label manner that aren't approved for this specific indication. So there are still unknowns in terms of their long-term safety and perhaps some of the side effects that many of these off-label drugs have needs to be managed. I think it is a great situation where the use of wearable technologies and remote monitoring can be of great help. It can also provide reassurance to patients and eliminate their need to visit a healthcare facility, essentially supporting the social distancing agenda. With all of these abilities, it is no wonder remote monitoring is gaining widespread use in clinical trials.

Pramod: Absolutely, and I'm sure you know these technologies will come into the fore more as we go forward. But again the other side of getting these technologies in terms of wearables and telemedicine using integrating technology is the data part of it. So, obviously, there's a huge increasing amount of data that's going to be generated and so will be the cost for stringent privacy norms. And again, it's a very difficult balance to keep together technology, privacy and data. What do you think is the way forward on this? I mean do we need to have a global patient registry especially being a pandemic and you need to quarantine and resolve some of these transmissions. Is it fair to say that, you know, we could have more data coming in, more information about the affected patients, and create a registry of sorts? Will that be good to explore? Or is it again going on through a very delicate position on the privacy part.

Ed: I believe that's a great question, Pramod and the answer is yes, definitely, and as you mentioned there will be concerns regarding privacy, but I believe these concerns can be addressed with proper security. We've been down this road before and protecting patient information is a problem we've solved many times and know how to do it. So for that, I think there are many compelling reasons why this should be considered. Let's take an example of plasma therapy for data pharmaceutical. This therapy relies on quickly identifying cured patients who have COVID antibodies in their blood. By doing a registry, it is very conceivable that we will be able to collect blood at scale because we're able to identify all the possible donors and get them in through a series of incentives to donate their blood so it can be turned into plasma. And then reused with other patients who are sick. Also, by collecting data on a sufficient number of the population that has developed immunity, we can better identify at-risk communities and enable enhanced vaccine deployment.

So you could imagine, for example, in New York City where they have had perhaps the strongest example of COVID infection that we are able to better identify who should get vaccines and protect the remaining population as we move forward with this crisis. And finally, another benefit is including in this data is the possibility of doing deeper data analysis to genomic profiling tools alongside additional diagnostic viral testing will ensure that mutations and the longer-term effects of this virus can be better understood. Certain viruses remain dormant and can have long-term impact on health. Payers and providers can use this information to predict risk profiling. Also, data can also prove the time taken to provide a point of testing results from days to a matter of minutes.

Pramod: Oh perfect! That's a great perspective. Wonderful having some of your thoughts shared. And again, you know, you know this is not the end of COVID-19 commentary if I have to say so. And I'm sure with the situation seen being so fluid, we might have to do another chit chat with you, you know, probably a few weeks down the line and then reflect back on some of those common things that we have done and then again look forward in terms of what the situation is going to be ahead. I know we have a limited time to end this podcast. I can't thank you enough. Thanks so much, Ed for having joined us on the show and sharing some of your wonderful insights and perspectives here.

Ed: Thanks, Pramod. Always happy to talk to you, and I'm glad to be here. Look forward to another session in the future.

Pramod: Wonderful. All right folks, so that concludes an exciting and interesting episode of Perspectives from Ed. Thank you again. Remember to log in and join us again next time. Take care. Stay safe and goodbye for now. Thank you so much.
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